ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

VidPrevtyn Beta solution and emulsion for emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

These are two multidose vials (antigen vial and adjuvant vial) that must be mixed before use. After mixing, the vaccine vial contains 10 doses of 0.5 mL.

One dose (0.5 mL) contains 5 micrograms of SARS-CoV-2 spike protein (B.1.351 strain) produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the fall armyworm, *Spodoptera frugiperda.*

AS03 adjuvant is composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).

VidPrevtyn Beta may contain traces of octylphenol ethoxylate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution and emulsion for emulsion for injection

The antigen solution is a colourless, clear liquid.
The adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VidPrevtyn Beta is indicated as a booster for active immunisation to prevent COVID-19 in adults who have previously received an mRNA or adenoviral vector COVID-19 vaccine (see sections 4.2 and 5.1).

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

4.2 Posology and method of administration

Posology

Individuals 18 years of age and older
VidPrevtyn Beta is administered intramuscularly as a single dose of 0.5 mL at least 4 months after a previous COVID-19 vaccine. VidPrevtyn Beta may be given once as a booster to adults that have received prior vaccination series with either mRNA or adenoviral vector COVID-19 vaccines (see section 5.1).

Elderly
No dose adjustment is required in elderly individuals ≥ 65 years of age.

Paediatric population
The safety and efficacy of VidPrevtyn Beta in children and adolescents less than 18 years of age have not yet been established. No data are available.

Method of administration

VidPrevtyn Beta is for intramuscular injection only after mixing. The preferred site is the deltoid muscle of the upper arm.

Do not inject this vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions on mixing, handling and disposal of the vaccine, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1, or to octylphenol ethoxylate (trace residual).

4.4 Special warnings and precautions for use

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.

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. However, the presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

The efficacy, safety and immunogenicity of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The immune response of VidPrevtyn Beta may be lower in immunosuppressed individuals.

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness

As with any vaccine, vaccination with VidPrevtyn Beta may not protect all vaccine recipients.

Excipients

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Potassium
This medicinal product contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant administration of VidPrevtyn Beta with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited experience with use of VidPrevtyn Beta in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3).

Administration of VidPrevtyn Beta during pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Breast-feeding

It is unknown whether VidPrevtyn Beta is excreted in human milk.

No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to VidPrevtyn Beta is negligible.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines

VidPrevtyn Beta has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety of VidPrevtyn Beta administered as a first booster in individuals previously vaccinated with a primary series of mRNA-based, adenovirus-vectored or protein-based COVID-19 vaccines was evaluated in an ongoing phase 3 clinical study. This study involved 705 participants 18 years of age and older who received the vaccine 4 to 10 months after receiving primary vaccination. Due to the size of the safety database for VidPrevtyn Beta, uncommon adverse reactions (≥ 1/1,000 to < 1/100) may not be detected. The median duration of safety follow-up was 145 days, with 610 (86.5%) participants completing more than 2 months safety follow-up after booster injection.

The most common adverse reactions with VidPrevtyn Beta were injection site pain (76.2%), headache (41.4%), myalgia (37.8%), malaise (33.0%), arthralgia (28.7%), and chills (19.9%).

The median duration of local and systemic adverse reactions was 1 to 3 days. Most adverse reactions occurred within 3 days following vaccination and were mild to moderate in severity.

Supportive safety data were collected in 7093 participants 18 years of age and older having received primary or booster vaccine formulation containing the same Beta antigen (Monovalent (B.1.351)/ bivalent (B.1.351 + D614)) and AS03 adjuvant. In general, the safety profile based on these supportive data is in accordance with the most common adverse reactions detected based on the VidPrevtyn Beta safety database (N=705). The majority of these participants received primary immunisation with bivalent (B.1.351 + D614) vaccine.

Tabulated list of adverse reactions

Adverse reactions observed during clinical studies are listed below according to the following frequency convention: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

Within each System Organ Class, adverse reactions are presented in order of decreasing frequency and then by decreasing seriousness (Table 1).

