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Search the U.S. Government's VAERS Data

Welcome to the VAERS *Wayback Machine*

Each month (or lately, each week), the U.S. Government publishes a new release of its VAERS database. Most of the differences between releases consist of new VAERS cases that were introduced since the previous release. But the government never closes a VAERS case, and may make changes to any case at any time. Sometimes cases are even deleted.

The VAERS *Wayback Machine* has a collection of old releases of the VAERS database, starting in 2003. It allows you to examine the government data more carefully and observe how the data changes over time. Here are some of the things that you can do with the VAERS Wayback Machine:

Search an Older Release of the VAERS Database

Do a search of an older VAERS release.

Release: 11/4/2022 Search

Search Results

From the 11/4/2022 release of VAERS data

Found cases where Vaccine is UNK and Manufacturer is UNKNOWN MANUFACTURER and CDC Split Type contains 'NLPFIZER'

Case Details

VAERS ID: 1664941 (history)
Form: Version 2.0
Age: 32.0
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-07-04
Submitted: 0000-00-00
Entered: 2021-09-02

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Amenorrhoea, Headache, Injection site inflammation, Injection site pain, Injection site warmth
SMQs:, Extravasation events (injections, infusions and implants) (broad), Fertility disorders (broad)
Life Threatening? Yes
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications: OXYCODONE; OXYCODONE; ELVANSE
Current Illness: Kidney stones (had 2 kidney stones operated)
Preexisting Conditions: Medical History/Concurrent Conditions: Drug hypersensitivity; Renal stone removal
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202101115147

Write-up: Other medications don''t work: painkillers don''t work: covid vaccination affects the effect of oxycodone; absence of menstruation; Headache; Inflammatory reaction at the reaction site: heat, pain; inflammatory reaction at the reaction site: heat, pain; Reaction at or around the injection site: pain; This is a spontaneous report from a contactable consumer (patient) downloaded from the regulatory agency-WEB, regulatory authority number NL-LRB-00664931. A 32-year-old female patient received bnt162b2 (COMIRNATY), first dose via an unspecified route of administration on 04Jul2021 (at age of 32-year-old) (Batch/Lot Number was unknown) as single dose for covid-19 immunisation; oxycodone (capsule 5 mg) via an unspecified route of administration from an unspecified date (Batch/Lot Number was unknown), at Capsule, 5 mg (milligram) for post procedural complication (severe pain following kidney stones removal, twice); oxycodone (capsule 10 mg), via an unspecified route of administration from an unspecified date (Batch/Lot Number was unknown), at 10 mg for post procedural complication (severe pain following kidney stones removal, twice). Medical history included ongoing Kidney stones (had 2 kidney stones operated, current condition with surgery), allergy to NSAID medications. No previous corona infection. Concomitant medication included lisdexamfetamine mesilate (ELVANSE). The patient experienced drug interaction with oxycodone on 14Jul2021 (it reported latency was 10 days after start bnt162b2), it reported before, oxycodon used to be effective with similar pain, other medications didn''t work: painkillers didn''t work: covid vaccination affected the effect of oxycodone. The patient experienced inflammatory reaction at the reaction site: heat, pain on 04Jul2021 (it also reported latency was ''1 day after start bnt162b2''). The patient experienced headache on 05Jul2021 (it also reported latency was ''1 day after start bnt162b2''). The patient experienced absence of menstruation on 08Jul2021 (it reported latency was 4 days after start bnt162b2), it also reported the patient with amenorrhoea (no menstruation for more than 40 days). The event drug interaction was serious with serious criteria of life threatening, caused or prolonged hospitalization. Treatment included that headache was treated with Paracetamol and ibruvan (?). Event outcome for ''other medications don''t work: painkillers don''t work: covid vaccination affects the effect of oxycodone'' was recovering; ''inflammatory reaction at the reaction site: heat, pain'' was recovered on 06Jul2021 and headache was recovered on 08Jul2021; absence of menstruation was not recovered. Reporter''s Comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no. Absence of menstruation. Hospitalization information: Pain control. And re-admission for even more pain suppression. And complications after 1st operation.Additional information ADR: I haven''t had my period in 40+ days. Other medications do not work. Hospitalization information: Pain control. And re-admission for even more pain suppression. And complications after 1st operation. Additional information ADR: I have been operated on 2 times for kidney stones, but each time I got complications that caused me to have excruciating pain. As a result, I had to take painkillers. They just didn''t work. I continued to have excruciating pains while in the past it had a positive effect on the pain. Now it was more like 3 weeks of infernal pain 24/7. citizen''s service number available: yes. confounding factors: confounding factors, allergy: Allergy to NSAID medications COVID-19: Previous COVID-19 infection: No. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reporter''s Comments:

Summary of reporter''s comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no confounding factors, allergy: Allergy to NSAID medications Previous COVID-19 infection: No

Case Details

VAERS ID: 1702563 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-07-17
Submitted: 0000-00-00
Entered: 2021-09-16

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Blood creatine, Drug interaction, Drug level below therapeutic, Fatigue, Malaise, Myalgia, Rhabdomyolysis
SMQs:, Rhabdomyolysis/myopathy (narrow), Neuroleptic malignant syndrome (broad), Eosinophilic pneumonia (broad), Tendinopathies and ligament disorders (broad)
Life Threatening? Yes
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: Pfizer, Inc. EUA 027034; CLOZAPINE; ARIPIPRAZOL
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 20210717; Test Name: CK; Result Unstructured Data: Test Result:more than 124000; Test Date: 20210717; Test Name: tox screening; Result Unstructured Data: Test Result:too low level; Comments: for therapeutic range
CDC Split Type: NLPFIZER INC202101143047

Write-up: Very severe rhabdomyolysis; muscle pain; drug interaction, tox screening: too low level (for therapeutic range); Fatigue; Not feeling well; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority -WEB NL-LRB-00671255 A 28-years-old male patient received second dose of bnt162b2 (COMIRNATY), via an unspecified route of administration on 04Jul2021 (Batch/Lot Number: Unknown) as single dose for covid-19 immunisation; clozapine, via an unspecified route of administration from 2019 (Batch/Lot number was not reported) to 17Jul2021, at 450 mg, 1x/day for schizophrenia. The patient medical history was not reported. Concomitant medication included aripiprazol. The patient previously received first dose of bnt162b2 (COMIRNATY), via an unspecified route of administration on 29May2021 (Batch/Lot Number: Unknown) as single dose for covid-19 immunisation. The patient experienced very severe rhabdomyolysis (life threatening), muscle pain, drug interaction, tox screening: too low level, fatigue and not feeling well on 17Jul2021. The patient underwent lab tests and procedures which included blood creatine phosphokinase(CK): more than 124000 on 17Jul2021, tox screening: too low level (for therapeutic range) on 17Jul2021. The action taken in response to the events for clozapine was permanently withdrawn on 17Jul2021. Therapeutic measures were taken as a result of very severe rhabdomyolysis. The outcome of the event rhabdomyolysis, fatigue, malaise was recovering, myalgia was recovered on 31Jul2021; drug interaction was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Case Details

