EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Comirnatie

tozinamérien / riltozinameran et tozinameran / famtozinameran et tozinameran / COVID-19 ARNm Vaccin (nucléoside modifié)

Table des matières

AUTORISÉ
Ce médicament est autorisé dans l'Union européenne.

SÉCURITÉ DES PATIENTS
Information sécurité patient

Aperçu

Comirnaty est un vaccin pour prévenir la maladie à coronavirus 2019 (COVID-19) chez les personnes âgées de 5 ans et plus.

Comirnaty contient du tozinamérane, une molécule d'ARN messager (ARNm) avec des instructions pour produire une protéine à partir de la souche originale du SRAS-CoV-2, le virus qui cause le COVID-19.

Comirnaty est également disponible sous forme de deux vaccins adaptés:

- Comirnaty Original/Omicron BA.1 contient du tozinamérane et du riltozinamérane, une autre molécule d'ARNm avec des instructions pour produire une protéine à partir de la sous-variante Omicron BA.1 du SRAS-CoV-2.
- Comirnaty Original/Omicron BA.4-5 contient du tozinaméran et du famtozinaméran, une autre molécule d'ARNm avec des instructions pour produire une protéine à partir des sous-variantes Omicron BA.4 et BA.5 du SRAS-CoV-2.

Les vaccins adaptés ne sont utilisés que chez les personnes âgées de 12 ans et plus qui ont reçu au moins une primovaccination contre la COVID-19.

Comirnaty et ses vaccins adaptés ne contiennent pas le virus lui-même et ne peuvent pas causer la COVID-19.

Comment Comirnaty est-il utilisé?

Primary vaccination

Comirnaty is given as two injections, usually into the muscle of the upper arm, 3 weeks apart. Adults and adolescents from the age of 12 are given 30 micrograms per dose; children aged 5 to 11 years are given 10 micrograms per dose.

An additional dose of Comirnaty may be given to people aged 5 years and older with a severely weakened immune system, at least 28 days after their second dose.

Booster vaccination

A booster dose of Comirnaty may be given to people aged 12 years and older at least 3 months after primary vaccination with Comirnaty. In adults a booster dose of Comirnaty can also be given after primary vaccination with another mRNA vaccine or an adenoviral vector vaccine.

A booster dose of Comirnaty Original/Omicron BA.1 or Comirnaty Original/Omicron BA.4-5 (30 micrograms per dose) may be given to people aged 12 years and older at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine.

The vaccines should be used according to official recommendations issued at national level by public health bodies.

For more information about using Comirnaty or its adapted vaccines, see the package leaflet or consult a healthcare professional.

Comment fonctionne Comirnaty?

Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body’s cells, and can differ between variants of the virus. Adapted vaccines work in the same way as Comirnaty and are expected to broaden protection against the virus as they also contain mRNA matching other variants of the virus.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person’s immune system will then recognise the protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2, their immune system will recognise it and be ready to defend the body against it.

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

Quels avantages de Comirnaty ont été démontrés dans les études?

Primary vaccination

A very large clinical trial showed that Comirnaty, given as a two-dose regimen, was effective at preventing COVID-19 in people from 12 years of age.

The trial involved around 44,000 people aged 16 and above in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.

Efficacy in people aged 16 and above was calculated in over 36,000 participants (including people over 75 years of age) who had no sign of previous infection. The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received a dummy injection (162 cases out of 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the trial.

The trial in people aged 16 years and older also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or obesity.

The trial was extended to include 2,260 children aged 12 to 15. It showed that the immune response to Comirnaty in this group was comparable to the immune response in the 16 to 25 age group (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in close to 2,000 children from 12 to 15 who had no sign of previous infection. These received either the vaccine or a placebo (a dummy injection), without knowing which one they were given. Of the 1,005 children receiving the vaccine, none developed COVID-19 compared with 16 children out of the 978 who received the dummy injection. This means that, in this study, the vaccine was 100% effective at preventing COVID-19 (although the true rate could be between 75% and 100%).

Another study showed that an additional dose of Comirnaty increased the ability to produce antibodies against SARS-CoV-2 in organ transplant adult patients with severely weakened immune systems.

A study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in almost 2,000 children from 5 to 11 years of age who had no sign of previous infection. These children received either the vaccine or a placebo. Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this

study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

Booster vaccination

Comirnaty

A booster dose of Comirnaty, given after primary vaccination with the vaccine, led to a rise in antibody levels in people from 18 to 55 years old with a normal immune system.