Table 1: Adverse reactions

MedDRA System Organ Class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Uncommon	Lymphadenopathy
Immune system disorders	Not known	Anaphylactic reactions Hypersensitivity (including rash, rash erythematous, urticaria, angioedema)
Nervous system disorders	Very common Rare	Headache Dizziness
Gastrointestinal disorders	Common	Nausea Diarrhoea
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Malaise Chills Injection site pain
	Common	Fever Fatigue Injection site swelling Injection site erythema
	Uncommon	Injection site pruritus Injection site bruising Injection site warmth

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

There is no specific treatment for an overdose with VidPrevtyn Beta. In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine, other viral vaccines, ATC code: J07BX03

Mechanism of action

VidPrevtyn Beta is an adjuvanted vaccine composed of the soluble trimeric SARS-CoV-2 recombinant spike (S) protein (B.1.351 strain) stabilised in its prefusion conformation and deleted of its transmembrane and intracellular domains. The combination of antigen and adjuvant enhances the magnitude of immune response, which may contribute to protection against COVID-19.

Immunogenicity

Efficacy of VidPrevtyn Beta has been inferred by immunobridging of immune responses to an authorised COVID-19 vaccine, for which vaccine efficacy has been established.

The clinical immunogenicity of VidPrevtyn Beta given as a first booster injection is being evaluated in two clinical studies: VAT00013 (Study 1) in COVID-19 mRNA vaccine-primed participants and VAT00002 Cohort 2, Beta arm (Study 2) that included participants primed with various types of COVID-19 vaccines.

Immunogenicity results from Study 1
Study 1 is a randomised, single-blinded multicenter investigator-initiated clinical study, which evaluated the immune response induced by a booster dose of either VidPrevtyn Beta or COVID-19 mRNA vaccine (nucleoside modified/tozinameran) in individuals previously vaccinated with 2 doses of COVID-19 mRNA vaccine (tozinameran). The per-protocol analysis population included 143 participants 18 years of age and older primed with 2 doses of COVID-19 mRNA vaccine (tozinameran) 3 to 7 months prior to receiving VidPrevtyn Beta (N=67), COVID-19 mRNA vaccine (tozinameran) (N=76). The mean age was comparable across groups with 41.4 and 40.4 years for VidPrevtyn Beta and COVID-19 mRNA vaccine (tozinameran), respectively. Age ranged from 20.0 to 69.0 years. The mean duration between the second dose of the primary series and the booster dose was comparable across groups, being 171.0 and 174.5 days for VidPrevtyn Beta and COVID-19 mRNA vaccine (tozinameran), respectively.

Among this per-protocol population, samples from prior to vaccination and 28 days after booster of 114 participants (54 from VidPrevtyn Beta and 60 from COVID-19 mRNA vaccine (tozinameran)) were tested by Pseudovirus Neutralisation Assay. The Geometric Mean Titers (GMT) of neutralising antibodies 28 days after VidPrevtyn Beta or COVID-19 mRNA vaccine (tozinameran) booster in COVID-19 mRNA vaccine-primed participants were compared.

Superiority of GMT against Omicron BA.1 was demonstrated for VidPrevtyn Beta group in comparison with COVID-19 mRNA vaccine (tozinameran) group, see Table 2.

Table 2: Post-booster GMT ratio for VidPrevtyn Beta versus COVID-19 mRNA vaccine (tozinameran) with individual neutralisation titres against Omicron BA.1 - 28 days post-booster dose – per-protocol analysis subset

VidPrevtyn Beta (N=54)			COVID-19 mRNA vaccine (tozinameran) (N=60)			VidPrevtyn Beta / COVID-19 mRNA vaccine (tozinameran)		
M	**GMT**	**(95% CI)**	**M**	**GMT**	**(95% CI)**	**GMT ratio**	**(95% CI)**	**Superiority demonstrated†**
54	1327.5	(1005.0; 1753.4)	58	524.0	(423.3; 648.6)	2.53	(1.80; 3.57)	Yes

M: number of participants with available data for the relevant endpoint;
N: number of participants in per-protocol analysis subset 28 days post-booster dose;
† Superiority is concluded if the lower limit of the 2-sided 95% Confidence Interval (CI) of the GMT ratio > 1.2.

Non-inferiority of seroresponse rate against Omicron BA.1 and D614G strains for VidPrevtyn Beta compared to COVID-19 mRNA vaccine (tozinameran) was demonstrated (see Table 3). Seroresponse rate was defined as a 4-fold or greater rise in serum neutralisation titre 28 days post-booster dose relative to pre-booster dose.