VAERS ID: 1747304 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 0000-00-00
Submitted: 0000-00-00
Entered: 2021-09-30

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Anticoagulant therapy, Deep vein thrombosis, Delivery, Exposure during pregnancy, Foetal death, Induced labour, Stillbirth
SMQs:, Embolic and thrombotic events, venous (narrow), Thrombophlebitis (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: BOOSTRIX POLIO; FRAGMIN
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Normal delivery; Normal pregnancy (The patient has two children from prior, uncomplicated pregnancies)
Allergies:
Diagnostic Lab Data: Test Name: fetus obduction; Result Unstructured Data: Test

Result:unknown result; Test Name: pathologic examination of the placenta; Result Unstructured Data: Test Result:unknown result
CDC Split Type: NLPFIZER INC202101216214
Write-up: still unexplained intra-uterine fetal death at 40+6 (autopsy still being performed); 34+4 thrombosis leg for which fragmin 5000 IU started; 28+2 blunt abdominal trauma; The patient was vaccinated at a pregnancy duration of 24 weeks; This is a spontaneous report from a contactable other healthcare professional downloaded from the regulatory authority, authority number NL-LRB-00683790. This reporter reported events for the same patient after two doses of the vaccine. This is the first report for the second dose. Only this report is serious. A 30-year-old pregnant female patient received bnt162b2 (COMIRNATY, Strength: 0.3 mL; Lot number was not reported), via an unspecified route of administration on an unspecified date as dose 2, 0.3 mL single for covid-19 immunization at 24 weeks of pregnancy. Information about mother and pregnancy: G3P2 Due date 04Sep2021. First 2 children were healthy, uncomplicated pregnancy and delivery. Concomitant medications included diphtheria vaccine toxoid, pertussis vaccine acellular 3-component, polio vaccine inact 3v (vero), tetanus vaccine toxoid (BOOSTRIX POLIO) taken for immunisation, start and stop date were not reported; dalteparin sodium (FRAGMIN) taken for deep vein thrombosis, start and stop date were not reported. The patient previously received bnt162b2 (COMIRNATY, Lot number was not reported), via an unspecified route of administration on an unspecified date as dose 1, single for covid-19 immunization at 18 weeks of pregnancy. On an unspecified date, the patient experienced still unexplained intra-uterine fetal death at 40+6; 34+4 thrombosis leg for which fragmin 5000 IU started; and 28+2 blunt abdominal trauma. Clinical course details: The patient had intra uterine death following administration of covid-19 vaccine Pfizer solution for injection for covid-19 immunisation. The patient was vaccinated at a pregnancy duration of 18 and 24 weeks. She also had DPTP (diphtheria, pertussis, tetanus, polio) vaccination, at a pregnancy duration of 28 weeks. At week 28+2 she had a blunt abdominal trauma, at week 34+4 she had a DVT (deep vein thrombosis) of the leg, which was treated with Dalteparin. Intra uterine death was diagnosed at a pregnancy duration of 40 weeks and 6 days. Labour was induced at 41 weeks. Obduction and pathologic examination of the placenta will follow. The patient has two children from prior, uncomplicated pregnancies. Information about child: 40+6 IUVD (intrauterine fetal death) detected when the patient came for induction due to threatening serotinity. Childbirth induced at 41 weeks went smoothly and uncomplicated. The mother was 40+6 weeks pregnant at the onset of the event. The mother was due to deliver on 04Sep2021. The mother delivered the pregnancy on an unknown date via vaginal delivery. The pregnancy resulted in still birth. The fetal outcome was intrauterine death. Labour was induced at 41 weeks. Obduction and pathologic examination of the placenta will follow. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender''s Comments: Linked Report(s) : NL-PFIZER INC-202101263583 Same reporter/patient/product; diferent events and dose

Case Details

VAERS ID: 1747315 (history)
Form: Version 2.0
Age: 34.0
Sex: Female
Location: Foreign

Vaccinated: 2021-08-26
Onset: 2021-08-26
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-09-30

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	FG4509 / 2	LA / -

Administered by: Other **Purchased by:** ?
Symptoms: Disability, Headache, Injection site pain, Nasopharyngitis, Syncope
SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Extravasation events (injections, infusions and implants) (broad), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? Yes
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202101273086

Write-up: Common cold; Headache; Second dose more than 42 days after the first one; Left arm reaction at or around injection site: pain; COVID-19 LIM This is a non-interventional study report from a contactable consumer (patient). This is the second of two reports. The first report was downloaded from the regulatory authority, regulatory authority number NL-LRB-COVID-00625040, Safety Report Unique Identifier NL-LRB-COVID-00674436. A 34-years-old female patient received bnt162b2 (COMIRNATY), dose 2 via an unspecified route of administration, administered in Arm Left on 26Aug2021 (Batch/Lot Number: FG4509) as single dose for covid-19 immunisation (Age at vaccination 34 years) . The patient medical history and concomitant medications were not reported. On 02JUl2021 the patient received the first dose of BNT162B2 (Lot number FE1573) vaccine and experienced several events including syncope. The patient experienced common cold (disability) on 28Aug2021 with outcome of not recovered , left arm reaction at or around injection site: pain (non-serious) on 26Aug2021 with outcome of recovered , headache (non-serious) on 28Aug2021 with outcome of recovering. The patient received the second dose more than 42 days after the first one (non serious) with outcome of unknown. Unspecified therapeutic measures were taken as a result of common cold (nasopharyngitis). No follow-up attempts possible. No further information expected.; Sender"s Comments: Linked Report(s) : NL-PFIZER INC-202100912291 The same patient, different events after 1st/2nd dose