The company also presented supporting evidence from a study of a booster dose of Comirnaty in adolescents aged 16 and over, together with published literature and post-authorisation data plus real-world evidence from the use of booster doses in young people in Israel. Taking all available knowledge into account, it was concluded that the immune response to a booster dose of Comirnaty in adolescents would be at least equal to that in adults.

Comirnaty Original/Omicron BA.1

Another study in adults over 55 years old who had previously received 3 doses of Comirnaty (primary vaccination and a booster) found that the immune response to the Omicron BA.1 subvariant was higher after a second booster dose of Comirnaty Original/Omicron BA.1 than after a second booster with the original Comirnaty vaccine (as measured by the level of antibodies against Omicron BA.1). In addition, the immune response to the original SARS-CoV-2 strain was comparable for both vaccines. The study involved more than 1,800 people, of whom about 300 received Comirnaty Original/Omicron BA.1 in its final composition.

Further data from a study involving over 600 people aged between 18 and 55 years who had previously received 3 doses of Comirnaty showed that the immune response to Omicron BA.1 was higher in people who received a booster with a vaccine containing only the Omicron BA.1 component (riltozinameran) than in those given a booster with the original Comirnaty vaccine.

Based on these data, it was concluded that the immune response to Omicron BA.1 following a booster with Comirnaty Original/Omicron BA.1 in people aged 18 to 55 years would be at least equal to that in people aged over 55. Further, based on previous data in younger people, it was also concluded that the immune response to a booster dose with Comirnaty Original/Omicron BA.1 in adolescents would be at least equal to that in adults.

Comirnaty Original/Omicron BA.4-5

Apart from containing mRNA matching different, but closely related, Omicron subvariants, Comirnaty Original/BA.1 and Comirnaty Original/Omicron BA.4-5 have the same composition. Therefore, based on clinical studies showing that Comirnaty Original/Omicron BA.1 triggers an immune response to the original strain and Omicron BA.1, Comirnaty Original/Omicron BA.4-5 is expected to generate an immune response against both the original strain and the subvariants BA.4 and BA.5. In particular, Comirnaty Original/Omicron BA.4-5 is expected to be more effective than Comirnaty at triggering an immune response against the BA.4 and BA.5

subvariants. These data are further supported by non-clinical laboratory data on the ability of Comirnaty Original/Omicron BA.4-5 to trigger an adequate immune response.

Les enfants peuvent-ils être vaccinés avec Comirnaty?

Comirnaty is not currently authorised for children below 5 years of age.

The adapted vaccines are currently not authorised for children below 12 years of age.

Les personnes immunodéprimées peuvent-elles être vaccinées avec Comirnaty?

There are limited data on immunocompromised people. Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Severely immunocompromised people may be given an additional dose of Comirnaty as part of their primary vaccination.

Les femmes enceintes ou qui allaitent peuvent-elles être vaccinées avec Comirnaty?

Comirnaty can be used during pregnancy. A large amount of data from pregnant women vaccinated with Comirnaty during the second or third trimester of their pregnancy has been analysed and showed no increase in pregnancy complications. Although data in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen.

Comirnaty can also be used during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breast-feeding women. However, based on similarity with the vaccine targeting the original strain, including a comparable safety profile, Comirnaty Original/Omicron BA.1 can be used during pregnancy and breast-feeding. In addition, based on the data available for Comirnaty and Comirnaty Original/Omicron BA.1, Comirnaty Original/Omicron BA.4-5 can also be used during pregnancy and breast-feeding.

Les personnes allergiques peuvent-elles être vaccinées avec Comirnaty?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred since the vaccine started being used in vaccination campaigns. Therefore, as for all vaccines, Comirnaty and its adapted vaccines should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given a dose of Comirnaty or its adapted vaccines should not receive subsequent doses.

Dans quelle mesure Comirnaty fonctionne-t-elle pour les personnes de différentes ethnies et sexes?

The main Comirnaty trial included people of different ethnicities and genders. Efficacy of around 95% was maintained across genders and ethnic groups.

Quels sont les risques associés à Comirnaty?

The most common side effects with Comirnaty are usually mild or moderate and get better within a few days after vaccination. These include pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhoea. They may affect more than 1 in 10 people.

Redness at the injection site, nausea and vomiting may occur in up to 1 in 10 people. Itching at the injection site, pain in the arm where the vaccine was injected, enlarged lymph nodes, difficulty sleeping, feeling unwell, decreased appetite, lethargy (lack of energy), hyperhidrosis (excessive sweating), night sweats, asthenia (weakness), and allergic reactions (such as rash, itching, itchy rash, and rapid swelling under the skin) are uncommon side effects (affecting less than 1 in 100 people). Weakness in muscles on one side of the face (acute peripheral facial paralysis or palsy) occurs in less than 1 in 1,000 people.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) may occur in up to 1 in 10,000 people.