Table 3: Seroresponse rate (SR) for VidPrevtyn Beta versus COVID-19 mRNA vaccine (tozinameran) with individual neutralisation titre against Omicron BA.1 and D614G - 28 days post-booster dose - per-protocol analysis subset

	VidPrevtyn Beta (N=54)			COVID-19 mRNA vaccine (tozinameran) (N=60)			VidPrevtyn Beta / COVID-19 mRNA vaccine (tozinameran)		
	n/M	**SR (%)**	**(95% CI)**	**n/M**	**SR (%)**	**(95% CI)**	**Difference (%)**	**(95% CI)**	**Non-inferiority demonstrated†**
D614G	51/53	96.2	(87.0; 99.5)	55/59	93.2	(83.5; 98.1)	3.0	(-6.9;12.8)	Yes
Omicron BA.1	50/50	100.0	(92.9; 100.0)	51/53	96.2	(87.0; 99.5)	3.8	(-3.9;12.8)	Yes

M: number of participants with available data for the relevant endpoint;
N: number of participants in per-protocol analysis subset 28 days post-booster dose;
n: Number of participants who achieve seroresponse;
† Non-inferiority is concluded if the lower limit of the 2-sided 95% Confidence Interval (CI) of the difference in seroresponse rate between groups is > -10%.

Levels of neutralising antibody titres against D614G 28 days post-booster dose observed in VidPrevtyn Beta group were higher than in COVID-19 mRNA vaccine (tozinameran) group, with the GMT ratio of 1.43 (95%CI 1.06; 1.94), see Table 4.

Table 4: Neutralising antibody Geometric Mean Titres (GMT) against D614G - 28 days post-booster dose - per-protocol analysis subset

VidPrevtyn Beta			COVID-19 mRNA vaccine (tozinameran)			VidPrevtyn Beta / COVID-19 mRNA vaccine (tozinameran)	
N	**GMT**	**(95% CI)**	**N**	**GMT**	**(95% CI)**	**GMT Ratio**	**(95% CI)**
54	6459	(5103; 8174)	60	4507	(3695; 5498)	1.43	(1.06; 1.94)

N: number of participants in per-protocol analysis subset 28 days post-booster dose;
CI: Confidence Interval

Immunogenicity results from Study 2
VidPrevtyn Beta given as a booster is being evaluated in an ongoing multicentre phase 3 clinical study in participants 18 years of age and older. Per-protocol analysis population included 543 participants who received VidPrevtyn Beta 4 to 10 months after receiving primary vaccination with 2 doses of COVID-19 mRNA vaccine (tozinameran) (n=325) or COVID-19 mRNA Vaccine (nucleoside modified/elasomeran) (n=93), COVID-19 Vaccine (ChAdOx1-S [recombinant]) (n=94), or with 1 dose of COVID-19 vaccine (Ad26.COV2-S [recombinant])(n=31).

In the per-protocol analysis population primed with mRNA vaccines and receiving VidPrevtyn Beta booster, the mean age of participants was 41.2 years (range 18-83 years); 347 (83.0%) were 18 to 55 years of age, 71 (17.0%) were 56 years of age and older, 25 (6.0%) were 65 years of age and older. Among them, 44.0% were male, 56.0% were female, 67.7% were White, 13.2% were Black or African American, 2.6% were Asian, and 1.0% were American Indian or Alaska Native.

In the per-protocol analysis population primed with adenoviral vector vaccines and receiving VidPrevtyn Beta booster, the mean age of participants was 50.4 years (range 24-77 years); 84 (67.2%) were 18 to 55 years of age, 41 (32.8%) were 56 years of age and older, 17 (13.6%) were 65 years of age and older. Among them, 52.8% were male, 47.2% were female, 78.4% were White, 13.6% were Black or African American, 4.0 % were Asian, and 2.4% were American Indian or Alaska Native.

Immunogenicity was assessed by measuring neutralising antibody titres (ID50) against a pseudovirus expressing the SARS-CoV-2 Spike protein from a USA_WA1/2020 isolate with the D614G mutation and B.1.351 variant using a SARS-CoV-2 Pseudovirus Neutralisation Assay.

A booster response to VidPrevtyn Beta was demonstrated regardless of the vaccine used for primary vaccination with the Geometric Mean Titres Ratio (GMTR, fold increase) 14 days post-booster relative to pre-booster against B.1.351 strain ranging from 38.5 to 72.3, and from 14.5 to 28.6 for D614G strain, see Table 5.