Case Details

VAERS ID: 1751522 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-09-06
Onset: 2021-09-07
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-10-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Chills, Fatigue, Feeling cold, Headache, Injection site inflammation, Injection site pain, Injection site swelling, Malaise, Myalgia, Pyrexia
SMQs:, Rhabdomyolysis/myopathy (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Extravasation events (injections, infusions and implants) (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Eosinophilic pneumonia (broad), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data: Test Date: 20210907; Test Name: Body temperature; Result Unstructured Data: Test Result:40.5 - 42 Centigrade
CDC Split Type: NLPFIZER INC202101220132
Write-up: Fever: 40.5 to 42 degrees Celsius; Fatigue; Not feeling well; inflammatory reaction at or around the injection site; inflammatory reaction at or around the injection site: pain; inflammatory reaction at or around the injection site: swelling; Headache; Muscle pain; Cold shivers; This is a spontaneous report from a contactable consumer downloaded from the regulatory agency. The regulatory authority number is NL-LRB-00684335. A 34-year-old female patient received BNT162b2 (COMIRNATY), via an unspecified route of administration on 06Sep2021 (Batch/Lot Number: Unknown) as dose 2, single for COVID-19 immunisation. The patient''s medical history and concomitant medications were not reported. Historical vaccine included BNT162b2 (COMIRNATY), via an unspecified route of administration on 07Aug2021 (Batch/Lot Number: unknown) as dose 1, 0.3 mL single for COVID-19 immunisation. The patient has no previous COVID-19 infection. On 07Sep2021, one day after vaccination, the patient experienced Fever: 40.5 to 42 degrees Celsius, fatigue, not feeling well, inflammatory reaction at the reaction site: pain, swelling, occurring within a week after vaccination, headache, muscle pain and cold shivers. The outcome of fever: 40.5 to 42 degrees Celsius was recovering; for fatigue and malaise was not recovered; for injection site inflammation, injection site pain, and injection site swelling was recovered on 08Sep2021; for headache and myalgia was recovered on 09Sep2021, while for chills was recovered on 10Sep2021. Reporter''s comment: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): yes ADRs: None. Date: 07Aug2021. Redness or Swelling. Extensive swelling of vaccinated limb: no. Previous COVID-19 infection: No. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reporter''s Comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): yes ADRs: None. Date: 07Aug2021. Redness or Swelling. Extensive swelling of vaccinated limb: no. Previous COVID-19 infection: No.

Case Details

VAERS ID: 1751523 (history)
Form: Version 2.0
Age: 29.0
Sex: Male
Location: Foreign

Vaccinated: 2021-09-08
Onset: 2021-09-08
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-10-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Bell's palsy, Feeling abnormal, Inappropriate schedule of product administration, Malaise
SMQs:, Dementia (broad), Hearing impairment (broad), Medication errors (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202101236968
Write-up: facial Bell''s palsy; not feeling well; Inappropriate schedule of vaccine administered; This is a spontaneous report from a contactable consumer or other non hcp downloaded from the regulatory agency WEB NL-LRB-00685842. This

contactable consumer or other non hcp reported different events for different vaccine doses for same patient. This is the first of two reports. A 29-year-old male patient received BNT162B2 (Comirnaty, formulation: Solution for injection, lot/batch number and expiry date were not reported), via an unspecified route of administration, on 08Sep2021 (age at vaccination: 29 years), as a dose 2, single for COVID-19 immunization. The patient''s medical history and concomitant medications were not reported. Reportedly the patient did not had previous COVID-19 infection. The patient historical vaccine includes BNT162B2 (Comirnaty, formulation: Solution for injection, lot/batch number and expiry date were not reported), via an unspecified route of administration, on 06Jul2021, as a dose 1, single for COVID-19 immunization. On 08Sep2021, within one day the patient was not feeling well. On 11Sep2021, 3 days after the start, the patient had facial Bell''s palsy. Reportedly the patient was treated with prednisolone for the event not feeling well. Outcome of the events was not recovered and event Inappropriate schedule of vaccine administered was unknown. Additional information ADR: The patient reported that left side of his face was almost not working. Started with a weird feeling on his tongue. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reporter''s Comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): yes ADRs: Only tired Date: 06Jul2021 Bell''s palsy Additional information ADR: Left side of my face is almost not working. Started with a weird feeling on my tongue. COVID-19 Previous COVID-19 infection: No Other diagnostic procedures: No; Sender''s Comments: Linked Report(s) : NL-PFIZER INC-202101281106 The same patient, different events after 1st/2nd dose

Case Details

VAERS ID: 1751527 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 0000-00-00
Submitted: 0000-00-00
Entered: 2021-10-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Chills, Dysphonia, Erythema, Fatigue, Feeling cold, Headache, Inflammation, Injection site bruising, Injection site pain, Injection site reaction, Injection site swelling, Intermenstrual bleeding, Malaise, Menstrual disorder, Pharyngitis streptococcal, Pyrexia, Swelling
SMQs:, Anaphylactic reaction (broad), Agranulocytosis (broad), Angioedema (broad), Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Parkinson-like events (broad), Oropharyngeal infections (narrow), Extravasation events (injections, infusions and implants) (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Hypersensitivity (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:

Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202101271053
Write-up: 1 serious throat infection; have her period several times that month; inflammation; problems with her throat; lose her voice often; This is a spontaneous report from a contactable consumer. This is second of two reports. The first report is a report from the regulatory agency [NL-LRB-00684293]. A 24-year-old female patient received bnt162b2 (COMIRNATY), dose 2 via an unspecified route of administration on an unspecified date in 2021 (Lot number was not reported) as dose 2, single for COVID-19 immunization. The patient medical history was not reported. Concomitant medication included unspecified intrauterine contraceptive device. The patient previously received the first dose of bnt162b2 (COMIRNATY, Lot Number was not reported), on 07Jun2021 (at the age of 24-year-old) as single dose for COVID-19 immunization and experienced fever: 40.5 to 42 degrees Celsius, been very sick, fatigue, inflammatory reaction at the reaction site: pain, swelling, cold shivers/chills, reaction at or around the injection site: bruising, voice often disappears, bizarre strep throat, malaise, menstruation was totally wrong: several times that month period (Break through bleeding), headache, redness, swelling and bizarre throat infection. After the second vaccination it was reported that the vaccine caused her to have her period several times that month (Break through bleeding). She has an IUD so she don''t get her period anymore. She also got 1 serious throat infection from the vaccine. Since then, she continues to have inflammation and problems with her throat and also lose her voice often. She has never experienced this before. The events occurred on unspecified date in 2021. The outcome of the events was unknown. No follow-up attempts are possible; information on batch/lot number cannot be obtained. No further information expected.