Very few cases of extensive swelling of the vaccinated arm, swelling of the face in people with a history of injections with dermal fillers (soft, gel-like substances injected under the skin), erythema multiforme (red patches on the skin with a dark red centre and paler red rings) paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling) and hypoesthesia (decreased feeling or sensitivity in the skin) have occurred. Allergic reactions have also occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis). As for all vaccines, Comirnaty and its adapted vaccine should be given under close supervision with appropriate medical treatment available.

Comirnaty Original/Omicron BA.1 has comparable side effects to Comirnaty.

Sur la base des données de sécurité pour Comirnaty et pour Comirnaty Original/Omicron BA.1, le profil de sécurité pour Comirnaty Original/Omicron BA.4-5 devrait être comparable à ceux de ces vaccins.

Pourquoi Comirnaty est-elle autorisée dans l'UE?

Comirnaty offre un niveau élevé de protection contre la COVID-19, un besoin critique dans la pandémie actuelle. Les principaux essais ont montré que le vaccin a un taux élevé efficacité dans tous les groupes d'âge. La plupart des effets secondaires sont légers à modérés et ont disparu en quelques jours.

Comirnaty Original/Omicron BA.1 a été trouvé pour déclencher des niveaux élevés d'anticorps contre la souche originale de SARS-CoV-2 et la sous-variante Omicron BA.1. Son profil de sécurité était comparable à celui de Comirnaty. De plus, Comirnaty Original/Omicron BA.4-5 devrait déclencher une immunité contre la souche originale de SARS-CoV-2 et les sous-

variantes BA.4 et BA.5, et son profil de sécurité devrait être comparable à celui de Comirnaty et Comirnaty Original/Omicron BA.1.

L'Agence a donc décidé que les avantages de Comirnaty, y compris ses vaccins adaptés, sont supérieurs à ses risques et qu'elle peut être autorisée à être utilisée dans l'UE.

Comirnaty a obtenu un autorisation de mise sur le marché conditionnelle. Cela signifie qu'il y a plus de preuves à venir sur le vaccin (voir ci-dessous), que la société est tenue de fournir. L'Agence examinera toute nouvelle information disponible et cette vue d'ensemble sera mise à jour au besoin.

Quelles informations sont encore attendues pour Comirnaty?

As Comirnaty received a conditional marketing authorisation, the company that markets Comirnaty will continue to provide results from the main trial in adults, which is ongoing for 2 years, as well as from the trials in children. These trials and additional studies, including independent studies of COVID-19 vaccines coordinated by EU authorities, will provide more information on the vaccine's long-term safety and its benefit.

Quelles sont les mesures prises pour assurer une utilisation sûre et efficace de Comirnaty?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Comirnaty and its adapted vaccines have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.

Safety measures for Comirnaty and its adapted vaccines are implemented in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Comirnaty will provide regular safety reports.

As for all medicines, data on the use of Comirnaty and its adapted vaccines are continuously monitored. Suspected side effects are carefully evaluated and any necessary action taken to protect patients.

Autres informations sur Comirnaty

Comirnaty received a conditional marketing authorisation valid throughout the EU on 21 December 2020.

More information about the COVID-19 vaccines, such as the use of adapted vaccines and boosters, is available on the COVID-19 vaccines key facts page.

Principaux développements depuis l'autorisation

Show 25 entries Search:

Date	Key developments
03/10/2022	Start of rolling review on the use of Comirnaty Original/Omicron BA.4-5 in children aged 5 to 11 years
15/09/2022	Recommendation to convert the conditional marketing authorisation into a standard marketing authorisation
15/09/2022	Recommendation to authorise use of Comirnaty as a booster dose for children from 5 to 11 years of age
12/09/2022	Recommendation to authorise Comirnaty Original/Omicron BA.4-5, a bivalent vaccine targeting the original SARS-CoV-2 and the Omicron BA.4 and BA.5 subvariants for use as a booster in people aged 12 years and older who have received at least primary vaccination against COVID-19
01/09/2022	Recommendation to authorise Comirnaty Original/Omicron BA.1, a bivalent vaccine targeting the original SARS-CoV-2 and the Omicron BA.1 subvariant for use as a booster in people aged 12 years and older who have received at least primary vaccination against COVID-19
18/07/2022	Start of evaluation of Comirnaty for children aged 6 months to 4 years
22/04/2022	Recommendation to authorise use of Comirnaty as a booster dose for adults who have had another mRNA vaccine or an adenoviral vector vaccine

