Package leaflet: Information for the user

# Comirnaty JN.1

**10 micrograms/dose dispersion for injection**
**Children 5 to 11 years**
**COVID-19 mRNA Vaccine**, bretovameran

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▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1 What Comirnaty JN.1 is and what it is used for

Comirnaty JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty JN.1 10 micrograms/dose dispersion for injection is given to children from 5 to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty JN.1 does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

## 2 What you need to know before your child receives Comirnaty JN.1

**Comirnaty JN.1 should not be given**
- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

**Warnings and precautions**
Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:
- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.
- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty JN.1 may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty JN.1 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

**Children**
Comirnaty JN.1 10 micrograms/dose dispersion for injection is not recommended for children aged under 5 years.

There are paediatric formulations available for infants and children aged 6 months to 4 years. For details, please refer to the Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

**Other medicines and Comirnaty JN.1**
Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

**Pregnancy and breast-feeding**
If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty JN.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty JN.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty JN.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty JN.1 can be used while breast-feeding.

**Driving and using machines**
Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

## 3 How Comirnaty JN.1 is given

Comirnaty JN.1 is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose.

If your child is immunocompromised, he/she may receive additional doses of Comirnaty JN.1.

If you have any further questions on the use of Comirnaty JN.1, ask your child's doctor, pharmacist or nurse.

## 4 Possible side effects

Like all vaccines, Comirnaty JN.1 can cause side effects, although not everybody gets them.

**Very common side effects:** may affect more than 1 in 10 people
- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

**Common side effects:** may affect up to 1 in 10 people
- nausea, vomiting
- injection site redness ('very common' in 5 to 11 years of age)
- enlarged lymph nodes (more frequently observed after a booster dose)

**Uncommon side effects:** may affect up to 1 in 100 people
- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

**Rare side effects:** may affect up to 1 in 1 000 people
- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

**Very rare side effects:** may affect up to 1 in 10 000 people
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

**Not known** (cannot be estimated from the available data)
- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

**Reporting of side effects**
If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

- **België/Belgique/Belgien**
  Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
  www.fagg.be
  Afdeling Vigilantie:
  Website: www.eenbijwerkingmelden.be
  e-mail: adr@fagg-afmps.be

  Agence fédérale des médicaments et des produits de santé
  www.afmps.be
  Division Vigilance:
  Site internet: www.notifieruneffetindesirable.be
  e-mail: adr@fagg-afmps.be

  Föderalagentur für Arzneimittel und Gesundheitsprodukte
  www.afmps.be
  Abteilung Vigilanz:
  Website: www.notifieruneffetindesirable.be
  e-mail: adr@fagg-afmps.be
- **България**
  Изпълнителна агенция по лекарствата, ул. „Дамян Груев" № 8, 1303 София, Тел.: +359 2 8903417
  уебсайт: www.bda.bg
- **Česká republika**
  Státní ústav pro kontrolu léčiv, Šrobárova 48, 100 41 Praha 10,
  Webové stránky: www.sukl.cz/nahlasit-nezadouci-ucinek
- **Danmark**
  Lægemiddelstyrelsen, Axel Heides Gade 1, DK-2300 København S,
  Websted: www.meldenbivirkning.dk
- **Deutschland**
  Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Paul-Ehrlich-Institut,
  Paul-Ehrlich-Str. 51-59, 63225 Langen, Tel: +49 6103 77 0,
  Fax: +49 6103 77 1234, Website: www.pei.de
- **Eesti**
  Ravimiamet, Koduleht: www.ravimiamet.ee
- **Ελλάδα**
  Εθνικός Οργανισμός Φαρμάκων,
  Μεσογείων 284, GR-15562 Χολαργός, Αθήνα,
  Τηλ: + 30 21 32040337
  Ιστότοπος: http://www.eof.gr
  http://www.kitrinikarta.gr
- **España**
  Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: www.notificaRAM.es
- **France**
  Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance
  Site internet: https://signalement.social-sante.gouv.fr/
- **Hrvatska**
  Agencija za lijekove i medicinske proizvode (HALMED)
  Internetska stranica: www.halmed.hr ili potražite HALMED aplikaciju putem Google Play ili Apple App Store trgovine
- **Ireland**
  HPRA Pharmacovigilance, Website: www.hpra.ie
- **Ísland**
  til Lyfjastofnunar, www.lyfjastofnun.is
- **Italia**
  Agenzia Italiana del Farmaco, Sito web: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse
- **Κύπρος**
  Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας, CY-1475 Λευκωσία, Τηλ: +357 22608607, Φαξ: + 357 22608669,
  Ιστότοπος: www.moh.gov.cy/phs
- **Latvija**
  Zāļu valsts aģentūra, Jersikas iela 15, Rīga, LV 1003,
  Tīmekļa vietne: www.zva.gov.lv
- **Lietuva**
  Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos
  Tel.: 8 800 73568
  El. paštas: NepageidaujamaR@vvkt.lt
  Pranešimo forma pildymui internetu:
  https://vapris.vvkt.lt/vvkt-web/public/nrv
  Pranešimo forma skelbiama
  https://www.vvkt.lt/index.php?4004286486
- **Luxembourg/Luxemburg**
  Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé
  Site internet : www.guichet.lu/pharmacovigilance