Case Details

VAERS ID: 1755505 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-08-26
Onset: 2021-08-27
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-10-02

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	FG4509 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Pain in extremity, Syncope
SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), Tendinopathies and ligament disorders (broad), Hypoglycaemia (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? Yes
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness: Mite allergy
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Name: blood pressure; Result Unstructured Data: Test Result:no results reported; Test Name: heart rate; Result Unstructured Data: Test Result:no results reported; Test Name: oxygen saturation; Result Unstructured Data:

Test Result:no results reported
CDC Split Type: NLPFIZER INC202101231965
Write-up: Syncope/fainted; Pain in arm/sore arm; This is a spontaneous report from a contactable consumer (parent) downloaded from the Regulatory authority. The regulatory authority number is NL-LRB-00674622. A 14-year-old male patient received BNT162b2 (COMIRNATY), via an unspecified route of administration on 26Aug2021 (Batch/Lot Number: FG4509) as dose 1, single for COVID-19 immunisation. Medical history included ongoing mite allergy. The patient''s concomitant medications were not reported. The patient has no previous COVID-19 infection. On 27Aug2021 (1 day after start), the patient experienced syncope and pain in arm. The patient fainted the next day after noon. He only indicated this day that he had a sore arm. After lunch, they went to the hairdresser. After 10 minutes in the chair, he fainted. Later at the general physician in the practice, he almost again. Diagnostics included oxygen saturation, heart rate, blood pressure (no results reported). The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

Case Details

VAERS ID: 1755525 (history)
Form: Version 2.0
Age:
Sex: Unknown
Location: Foreign

Vaccinated: 0000-00-00
Onset: 0000-00-00
Submitted: 0000-00-00
Entered: 2021-10-02

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Transient ischaemic attack
SMQs:, Ischaemic central nervous system vascular conditions (narrow), Embolic and thrombotic events, arterial (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202101282971
Write-up: TIA; This a spontaneous report from a contactable consumer reporting same event under the same suspect product for four patients. This is one of four reports. The first report is a report downloaded from the Regulatory authority. A patient of unspecified age and gender received bnt162b2 (COMIRNATY), via an unspecified

route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for covid-19 immunisation. The patient''s medical history and concomitant medications were not reported. The patient experienced TIA on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about batch number cannot be obtained. No further information is expected.; Sender''s Comments: Linked Report(s) : NL-PFIZER INC-202101171318 same reporter, drug and event, different patient

Case Details

VAERS ID: 1826953 (history)
Form: Version 2.0
Age: 61.0
Sex: Male
Location: Foreign

Vaccinated: 2021-05-07
Onset: 2021-05-01
Submitted: 0000-00-00
Entered: 2021-10-29

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Burning sensation, Drug interaction, Dyspepsia, Fatigue, Headache, Injection site swelling, Malaise, Myalgia, Nausea, Oropharyngeal pain, Pharyngeal swelling, Pyrexia
SMQs:, Rhabdomyolysis/myopathy (broad), Anaphylactic reaction (broad), Acute pancreatitis (broad), Angioedema (narrow), Peripheral neuropathy (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Oropharyngeal conditions (excl neoplasms, infections and allergies) (narrow), Extravasation events (injections, infusions and implants) (broad), Gastrointestinal nonspecific dysfunction (narrow), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Haemodynamic oedema, effusions and fluid overload (narrow), Eosinophilic pneumonia (broad), Hypersensitivity (narrow), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:

Other Medications: Pantoprazole; COVID-19 VACCINE
Current Illness: COVID-19
Preexisting Conditions: Medical History/Concurrent Conditions: Gastric bypass; Comments: None
Allergies:
Diagnostic Lab Data: Test Date: 20210501; Test Name: Body temperature; Result Unstructured Data: Test Result:Pyrexia; Test Date: 20201201; Test Name: SARS-CoV-2 test; Test Result: Positive
CDC Split Type: NLPFIZER INC2021682952
Write-up: This spontaneous case was received from regulatory authority(NL-LRB-00544935) on 09Jun2021. Other reference number: NL-LRB-00530364. This is a non-serious case with the events of malaise, drug interaction, injection site swelling, headache, burning sensation, throat pain, pyrexia, throat swelling, myalgia, fatigue, heartburn and nausea [causality: not reported]. No further information is available. A 61-year-old male patient received pantoprazole (PANTOPRAZOL), via an unknown route of administration, from 2019 to 07May2021, at an unspecified dose and frequency, for an unknown indication, and received a dose of COVID-19 VACCINE (lot number ABW7197), via an unspecified route of administration on 01May2021 for COVID-19 immunisation. Medical history included COVID-19 confirmed with a positive positive SARSCoV- 2 test on 01Dec2020, and gastric bypass. Concomitant medications were not reported. The patient previously experienced drug allergy with carbamazepine and had received a dose of an unspecified COVID-19 vaccine for COVID-19 immunisation. On 01May2021 the patient experienced malaise, injection site swelling, headache, burning sensation, throat pain, pyrexia, throat swelling, myalgia, fatigue, heartburn and nausea. The action taken with pantoprazole was permanently withdrawn and replaced by omeprazole. The action taken with the vaccine was not applicable. The patient had not recovered from headache, myalgia, fatigue, drug interaction, heartburn, nausea throat swelling, malaise, and injection site swelling, was recovering from pyrexia, and had recovered from burning sensation, and throat pain. Causality Assessment: PANTOPRAZOLE, COVID-19 VACCINE . Nausea, Heartburn, Fatigue, Myalgia, Throat swelling, Pyrexia, Throat pain, burning sensation, Headache, Injection site swelling, Drug interaction, Malaise, per reporter: Not Reported, Per company (Takeda): Related Follow-up (21Sep2021): This is a follow up spontaneous report from a contactable consumer via regulatory health authority (Regulatory authority number: NL-LRB- 00530364, NL-LRB-00684922, NL-LRB-00536183 and NL-LRB-00544935), based on information received by Pfizer from (manufacturer control number: NLTAKEDA- 2021TEU005374), license party for pantoprazole. New event added myalgia, fatigue, heartburn and nausea. Causality added, suspect covid- 19 vaccine was added. Clinical information updated. Follow-up (24Sep2021): New information was received from the patient''s height was confirmed as 183 cm and not 185 cm as previously reported. Additionally, Pfizer suspect drug BNT162b2 has been removed since as per the only vaccine administered for COVID-19 immunisation was the one. Since BNT162b2 was removed, the previously reported events "interchange of vaccine products'' and ''off label use'' have been removed as well.