Table 5: Neutralising antibody Geometric Mean Titres (ID50) at 14 days post-booster dose and Geometric Mean Titres Ratio (14 days post-booster dose relative to pre-booster dose) against a pseudovirus expressing the SARS-CoV-2 Spike protein in participants 18 years of age and older - per-protocol analysis set

	mRNA primed[1] (N=418)			Ad-vector primed[2] (N=125)		
Pre-booster GMT						
	M	**GMT**	**(95% CI)**	**M**	**GMT**	**(95% CI)**
D614G	407	751	(633; 892)	118	228	(159; 325)
Beta	383	191	(158; 231)	117	69.9	(50.3; 97.2)
GMT at 14 days post-booster dose						
	M	**GMT**	**(95% CI)**	**M**	**GMT**	**(95% CI)**
D614G	418	10814	(9793; 11941)	125	6565	(5397;7986)
Beta	418	7501	(6754; 8330)	124	5077	(4168; 6185)
GMT ratio - 14 days post-booster dose relative to pre-booster dose						
	M	**GMTR**	**(95% CI)**	**M**	**GMTR**	**(95% CI)**
D614G	407	14.5	(12.2;17.2)	118	28.6	(21.1;38.9)
Beta	383	38.5	(31.8; 46.6)	116	72.3	(52.4; 99.8)

M: number of participants with available data for the relevant endpoint;
N: number of participants in per-protocol analysis set
CI: Confidence Interval
ID50- serum dilution conferring 50% inhibition of pseudovirus infection
GMTR (geometric mean titre ratio): geometric mean of individual titre ratios (post-vaccination/pre-vaccination)
[1-2] - Priming vaccines: [1-] COVID-19 mRNA vaccine (tozinameran) and COVID-19 mRNA vaccine (elasomeran); [2] - COVID-19 Vaccine (ChAdOx1-S [recombinant]) and COVID-19 vaccine (Ad26.COV2-S [recombinant])

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with VidPrevtyn Beta in one or more subsets of the paediatric population in prevention of COVID-19 (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and toxicity to reproduction and development.

Genotoxicity and carcinogenicity

No genotoxicity was observed for the adjuvant based on *in vitro* and *in vivo* tests. Genotoxicity of the antigen was not evaluated, as its biological nature is not expected to have genotoxic potential. Carcinogenicity studies were not performed.

Reproductive toxicity and fertility

In a developmental and reproductive toxicity study, 0.5 mL of a vaccine formulation containing up to 15 micrograms (three human doses) of recombinant protein adjuvanted with AS03 was administered to female rabbits by intramuscular injection on five occasions: 24 and 10 days prior to mating and on gestation days 6, 12 and 27. No vaccine-related adverse effects on female fertility, embryo/foetal or postnatal development were observed up to postnatal day 35. In this study, high S-specific anti-SARS-CoV-2 IgG response was detected in maternal animals, as well as in foetuses and pups, indicating placental transfer of the maternal antibodies. No data are available on vaccine excretion in milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Antigen vial

Sodium dihydrogen phosphate monohydrate
Disodium phosphate dodecahydrate
Sodium chloride
Polysorbate 20
Water for injections

Adjuvant vial

Sodium chloride
Disodium hydrogen phosphate
Potassium dihydrogen phosphate
Potassium chloride
Water for injections

For adjuvant, see section 2.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products or diluted.

6.3 Shelf life

1 year.

After mixing, the product should be used within 6 hours, if stored at 2 °C – 8 °C and **protected from light.**

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Keep the vials in the outer carton in order to protect from light.

For storage conditions after mixing of the medicinal product, see section 6.3.

6.5 Nature and contents of container

VidPrevtyn Beta is presented as:

- 2.5 mL antigen solution in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a green plastic flip-off cap;
- 2.5 mL adjuvant emulsion in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a yellow plastic flip-off cap.

Each pack contains 10 multidose antigen vials and 10 multidose adjuvant vials.