  Centre Régional de Pharmacovigilance de Nancy oder Abteilung Pharmazie und Medikamente (Division de la pharmacie et des médicaments) der Gesundheitsbehörde in Luxemburg
  Website: www.guichet.lu/pharmakovigilanz
- **Magyarország**
  Nemzeti Népegészségügyi és Gyógyszerészeti Központ
  Postafiók 450, H-1372 Budapest
  Honlap: www.ogyei.gov.hu
  elektronikus bejelentő form: https://mellekhatas.ogyei.gov.hu/
  e-mail: adr.box@ogyei.gov.hu
- **Malta**
  ADR Reporting Website:
  www.medicinesauthority.gov.mt/adrportal
- **Nederland**
  Nederlands Bijwerkingen Centrum Lareb
  Website: www.lareb.nl
- **Norge**
  Direktoratet for medisinske produkter
  Nettside: www.dmp.no/pasientmelding
- **Österreich**
  Bundesamt für Sicherheit im Gesundheitswesen,
  Traisengasse 5, 1200 WIEN, ÖSTERREICH
  Fax: + 43 (0) 50 555 36207,
  Website: http://www.basg.gv.at/
- **Polska**
  Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych,
  Al. Jerozolimskie 181C, PL-02 222 Warszawa
  Tel.: + 48 22 49 21 301, Faks: + 48 22 49 21 309
  Strona internetowa: https://smz.ezdrowie.gov.pl
- **Portugal**
  Sítio da internet:
  http://www.infarmed.pt/web/infarmed/submissaoram (preferencialmente) ou através dos seguintes contactos:
  Direção de Gestão do Risco de Medicamentos Parque da Saúde de Lisboa, Av. Brasil 53, 1749-004 Lisboa
  Tel: +351 21 798 73 73
  Linha do Medicamento: 800222444 (gratuita)
  e-mail: farmacovigilancia@infarmed.pt
- **România**
  Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România Str. Aviator Sănătescu nr. 48, sector 1 București 011478- RO
  e-mail: adr@anm.ro, Website: www.anm.ro
- **Slovenija**
  Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Sektor za farmakovigilanco, Nacionalni center za farmakovigilanco, Slovenčeva ulica 22, SI-1000 Ljubljana
  Tel: +386 (0)8 2000 500, Faks: +386 (0)8 2000 510
  e-pošta: h-farmakovigilanca@jazmp.si
  spletna stran: www.jazmp.si
- **Slovenská republika**
  Štátny ústav pre kontrolu liečiv, Sekcia klinického skúšania liekov a farmakovigilancie, Kvetná 11,
  SK-825 08 Bratislava,
  Tel: + 421 2 507 01 206
  e-mail: neziaduce.ucinky@sukl.sk
  Tlačivo na hlásenie podozrenia na nežiaduci účinok lieku je na webovej stránke www.sukl.sk v časti Bezpečnosť liekov/Hlásenie podozrení na nežiaduce účinky liekov, Formulár na elektronické podávanie hlásení:
  https://portal.sukl.sk/eskadra/
- **Suomi/Finland**
  www-sivusto: www.fimea.fi, Lääkealan turvallisuus- ja kehittämiskeskus Fimea, Lääkkeiden haittavaikutusrekisteri, PL 55, 00034 FIMEA
  webbplats: www.fimea.fi,
  Säkerhets- och utvecklingscentret för läkemedelsområdet Fimea, Biverkningsregistret, PB 55, 00034 FIMEA
- **Sverige**
  Läkemedelsverket, Box 26, 751 03 Uppsala
  Webbplats: www.lakemedelsverket.se
- **United Kingdom (Northern Ireland)**
  Yellow Card Scheme
  Website: https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

## 5 How to store Comirnaty JN.1

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials can be handled in room light conditions.