Case Details

VAERS ID: 1966204 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-02-01
Submitted: 0000-00-00
Entered: 2021-12-21

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Drug ineffective, Drug interaction, Lymphocyte count increased, Lymphopenia, Magnetic resonance imaging
SMQs:, Haematopoietic leukopenia (narrow), Lack of efficacy/effect (narrow), Systemic lupus erythematosus (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? Yes
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: Pfizer, Inc. 027034; GILENYA; VITAMIN D 3
Current Illness: Multiple sclerosis (no family history)
Preexisting Conditions: Medical History/Concurrent Conditions: Activities of daily living impaired
Allergies:
Diagnostic Lab Data: Test Name: Lymphocytes; Result Unstructured Data: Test Result:increased; Comments: unit and normal range not reported.; Test Date: 202102; Test Name: Lymphocytes; Result Unstructured Data: Test Result:low; Comments: unit

and normal range not reported.; Test Name: MRI; Result Unstructured Data: Test Result:unknown results; Comments: +/- no new deviations
CDC Split Type: NLPFIZER INC202101737546
Write-up: This is a spontaneous report received from contactable reporter(s) (Physician, Consumer or other non HCP and Other HCP) from the regulatory authority. Regulatory number: NL-EMA-DD-20211201-kumarvn_p-115230 (RA). Other Case identifier(s): NL-LRB-00701968 (EVDUP#CBGMEB), NL-LRB-00604592 (EVDUP#CBGMEB), NL-002147023-NVSC2021NL153227 (EVDUP#CBGMEB). A 45 year-old female patient received bnt162b2 (COMIRNATY) (Lot number: Unknown) as dose number unknown, single for covid-19 immunisation; fingolimod hydrochloride (GILENYA) Capsule, hard, first regimen since 2012 (Lot number: Unknown), second regimen from 01Aug2013 (Lot number: Unknown) to 01Mar2021 at 0.5 mg 1x/day and third regimen since 01Jun2020 (ongoing) (Lot number: Unknown) for multiple sclerosis. Relevant medical history included: "Activities of daily living impaired" (unspecified if ongoing); "Multiple sclerosis" (ongoing), notes: no family history. Concomitant medication(s) included: VITAMIN D 3. Vaccination history included: Comirnaty (1st dose), for COVID-19 immunisation. The following information was reported: DRUG INEFFECTIVE (disability, medically significant) with onset 21Feb2021, outcome "not recovered", described as "No antibody production after COVID vaccination (Pfizer)"; DRUG INTERACTION (medically significant), outcome "not recovered", described as "No production of antibodies after covid vaccination with Pfizer"; LYMPHOPENIA (medically significant) with onset Feb2021, outcome "not recovered", described as "Lymphopenia/ Deep Lymphopenia". The patient underwent the following laboratory tests and procedures: lymphocyte count: (unspecified date) increased, notes: unit and normal range not reported; (Feb2021) low, notes: unit and normal range not reported; magnetic resonance imaging: (unspecified date) unknown results, notes: +/- no new deviations. The action taken for fingolimod hydrochloride was dosage not changed. Clinical course: The patient was only partially able to perform her activities as physician (geriatrician) and was now in risk (word incomplete, probably incapacity for work). At first Gilenya was stopped for three months, after which there was hardly any increase of lymphocytes while no prospect of a vaccine yet, so Gilenya was restarted. The patient had no prior history of the events. Due to her activities as physician, the patient was daily at risk of contamination and the patient was very much worried. The outcome of the event vaccination failure was reported as condition deteriorated. The causality of vaccination failure and lymphopenia with Gilenya was reported as suspected. The causality of drug interaction with Gilenya was not reported. Sender"s comments: Considering immunomodulatory actions of the drug, reported lymphopenia, positive temporality, causal role of fingolimod could not be completely ruled out with event vaccination failure. hence, assessed as suspected No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Case Details

VAERS ID: 2061294 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-01-19
Submitted: 0000-00-00
Entered: 2022-01-25

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Condition aggravated, Depression, Drug interaction
SMQs:, Depression (excl suicide and self injury) (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, 7 days
Extended hospital stay? No
Previous Vaccinations:
Other Medications: PROZAC
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Depression; Disease risk factor
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202200044352
Write-up: It feels like antidepressants work less since vaccination, after every new vaccination it starts again; Increase in depression; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the

regulatory agency-WEB. Regulatory number: NL-LRB-00736776. A 27-year-old female patient received BNT162B2 (COMIRNATY), administration date 16Jan2021 (Lot number: EJ6795) as dose 1, 0.3ml single for COVID-19 immunization; fluoxetine hydrochloride (PROZAC), since 2016 (Lot number: Unknown) at 30 mg 1x/day (30 mg, 1x/day, 1.5 pill) for depressed mood. Relevant medical history included: "Disease risk factor" (unspecified if ongoing); "depression" (unspecified if ongoing). The patient"s concomitant medications were not reported. The following information was reported: DEPRESSION (hospitalization) with onset 19Jan2021, outcome "not recovered", described as "Increase in depression"; DRUG INTERACTION (hospitalization), outcome "unknown", described as "It feels like antidepressants work less since vaccination, after every new vaccination it starts again". The patient was hospitalized for depression, drug interaction (hospitalization duration: 7 day(s)). The action taken for fluoxetine hydrochloride was dosage not changed. Clinical course: Patient describes that she feels like her antidepressant fluoxetine does not work as well after the COVID vaccination. She experienced this after all her COVID vaccinations. Patient was admitted for a week in a psychiatric unit due to sudden increase of depression. After each new vaccination, it starts all over again. The patient had no previous COVID-19 infection. No follow-up attempts are possible. No further information is expected.