6.6 Special precautions for disposal and other handling

Handling instructions

This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

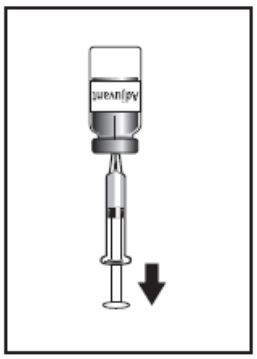
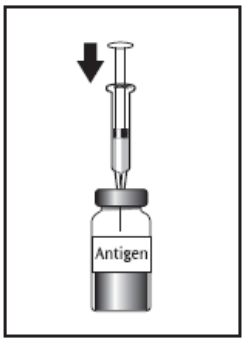
Instructions for mixing

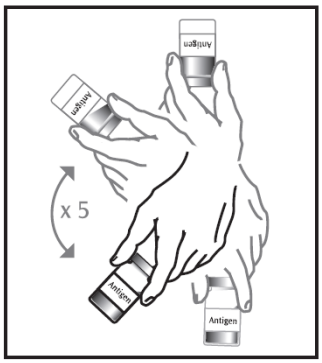
VidPrevtyn Beta is supplied as 2 separate vials: an antigen vial and an adjuvant vial.
Prior to administration, the two components must be mixed as per steps below.

Step 1: Place the vials at room temperature (up to 25 °C) for a minimum of 15 minutes before mixing, **protecting them from light.**

Step 2: Invert (without shaking) each vial and inspect them visually for any particulate matter or discoloration. If either of these conditions exist, do not administer the vaccine.

Step 3: After removing the flip-off caps, cleanse both vial stoppers with antiseptic swabs.

Step 4  **Vial 2 of 2**	Using a sterile 21-gauge or narrower needle and a sterile syringe, withdraw the entire contents from the adjuvant vial (yellow cap) into a syringe. Invert the adjuvant vial to facilitate the withdrawal of the full contents.
Step 5  **Vial 1 of 2**	Transfer the full syringe contents into the antigen vial (green cap).

Step 6  **Vial 1 of 2**	Remove the syringe with the needle from the antigen vial. Mix the contents by inverting the vial 5 times. Do not shake. The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.

Step 7: Record the discard date and time (6 hours after mixing) on designated area of vial label.

The volume of the vaccine after mixing is at least 5 mL. It contains 10 doses of 0.5 mL.
An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered.

After mixing, administer immediately or store the vaccine at 2 °C to 8 °C, **protected from light**, and use within 6 hours (see section 6.3). After this time period, discard the vaccine.

Preparation of individual doses

Prior to each administration, mix the vial thoroughly by inversion 5 times. Do not shake.
Visually inspect it for any particulate matter and discoloration (see Step 6 for the aspect of the vaccine). If either of these conditions exists, do not administer the vaccine.

Using appropriate syringe and needle, withdraw 0.5 mL from the vial containing the mixed vaccine and administer intramuscularly (see section 4.2).

Disposal

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

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur
14 Espace Henry Vallée
69007 Lyon
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1580/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 November 2022

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Sanofi Chimie
9 Quai Jules Guesde
94403 Vitry sur Seine Cedex
France

Genzyme Corporation
68 and 74 New York Avenue
Framingham, MA 01701
United States

Name and address of the manufacturer(s) responsible for batch release

Sanofi Pasteur
1541 avenue Marcel Mérieux
69280 Marcy l'Etoile
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;

- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
PACK CONTAINING A CARTON OF VIALS OF ANTIGEN SOLUTION AND A CARTON OF VIALS OF ADJUVANT EMULSION
5 micrograms Beta

1. NAME OF THE MEDICINAL PRODUCT

VidPrevtyn Beta solution and emulsion for emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

After mixing, each 0.5 mL dose contains:
Recombinant SARS-CoV-2 spike protein ……..……..……..…5 micrograms

AS03 adjuvant composed of squalene, DL-α-tocopherol and polysorbate 80.

3. LIST OF EXCIPIENTS

Excipients: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, polysorbate 20, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution and emulsion for emulsion for injection

10 multidose antigen vials
10 multidose adjuvant vials

After mixing, each vial contains 10 doses of 0.5 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

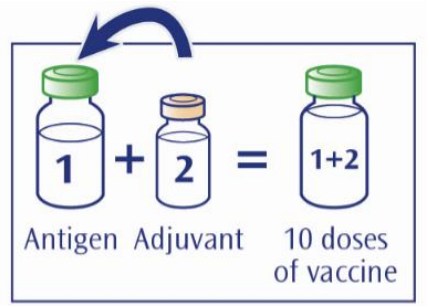
Intramuscular use
Mix the vaccine thoroughly by inversion before each injection.
Read the package leaflet before use.
QR code to be included + For more information, scan here or visit https://vidprevtyn-beta.info.sanofi

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Antigen and adjuvant to be mixed before use.