24/03/2022

Recommendation to extend the shelf-life from 9 months to 12 months for the ready-to-use (grey cap) and paediatric (orange cap) formulations

24/03/2022

Recommendation to approve changes to increase capacity at a finished product manufacturing site in Puurs, Belgium

24/02/2022

Recommendation to authorise booster doses for adolescents from 12 years of age

15/02/2022

Update of product information with data on use during pregnancy and breastfeeding

09/12/2021

Recommendation to change shelf-life of dispersions (002 and 003) and concentrates (004 and 005) from 6 months to 9 months

25/11/2021

Recommendation to extend authorisation to include use in children aged 5 to 11 years

03/11/2021

Renewal of marketing authorisation

04/10/2021

Recommendation to authorise booster doses for adults and an additional dose for immunocompromised people

10/09/2021

Recommendation to change shelf-life of a concentrate (001) from 6 months to 9 months

08/07/2021

Recommendation to include myocarditis and pericarditis as side effects in product information

28/05/2021

Recommendation to authorise Comirnaty for adolescents aged 12 to 15 years

21/12/2020

Conditional marketing authorisation of Comirnaty

Showing 1 to 19 of 19 entries Previous 1 Next

The 'Assessment history' section contains a complete list of developments since authorisation.

More information on safety is available in the 'Safety updates' section.

The 'News' section contains information on manufacturing changes before 2022.

Comirnaty: EPAR - Aperçu des médicaments (PDF/179.24 KO) (actualisé)

Première publication: 23/12/2020
Dernière mise à jour: 13/09/2022
MME/365655/2022

Langues disponibles (22)

Comirnaty: EPAR - Plan de gestion des risques (PDF/14.34 MB) (actualisé)

First published: 23/12/2020
Last updated: 23/09/2022

This EPAR was last updated on 06/10/2022

Authorisation details

Name

Comirnaty

Agency product number

EMEA/H/C/005735

Active substance

Single-stranded, 5’-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2

International non-proprietary name (INN) or common name

- tozinameran
- riltozinameran and tozinameran
- famtozinameran and tozinameran
- COVID-19 mRNA Vaccine (nucleoside modified)

Therapeutic area (MeSH)

COVID-19 virus infection

Anatomical therapeutic chemical (ATC) code

J07BX

Additional monitoring ▼

This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring.

Conditional approval

This medicine received a conditional marketing authorisation. This was granted in the interest of public health because the medicine addresses an unmet medical need and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required. For more information, see Conditional marketing authorisation.

Marketing-authorisation holder

BioNTech Manufacturing GmbH

Revision

30

Date of issue of marketing authorisation valid throughout the European Union

21/12/2020

Contact address

An der Goldgrube 12
55131 Mainz
Germany

Product information

16/09/2022 Comirnaty - EMEA/H/C/005735 - II/0129

Comirnaty : EPAR - Product information (PDF/4.48 MB) (updated)

Adopted

First published: 12/01/2021
Last updated: 30/09/2022

Available languages (24)

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

You can find product information documents for centrally authorised human medicines on this website. For centrally authorised veterinary medicines authorised or updated from February 2022, see the Veterinary Medicines Information website.

Comirnaty : EPAR - All authorised presentations (PDF/31.06 KB) (updated)

First published: 23/12/2020
Last updated: 22/09/2022

Available languages (24)

Pharmacotherapeutic group

Vaccines

Therapeutic indication

Comirnaty 10 micrograms/dose is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in children aged 5 to 11 years.

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

Comirnaty 30 micrograms/dose is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.

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

Assessment history

Changes since initial authorisation of medicine

Comirnaty : EPAR - Procedural steps taken and scientific information after authorisation (PDF/485.36 KB) (updated)

First published: 12/01/2021
Last updated: 30/09/2022

Comirnaty-H-C-5735-II-0093 : EPAR - Assessment report - Variation (PDF/2.36 MB)

Adopted

First published: 23/08/2022
EMA/134008/2022

Comirnaty-H-C-5735-II-0111 : EPAR - Assessment report - Variation (PDF/272.3 KB)

Adopted

First published: 23/08/2022
EMA/134030/2022

Comirnaty-H-C-5735-X-0077 : EPAR - Assessment report - Extension (PDF/4.9 MB)

Adopted

First published: 15/12/2021
Last updated: 07/01/2022
EMA/719541/2021 Corr.