Case Details

VAERS ID: 2086957 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-07-09
Onset: 2021-10-20
Days after vaccination: 103
Submitted: 0000-00-00
Entered: 2022-02-04

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Haematocrit increased, Inappropriate schedule of product administration, No reaction on previous exposure to drug
SMQs:, Medication errors (narrow)
Life Threatening? Yes
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? Yes
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: SUSTANON [TESTOSTERONE DECANOATE;TESTOSTERONE ISOCAPROATE;TESTOSTERONE PHENYLPROPIONATE;TESTOSTERONE
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Name: Hematocrit; Result Unstructured Data: Test Result:0.56; Comments: After vaccination; Test Name: Hematocrit; Result

Unstructured Data: Test Result:0.45; Comments: Before vaccination
CDC Split Type: NLPFIZER INC202200144246
Write-up: I think the combination is not good; Hematocrit way too high/Hematocrit increased from 0,45 to 0,56; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the regulatory agency-WEB. Regulatory number: NL-LRB-00770952. A 19 year-old male patient received bnt162b2 (COMIRNATY), administration date 15Aug2021 (Lot number: Unknown) as dose 2, single for covid-19 immunisation; testosterone decanoate, testosterone isocaproate, testosterone phenylpropionate, testosterone propionate (SUSTANON [TESTOSTERONE DECANOATE;TESTOSTERONE ISOCAPROATE;TESTOSTERONE PHENYLPROPIONATE;TESTOSTERONE PROPIONATE]), from 09Jul2021 (Lot number: unknown) to 25Oct2021 at cyclic (1 x every 2 weeks, cyclic) for hormone therapy. The patient"s relevant medical history and concomitant medications were not reported. The patient did not have any previous COVID-19 infection. Vaccination history included: Comirnaty (Dose 1), administration date: 10Jul2021, for COVID-19 immunization, reaction(s): "No adverse event". The following information was reported: HAEMATOCRIT INCREASED (life threatening) with onset 20Oct2021, outcome "recovered" (07Jan2022), described as "Hematocrit way too high/Hematocrit increased from 0,45 to 0,56"; DRUG INTERACTION (non-serious), outcome "unknown", described as "I think the combination is not good". The patient underwent the following laboratory tests and procedures: haematocrit: 0.56, notes: After vaccination; 0.45, notes: Before vaccination. Hematocrit increased from 0,45 to 0,56 which resulted in the withdrawal of Sustanon. Hematocrit increased 2 months after start of Pfizer vaccine and 3 months after start of SUSTANON. It went from 0.45 to 0.56 and according to the HRH this was much too high, so it had to be stopped, because it could lead to heart attacks. They also said that it had nothing to do with each other. But now that it had stopped and the vaccine had been worked out, it was going down again. No diagnostic procedures were done. The action taken for testosterone decanoate, testosterone isocaproate, testosterone phenylpropionate, testosterone propionate was dosage permanently withdrawn on 25Oct2021. Health Authority comment: Hematocrit way too high. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Case Details

VAERS ID: 2103701 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2020-08-27
Onset: 2022-01-01
Days after vaccination: 492
Submitted: 0000-00-00
Entered: 2022-02-11

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Abortion spontaneous, Drug interaction, Dysmenorrhoea, Hypomenorrhoea, Intermenstrual bleeding, Pregnancy test negative, Pregnancy test positive, Pregnancy with contraceptive device, Ultrasound scan
SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Fertility disorders (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: MIRENA
Current Illness: Latex allergy; Plaster allergy; Soap allergy
Preexisting Conditions: Medical History/Concurrent Conditions: Ehlers-Danlos syndrome
Allergies:

Diagnostic Lab Data: Test Date: 20211227; Test Name: negative pregnancy test; Test Result: Negative ; Test Date: 20211224; Test Name: positive pregnancy test; Test Result: Positive ; Test Name: ultrasound; Result Unstructured Data: Test Result:unknown
CDC Split Type: NLPFIZER INC202200170463
Write-up: Pregnancy; pregnant / mirena; Had 2 light periods with severe cramps; 2 light menstruation; 2 light periods, pregnancy and subsequent miscarriage; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the regulatory agency-WEB. Regulatory number: NL-LRB-00776895. A 33 year-old female patient (pregnant) received bnt162b2 (COMIRNATY), administration date 03Jul2021 (Batch/Lot number: unknown) as dose 2, single for covid-19 immunisation; levonorgestrel (MIRENA), since 27Aug2020 (Batch/Lot number: unknown) for contraception. Relevant medical history included: "Ehlers-Danlos syndrome" (unspecified if ongoing); "Latex allergy" (ongoing); "Plaster allergy" (ongoing); "Soap allergy" (ongoing). The patient"s concomitant medications were not reported. Vaccination history included: Comirnaty (DOSE 1), administration date: 29May2021, for COVID-19 immunisation, reaction(s): "no adverse reaction". The following information was reported: ABORTION SPONTANEOUS (medically significant) with onset Jan2022, outcome "unknown", described as "2 light periods, pregnancy and subsequent miscarriage"; PREGNANCY WITH CONTRACEPTIVE DEVICE (medically significant), outcome "unknown", described as "Pregnancy"; DRUG INTERACTION (non-serious), outcome "unknown", described as "pregnant / mirena"; DYSMENORRHOEA (non-serious), outcome "not recovered", described as "Had 2 light periods with severe cramps"; INTERMENSTRUAL BLEEDING (non-serious), outcome "not recovered", described as "2 light menstruation". The pregnancy resulted in spontaneous abortion. The patient underwent the following laboratory tests and procedures: pregnancy test: (27Dec2021) negative; (24Dec2021) positive; ultrasound scan: (unspecified date) unknown. The action taken for levonorgestrel was dosage not changed. Clinical course: Patient became pregnant immediately after having sex once. After 01Mar2021 was my last menstruation; shortly after her second vaccination she had 2 light menstruations with heavy cramp. On or around 24Dec2021, she had a positive test. After 3 days it was negative. Since +- 10Jan2022 she had been losing some blood. she had an ultrasound on Wednesday to see if the coil is still in place. Patient was not had previous COVID-19 infection. it was reported that patient will have another ultrasound. Sender Comment: Since the nature of the reported reaction does imply seriousness according to one of the critera, the reaction was considered as serious by the regulatory agency. Reporter"s comments: 2 light periods, pregnancy and subsequent miscarriage No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Case Details

VAERS ID: 2118165 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-09-01
Submitted: 0000-00-00
Entered: 2022-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Amenorrhoea, Drug interaction, Maternal exposure before pregnancy, Pregnancy on oral contraceptive
SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Normal pregnancy conditions and outcomes (narrow), Fertility disorders (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: Comirnaty; ACELYN; INFLIXIMAB
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Contraception; Disease risk factor; Suspected COVID-19 (at 23:00 Disease symptoms: quite)
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202200188468