8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Store in the original carton in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur
14 Espace Henry Vallée
69007 Lyon - France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1580/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE INTERMEDIATE PACKAGING
PACK OF 10 VIALS OF ANTIGEN SOLUTION
5 micrograms Beta

1. NAME OF THE MEDICINAL PRODUCT

Antigen for VidPrevtyn Beta solution for injection
COVID-19 vaccine (recombinant, adjuvanted)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

After mixing, each 0.5 mL dose contains:
Recombinant SARS-CoV-2 spike protein ..……..……5 micrograms

3. LIST OF EXCIPIENTS

Excipients: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, polysorbate 20, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Antigen solution for injection

10 multidose vials
2.5 mL per vial

After mixing the antigen with the adjuvant: 10 doses of 0.5 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

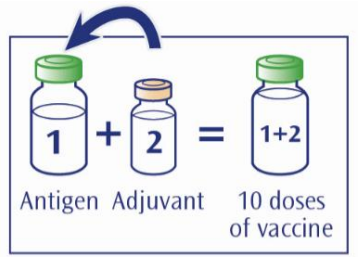
Intramuscular use
Read the package leaflet before use.
QR code to be included + For more information, scan here or visit https://vidprevtyn-beta.info.sanofi

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Mix with adjuvant before use
After mixing, label the vial (now containing the vaccine) with the discard date and time in the designated area on the vial label.



8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Storage before mixing: store in a refrigerator. Do not freeze.
Store in the original carton in order to protect from light.

Storage after mixing: store the vaccine at 2 °C to 8 °C for up to 6 hours, protected from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur
14 Espace Henry Vallée
69007 Lyon
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1580/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17.	UNIQUE IDENTIFIER – 2D BARCODE

18.	UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
ANTIGEN SOLUTION VIAL
5 micrograms Beta

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Antigen for VidPrevtyn Beta
COVID-19 vaccine (recombinant, adjuvanted)
IM

2. METHOD OF ADMINISTRATION

Mix with adjuvant before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2.5 mL
After mixing: 10 doses of 0.5 mL

6. OTHER

Vial 1 of 2
Discard date/time:

PARTICULARS TO APPEAR ON THE INTERMEDIATE PACKAGING
PACK OF 10 MULTIDOSE VIALS OF EMULSION (ADJUVANT)

1. NAME OF THE MEDICINAL PRODUCT

Adjuvant emulsion for emulsion for injection for VidPrevtyn Beta

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 dose contains: AS03 adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Emulsion for emulsion for injection
After mixing with antigen each vial contains 10 doses
10 multidose vials:
2.5 mL/vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use.
Mix with antigen before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur
14 Espace Henry Vallée
69007 Lyon - France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1580/001

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
EMULSION VIAL LABEL (ADJUVANT)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Adjuvant emulsion for VidPrevtyn Beta

2. METHOD OF ADMINISTRATION

Mix with antigen before use

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2.5 mL multidose vial

6. OTHER

Store in a refrigerator.
Vial 2 of 2

B. PACKAGE LEAFLET

Package leaflet: Information for the user

VidPrevtyn Beta solution and emulsion for emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)

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

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your 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 VidPrevtyn Beta is and what it is used for

VidPrevtyn Beta is a vaccine used for preventing COVID-19.
VidPrevtyn Beta is given to adults who previously received either mRNA or adenoviral vector COVID-19 vaccine.

The vaccine stimulates the immune system (the body's natural defences) to produce specific antibodies that work against the virus, giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive VidPrevtyn Beta

Do not use VidPrevtyn Beta:
If you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
If you are allergic to octylphenol ethoxylate, a substance that is used in the manufacturing process. Small amounts of this substance may remain after manufacturing.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given the vaccine if:
- you have ever had a severe allergic reaction after any other vaccine injection or after you were given VidPrevtyn Beta in the past;
- you have ever fainted following any needle injection;
- you have a severe illness or infection with a high temperature (over 38 °C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood clots.
- you have a weakened immune system (immunodeficiency) or you are using medicines that weaken the immune system (such as high-dose corticosteroids or cancer medicines).

As with any vaccine, VidPrevtyn Beta may not fully protect all those who receive it. It is not known how long you will be protected.

Children and adolescents
VidPrevtyn Beta is not recommended for children aged under 18 years. Currently there is no information available on the use of VidPrevtyn Beta in children and adolescents younger than 18 years of age.