Comirnaty-H-C-5735-X-0044-G : EPAR - Assessment report - Extension (PDF/470.38 KB)

Adopted

First published: 15/11/2021
EMA/594686/2021

Comirnaty-H-C-5735-R-0046 : EPAR - Assessment report - Renewal (PDF/1.57 MB)

Adopted

First published: 15/11/2021
EMA/596333/2021

Comirnaty-H-C-5735-II-0067 : EPAR - Assessment report - Variation (PDF/2.26 MB)

Adopted

First published: 28/10/2021
EMA/497785/2021

Comirnaty-H-C-5735-II-0062 : EPAR - Assessment report - Variation (PDF/461.93 KB)

Adopted

First published: 28/10/2021
EMA/472994/2021

Comirnaty-H-C-5735-II-0030 : EPAR - Assessment report - Variation (PDF/6.78 MB)

Adopted

First published: 30/06/2021
Last updated: 24/08/2021
EMA/CHMP/282047/2021 Rev.1

CHMP post-authorisation summary of positive opinion for Comirnaty (II-30) (PDF/153.07 KB)

Adopted

First published: 28/05/2021
EMA/303424/2021

Initial marketing-authorisation documents

Comirnaty : EPAR - Public assessment report (PDF/3.75 MB)

Adopted

First published: 23/12/2020
EMA/707383/2020 Corr.

CHMP summary of positive opinion for Comirnaty (PDF/130.67 KB)

Adopted

First published: 21/12/2020
EMA/660602/2020

Safety updates

COVID-19 vaccines - Safety update: 6 October 2022 (PDF/179.91 KB) (new)

First published: 06/10/2022

COVID-19 vaccines - Safety update: 8 September 2022 (PDF/194.49 KB)

Adopted

First published: 08/09/2022

COVID-19 vaccines - Safety update: 14 July 2022 (PDF/198.21 KB)

Adopted

First published: 14/07/2022
Last updated: 03/08/2022
Rev. 1

COVID-19 vaccines - Safety update: 17 June 2022 (PDF/235.43 KB)

Adopted

First published: 17/06/2022

COVID-19 vaccines - Safety update: 12 May 2022 (PDF/203.03 KB)

Adopted

First published: 12/05/2022

COVID-19 vaccines - Safety update: 13 April 2022 (PDF/214.65 KB)

Adopted

First published: 13/04/2022

COVID-19 vaccines - Safety update: 17 March 2022 (PDF/221.74 KB)

Adopted

First published: 17/03/2022

COVID-19 vaccines - Safety update: 17 February 2022 (PDF/212.51 KB)

Adopted

First published: 17/02/2022

COVID-19 vaccines - Safety update: 20 January 2022 (PDF/234.12 KB)

Adopted

First published: 20/01/2022

COVID-19 vaccine safety update for Comirnaty: 9 December 2021 (PDF/192.42 KB)

Adopted

First published: 09/12/2021

COVID-19 vaccine safety update for Comirnaty: 11 November 2021 (PDF/88.55 KB)

Adopted

First published: 11/11/2021

COVID-19 vaccine safety update for Comirnaty: 6 October 2021 (PDF/141.93 KB)

Adopted

First published: 06/10/2021

COVID-19 vaccine safety update for Comirnaty: 8 September 2021 (PDF/104.84 KB)

Adopted

First published: 08/09/2021

COVID-19 vaccine safety update for Comirnaty: 11 August 2021 (PDF/88.96 KB)

Adopted

First published: 11/08/2021

COVID-19 vaccine safety update for Comirnaty: 14 July 2021 (PDF/97.84 KB)

Adopted

First published: 14/07/2021

COVID-19 vaccine safety update for Comirnaty: 18 June 2021 (PDF/171.28 KB)

Adopted

First published: 18/06/2021

COVID-19 vaccine safety update for Comirnaty: 11 May 2021 (PDF/80.68 KB)

Adopted

First published: 12/05/2021

COVID-19 vaccine safety update for Comirnaty: 14 April 2021 (PDF/77.06 KB)

Adopted

First published: 16/04/2021

COVID-19 vaccine safety update for Comirnaty: 29 March 2021 (PDF/172.68 KB)

Adopted

First published: 30/03/2021

COVID-19 vaccine safety update for Comirnaty: 4 March 2021 (PDF/85.12 KB)