Opened vials: After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6 information

**What Comirnaty JN.1 contains**
- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called bretovameran.
  - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of bretovameran per dose.
  - A multidose vial contains 6 doses of 0.3 mL with 10 micrograms of bretovameran per dose.
- The other ingredients are:
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol
  - trometamol
  - trometamol hydrochloride
  - sucrose
  - water for injections

**What Comirnaty JN.1 looks like and contents of the pack**
The vaccine is a clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided in either:
- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Single dose vials pack size: 10 vials
Multidose vials pack size: 10 vials
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

**Manufacturer**
BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
- **België/Belgique/Belgien, Luxembourg/Luxemburg**: Pfizer S.A./N.V., Tél/Tel: +32 (0)2 554 62 11
- **България**: Пфайзер Люксембург САРЛ, Клон България, Тел: +359 2 970 4333
- **Česká republika**: Pfizer, spol. s r.o., Tel: +420 283 004 111
- **Danmark**: Pfizer ApS, Tlf: +45 44 201 100
- **Deutschland**: BioNTech Manufacturing GmbH, Tel: +49 6131 90840
- **Eesti**: Pfizer Luxembourg SARL Eesti filiaal, Tel: +372 666 7500
- **Ελλάδα**: Pfizer Ελλάς A.E., Τηλ.: +30 210 6785 800
- **España**: Pfizer, S.L., Tel: +34914909900
- **France**: Pfizer, Tél +33 1 58 07 34 40
- **Hrvatska**: Pfizer Croatia d.o.o., Tel: +385 1 3908 777
- **Ireland**: Pfizer Healthcare Ireland, Tel: 1800 633 363 (toll free), +44 (0)1304 616161
- **Ísland**: Icepharma hf, Simi: +354 540 8000
- **Italia**: Pfizer S.r.l., Tel: +39 06 33 18 21
- **Κύπρος**: Pfizer Ελλάς A.E. (Cyprus Branch), Τηλ: +357 22 817690
- **Latvija**: Pfizer Luxembourg SARL filiāle Latvijā,Tel.: +371 670 35 775
- **Lietuva**: Pfizer Luxembourg SARL filialas Lietuvoje, Tel. +370 52 51 4000
- **Magyarország**: Pfizer Kft, Tel: +36 1 488 3700
- **Malta**: Vivian Corporation Ltd., Tel: +35621 344610
- **Norge**: Pfizer AS, Tlf: +47 67 526 100
- **Nederland**: Pfizer BV, Tel: +31 (0)10 406 43 01

- **Österreich**: Pfizer Corporation Austria Ges.m.b.H, Tel: +43 (0)1 521 15-0
- **Polska**: Pfizer Polska Sp. z o.o., Tel.: +48 22 335 61 00
- **Portugal**: Laboratórios Pfizer, Lda., Tel: +351 21 423 5500
- **România:** Pfizer Romania S.R.L, Tel: +40 (0) 21 207 28 00
- **Slovenija**: Pfizer Luxembourg SARL, Pfizer, podružnica za svetovanje s področja farmacevtske dejavnosti, Ljubljana, Tel.: +386 (0) 1 52 11 400
- **Slovenská republika**: Pfizer Luxembourg SARL, organizačná zložka, Tel: +421 2 3355 5500
- **Suomi/Finland**: Pfizer Oy, Puh/Tel: +358 (0)9 430 040
- **Sverige**: Pfizer AB, Tel: +46 (0)8 550 520 00
- **United Kingdom (Northern Ireland)**: Pfizer Limited, Tel: +44 (0) 1304 616161

**This leaflet was last revised in 07/2024.**

Scan the code with a mobile device to get the package leaflet in different languages.

URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency website: https://www.ema.europa.eu.

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**The following information is intended for healthcare professionals only:**
Administer Comirnaty JN.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

**Traceability**
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

**Handling instructions prior to use**
Comirnaty JN.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty JN.1 10 micrograms/dose dispersion for injection** (children 5 to 11 years)**.**
- If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
  - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
  - Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.
- Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.

**Preparation of 0.3 mL doses**
- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
  - Single dose vials
    - Withdraw a single 0.3 mL dose of vaccine.
    - Discard vial and any excess volume.
  - Multidose vials
    - Multidose vials contain 6 doses of 0.3 mL each.
    - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
    - Withdraw 0.3 mL of Comirnaty JN.1 for children aged 5 to 11 years.

**Low dead-volume syringes and/or needles** should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

**Disposal**
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.