Write-up: Pregnancy on oral contraceptive/ Pill not working, got pregnant; Drug interaction; Maternal exposure before pregnancy; did not menstruate; This is a spontaneous report received from a contactable reporter (consumer) from the regulatory agency-WEB. The reporter is the patient. Regulatory number: NL-LRB-00777075. Other Case identifier: NL-LRB-00785397. A 20 year-old female patient (pregnant) received BNT162b2 (COMIRNATY), administration date 16Sep2021 (Lot number: FF2834) as dose 1, single for COVID-19 immunisation; ethinylestradiol (ACELYN), from 14Aug2019 (Batch/Lot number: unknown) to 24Sep2021 at 0.05 mg for contraception. The patient was not pregnant at time of vaccination. Relevant medical history included: "Suspected COVID-19", start date: 09Mar2020 (unspecified if ongoing), notes: at 23:00, Disease symptoms: quite; "Disease risk factor" (unspecified if ongoing); Contraception", start date: 14Aug2019, stop date: 24Sep2021. Concomitant medication included: INFLIXIMAB. The following information was reported: PREGNANCY ON ORAL CONTRACEPTIVE (medically significant) with onset 23Sep2021, outcome "not recovered", described as "Pregnancy on oral contraceptive/ Pill not working, got pregnant"; DRUG INTERACTION (medically significant) with onset 23Sep2021, outcome "not recovered", described as "Drug interaction"; AMENORRHOEA (non-serious) with onset Sep2021, outcome "unknown", described as "did not menstruate"; MATERNAL EXPOSURE BEFORE PREGNANCY (non-serious) with onset 23Sep2021, outcome "unknown", described as "Maternal exposure before pregnancy". The action taken for ethinylestradiol was dosage permanently withdrawn on 24Sep2021. Additional information: The patient reported that the birth-control pill did not work because of the vaccine, as a result of which she got pregnant. One week after the vaccination, the patient had the pill-free week, at which point she did not get her period and at first, she thought it was because of the vaccination. Other than the birth-control pill, the patient did not use any other contraceptives. She had the same partner for 5 years and this has always just been fine. No follow-up attempts are possible. No further information is expected.

Case Details

VAERS ID: 2122250 (history)
Form: Version 2.0
Age: 41.0
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2022-01-03
Submitted: 0000-00-00
Entered: 2022-02-18

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Affective disorder, Arthralgia, Chills, Condition aggravated, Confusional state, Crying, Depression, Drug ineffective, Drug interaction, Fatigue, Feeling abnormal, Hypoaesthesia, Inappropriate schedule of product administration, Injection site reaction, Insomnia, Malaise, Mood altered, Myalgia, Pain in extremity, Pyrexia, Restlessness, Sleep disorder, Suicidal ideation, Vaccination site induration, Vaccination site pain
SMQs:, Rhabdomyolysis/myopathy (broad), Lack of efficacy/effect (narrow), Peripheral neuropathy (broad), Suicide/self-injury (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Akathisia (broad), Psychosis and psychotic disorders (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Eosinophilic pneumonia (broad), Depression (excl suicide and self injury) (narrow), Arthritis (broad), Tendinopathies and ligament disorders (broad), Medication errors (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad), Sexual dysfunction (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No

ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: Pfizer, Inc. EUA 027034; Efexor; LEVOTHYROXINE
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Suspected COVID-19
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202200209205
Write-up: Suicidal ideation; My mood flipped 180 degrees about 24 hours after the vaccination, after a virtually sleepless and very restless night; sudden change of mood; Depressed state; feeling that Effexor contributes nothing more; Fatigue; Reaction at or around the injection site: hardening, occurring later than one week after vaccination; Generalized joint pain; Reaction at or around the injection site: pain; Myalgia; Not feeling well; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the regulatory authority. Regulatory number: NL-LRB-00766686. A 41 year-old female patient received bnt162b2 (COMIRNATY), administration date 03Jan2022 (Lot number: FF2382) at the age of 41 years as dose 3 (booster), single for covid-19 immunisation; venlafaxine hcl (EFEXOR) (Batch/Lot number: unknown) at 112 mg (112 mg (1 x 75 and 1 x 37.5 daily)) for affective disorder. Relevant medical history included: "Suspected COVID-19", start date: 26Feb2020 (unspecified if ongoing). Concomitant medication(s) included: LEVOTHYROXINE. Past drug history included: Efexor xr for Drug interaction. Vaccination history included: Comirnaty (1st dose), administration date: 17Jun2021, for covid-19 immunisation, reaction(s): "Pain in arm"; Comirnaty (2nd dose), administration date: 22Jul2021, for covid-19 immunisation, reaction(s): "Myalgia", "Numbness in fingers", "Confused", "Chills", "Fever". The following information was reported: SUICIDAL IDEATION (medically significant), outcome "not recovered", described as "Suicidal ideation"; MYALGIA (non-serious) with onset 03Jan2022, outcome "recovered" (04Jan2022), described as "Myalgia"; MALAISE (non-serious) with onset 03Jan2022, outcome "recovered" (05Jan2022), described as "Not feeling well"; FATIGUE (non-serious) with onset 04Jan2022, outcome "recovering", described as "Fatigue"; INSOMNIA (non-serious), outcome "not recovered", described as "My mood flipped 180 degrees about 24 hours after the vaccination, after a virtually sleepless and very restless night"; ARTHRALGIA (non-serious) with onset 03Jan2022, outcome "recovered" (04Jan2022), described as "Generalized joint pain"; VACCINATION SITE PAIN (non-serious) with onset 03Jan2022, outcome "not recovered", described as "Reaction at or around the injection site: pain"; MOOD ALTERED (non-serious), outcome "not recovered", described as "sudden change of mood"; DEPRESSION (non-serious), outcome "not recovered", described as "Depressed state"; VACCINATION SITE INDURATION (non-serious) with onset 03Jan2022, outcome "not recovered", described as "Reaction at or around the injection site: hardening, occurring later than one week after vaccination"; DRUG INTERACTION (non-serious), outcome "not recovered", described as "feeling that Effexor contributes nothing more". The action taken for venlafaxine hcl was