Adopted

First published: 04/03/2021

COVID-19 vaccine safety update for Comirnaty: 28 January 2021 (PDF/163.12 KB)

Adopted

First published: 29/01/2021

Patient Safety

- COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy
  18/01/2022
- Comirnaty and Spikevax: possible link to very rare cases of myocarditis and pericarditis
  09/07/2021
- COVID-19 vaccines: update on ongoing evaluation of myocarditis and pericarditis
  11/06/2021

News

- EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines
  16/09/2022
- Adapted vaccine targeting BA.4 and BA.5 Omicron variants and original SARS-CoV-2 recommended for approval
  12/09/2022
- ECDC-EMA statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines
  06/09/2022
- First adapted COVID-19 booster vaccines recommended for approval in the EU
  01/09/2022
- Start of rolling review for adapted Comirnaty COVID-19 vaccine
  15/06/2022
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 April 2022
  08/04/2022
- ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines
  06/04/2022
- EMA recommends authorisation of booster doses of Comirnaty from 12 years of age
  24/02/2022
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 - 10 February 2022
  11/02/2022
- EMA evaluating data on booster dose of COVID-19 vaccine Comirnaty in adolescents
  08/02/2022
- Increase in manufacturing capacity for COVID-19 vaccines from Janssen, Moderna and BioNTech/Pfizer
  16/12/2021
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29 November - 2 December 2021
  03/12/2021
- Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11
  25/11/2021
- EMA starts evaluating use of COVID-19 vaccine Comirnaty in children aged 5 to 11
  18/10/2021
- New manufacturing sites and new formulation approved for COVID-19 vaccine from BioNTech/Pfizer
  18/10/2021
- Comirnaty and Spikevax: EMA recommendations on extra doses and boosters
  04/10/2021
- Increase in manufacturing capacity for COVID-19 vaccine from BioNTech/Pfizer
  09/09/2021
- EMA evaluating data on booster dose of COVID-19 vaccine Comirnaty

06/09/2021

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 30 August – 2 September 2021
  03/09/2021
- Increase in vaccine manufacturing capacity for COVID-19 vaccines from BioNTech / Pfizer and Moderna
  24/08/2021
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5-8 July 2021
  09/07/2021
- Two additional manufacturing sites for BioNTech/Pfizer's COVID-19 vaccine
  22/06/2021
- Additional manufacturing capacity for BioNTech/Pfizer's COVID-19 vaccine
  01/06/2021
- First COVID-19 vaccine approved for children aged 12 to 15 in EU
  28/05/2021
- More flexible storage conditions for BioNTech/Pfizer's COVID-19 vaccine
  17/05/2021
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021
  07/05/2021
- EMA starts evaluating use of COVID-19 vaccine Comirnaty in young people aged 12 to 15
  03/05/2021
- Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from BioNTech/Pfizer and Moderna
  23/04/2021
- Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from AstraZeneca, BioNTech/Pfizer and Moderna
  26/03/2021
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 March 2021
  12/03/2021
- First COVID-19 vaccine safety update published
  29/01/2021
- Clarification of Comirnaty dosage interval
  28/01/2021
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 11-14 January 2021
  15/01/2021
- Extra dose from vials of Comirnaty COVID-19 vaccine
  08/01/2021
- EMA recommends first COVID-19 vaccine for authorisation in the EU

21/12/2020

- Update on assessment of the BioNTech and Pfizer BNT162b2 vaccine marketing authorisation application

  15/12/2020
- EMA receives application for conditional marketing authorisation of COVID-19 mRNA vaccine BNT162b2

  01/12/2020
- EMA starts second rolling review of a COVID-19 vaccine

  06/10/2020

Direct healthcare professional communications (DHPC)

- COVID-19 mRNA Vaccines Comirnaty and Spikevax: risk of myocarditis and pericarditis (19/07/2021)

Signal assessment report

Signal assessment report on myocarditis, pericarditis with Tozinameran (COVID-19 mRNA vaccine (nucleosidemodified) – Comirnaty) (PDF/1.62 MB)

Adopted

First published: 19/01/2022
EMA/PRAC/575791/2021

Updated signal assessment report on myocarditis, pericarditis with Tozinameran (COVID-19 mRNA vaccine (nucleoside-modified) – Comirnaty) (PDF/2.02 MB)

Adopted

First published: 17/09/2021
EMA/PRAC/325882/2021

Related content

- Treatments and vaccines for COVID-19

Publications

- The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines

External links

- Clinical data (login required)

Related content

- Comirnaty: Paediatric investigation plan

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