unknown. Therapeutic measures were taken as a result of vaccination site pain, vaccination site induration. Clinical course: The patient had altered mood just at once (180 degree switch) form feeling well to feeling depressed/suicidal ideation/crying al lot. That was the day following vaccination and after a night with insomnia. She felt as if her medication venlafaxine did not work properly or that the vaccine had influenced serotonin and dopamine as neurotransmitters in her brain. Treatment Injection site induration is treated with ibuprofen, paracetamol, personal initiative, injection site pain is treated with ibuprofen, paracetamol and personal initiative. venlafaxine capsule modified release 37,5mg. Additional information: I felt mentally still good on 03Jan . I am familiar with mood issues, but since I have been using Effexor and my life is in fairly calm waters things are going pretty well. Had a nice walk by the sea that day, felt good. 03Jan afternoon I took the booster. Had a sleepless night. The next day I was tired and not very interested when I visited a friend. Was not feeling well in my skin. Mood suddenly changed and is like this until today. Crying fits, desire for death stronger than ever, feeling that Effexor doesn"t contribute or do anything anymore. I drag myself through the days. Before that I was in an upward spiral, so it is remarkable. I hope it will blow over, but I have the feeling that the vaccine has done something to boost serotonin or dopamine. Was so restless that night not sick but felt very strange mentally. 20Jan2021 Follow up received I would like to explain, as succinctly as possible, a previous report x. On 03Jan I (female, 41) got my booster vaccination. I have been known (for quite some time unfortunately) to have depressive episodes/voting problems. For this I have been using venlafaxine for a number of years, which has benefited me greatly. At the time of the shot a dose of 112.5 mg. My mood changed 180 degrees about 24 hours after the vaccination, after an almost sleepless and very restless night (at 2nd vaccination also restless and a bit confused, but significantly less than now). In the morning of 03JanI still felt good (I had walked along the beach, the weather was nice, I was glad that I could get the shot earlier thanks to a friend who works where they had vaccines available), but about 24 hours after the shot my mood changed to restlessness, I never had a crying fit in the train (usually I was able to control myself and also the venlafaxine normally helps to prevent such disinhibition). Only on Friday 14Jan did the mood slowly change back in the right direction. It is then as if the light in my head goes back on, or in other words, it storms and rains in your head for days, and it slowly clears up. It seemed as if the medication that normally helps me so much to cope with (working) life, did not do anything anymore. I suffered a lot from this, it was a real struggle to stay upright, to keep going to work, to get out of bed, etc. I was also (and still am) forgetful, chaotic and cognitively not quite the same as before. But I"m sure that will come back. No doubt the easing up also contributed to an improvement in mood, as the lockdown was not easy either (despite job 32 hours on site I missed certain activities outside the house) like many I think.Reporter wouldn"t be surprised if more people vulnerable to depression and mood problems (and possibly psychosis) have a chance of getting these kinds of symptoms after a vaccine. I"m not a doctor, but it wouldn"t surprise me if when the immune system is challenged (by vaccine or going through whatever virus-driven illness), it can also cause some turmoil in the brain (so it doesn"t have to, but is a possibility). I think it would be good if the regulatory authority was aware of this, and that if necessary psychologically vulnerable people could adapt their lives in time to

this (e.g. planning the vaccination at a favourable moment - during free time - asking friends to keep an eye on things, contacting possible personal counsellor in advance etc), in order to prevent problems and unnecessary suffering. Further research within the field of psyche would not be wrong I think. Now that I''m feeling better about myself, I''ll dare next possible booster again I think. But I''m going to take into account another episode of depression and restlessness. Hopefully next time it won''t be so bad. And I know that it will blow over on its own one day. No follow-up attempts are possible. No further information is expected.; Sender''s Comments: Linked Report(s) : NL-PFIZER INC-202200253857 the same patinet/ different dose of vaccine;NL-PFIZER INC-202200254043 the same patinet/ different dose of vaccine;NL-PFIZER INC-202200254294 the same patient/ different drug;NL-PFIZER INC-202200254043 same patient, different comirnaty dose;NL-PFIZER INC-202200253857 same patient, different comirnaty dose

Case Details

VAERS ID: 2125471 (history)
Form: Version 2.0
Age: 55.0
Sex: Female
Location: Foreign

Vaccinated: 0000-00-00
Onset: 2021-11-03
Submitted: 0000-00-00
Entered: 2022-02-19

Vaccination / Manufacturer	Lot / Dose	Site / Route
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Drug interaction, Menopausal symptoms, Oligomenorrhoea, Postmenopausal haemorrhage
SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Fertility disorders (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: SYSTEN [ESTRADIOL]
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Disease risk factor; Menopausal symptoms
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC202200222604
Write-up: Hormones / menopause, I use hormone patches, I suffer from that when I take the patches off, there comes irritation on the skin, eczema.; And my menopausal

symptoms have gotten worse.; My menstrual period lasted 4 weeks from 03Nov2021 to 07Dec2021; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the regulatory agency-WEB. Regulatory number: NL-LRB-00734664. A 55 year-old female patient received bnt162b2 (COMIRNATY), administration date 08Nov2021 (Lot number: FG6273) at the age of 55 years as dose 1, 0.3 ml, single for covid-19 immunisation; estradiol (SYSTEN [ESTRADIOL]) (Batch/Lot number: unknown). Relevant medical history included: "Menopausal symptoms" (unspecified if ongoing); "Disease risk factor" (unspecified if ongoing). Previous COVID-19 infection: No. The patient"s concomitant medications were not reported. The following information was reported: POSTMENOPAUSAL HAEMORRHAGE (medically significant) with onset 03Nov2021, outcome "recovered" (07Dec2021), described as "My menstrual period lasted 4 weeks from 03Nov2021 to 07Dec2021"; DRUG INTERACTION (non-serious), outcome "unknown", described as "Hormones / menopause, I use hormone patches, I suffer from that when I take the patches off, there comes irritation on the skin, eczema."; MENOPAUSAL SYMPTOMS (non-serious), outcome "not recovered", described as "And my menopausal symptoms have gotten worse.". Therapeutic measures were taken as a result of drug interaction. Clinical course: She use hormone patches, they bother her when she took the patches off, there appears irritation on the skin, eczema. Her menstrual period lasted 4 weeks from 03Nov2021 to 07Dec2021. Her menopausal symptoms have worsened. diagnostic procedures: No. Treatment: Drug interaction is treated with Triamcinolon. Still working on it. Latency for event dug interaction and menopausal symptoms have gotten worse was 5 weeks. No follow-up attempts are possible. No further information is expected.