Other medicines and VidPrevtyn Beta
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines or vaccines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of VidPrevtyn Beta mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

VidPrevtyn Beta contains sodium and potassium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

3. How VidPrevtyn Beta is given

Your doctor, pharmacist or nurse will inject the vaccine into a muscle, usually in your upper arm.

You will receive one injection.
It is recommended that you receive VidPrevtyn Beta once as a booster dose at minimum 4 months following the prior vaccination series with either mRNA or adenoviral vector COVID-19 vaccine.

After the injection, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects occur within 3 days of getting the vaccine and go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist or nurse.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction shortly after vaccination. Such symptoms may include:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat

- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain.

The following side effects may occur with VidPrevtyn Beta:
Side effects which may affect up to 1 in 100 people may not have all been detected in the clinical studies done to date.

Very common (may affect more than 1 in 10 people):
- Headache
- Muscle pain
- Joint pain
- Feeling unwell
- Chills
- Pain where the vaccine is injected

Common (may affect up to 1 in 10 people):
- Fever (≥ 38.0ºC)
- Tiredness
- Feeling sick (nausea)
- Diarrhoea
- Redness or swelling where the vaccine is injected

Uncommon (may affect up to 1 in 100 people):
- Enlarged lymph nodes
- Itching, bruising or warmth where the vaccine is injected.

Rare (may affect up to 1 in 1,000 people)
- Dizziness

Not known (cannot be estimated from available data):
- Allergic reactions such as rash or hives or swelling of the face
- Severe allergic reactions (anaphylaxis)

Reporting of side effects
If you get any side effects, talk to your 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 in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VidPrevtyn Beta

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

Information about storage, use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

6. Contents of the pack and other information

What VidPrevtyn Beta contains
- There are two multidose vials (antigen vial and adjuvant vial) that must be mixed before use. After mixing, the vaccine vial contains 10 doses of 0.5 mL.

- One dose (0.5 mL) contains 5 micrograms of recombinant SARS-CoV-2 spike protein antigen (B.1.351 strain).
- AS03 is included in this vaccine as an adjuvant to enhance production of specific antibodies. This adjuvant contains squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).
- The other ingredients are: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, polysorbate 20, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, water for injections.

What VidPrevtyn Beta looks like and contents of the pack
- The antigen solution is a colourless, clear liquid.
- The adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.
- Prior to administration, the two components should be mixed. The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.

Each pack contains 10 multidose antigen vials and 10 multidose adjuvant vials.
- Each antigen vial contains 2.5 mL antigen solution in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a green plastic flip-off cap
- Each adjuvant vial contains 2.5 mL adjuvant emulsion in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a yellow plastic flip-off cap.

After mixing the antigen solution with the adjuvant emulsion, the vial contains 10 doses of 0.5 mL.

Marketing Authorisation Holder
Sanofi Pasteur - 14 Espace Henry Vallée - 69007 Lyon – France

Manufacturer
Sanofi Pasteur - 1541 avenue Marcel Mérieux - 69280 Marcy l'Etoile – France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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sanofi-aventis Ireland Ltd. T/A SANOFI
Tel: +44 (0) 800 035 2525

This leaflet was last revised in

Other sources of information

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

This leaflet is available in all EU/EEA languages on the European Medicines Agency website. You may also scan the QR code below with a mobile device to get the package leaflet in different languages or visit the URL https://vidprevtyn-beta.info.sanofi.

QR code to be included

The following information is intended for healthcare professionals only:

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.

Posology

VidPrevtyn Beta is administered intramuscularly as a single dose of 0.5 mL at least 4 months after a previous COVID-19 vaccine. VidPrevtyn Beta may be given once as a booster to adults that have received prior vaccination series with either mRNA or adenoviral vector COVID-19 vaccines.

Storage before mixing

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Keep the vials in the outer carton in order to protect from light.

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

Handling instructions

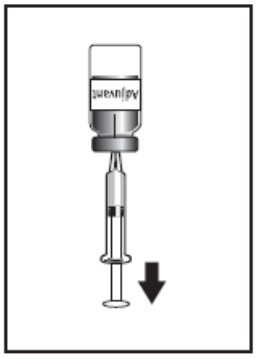
This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

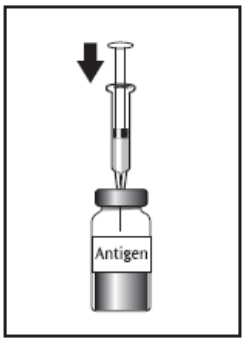
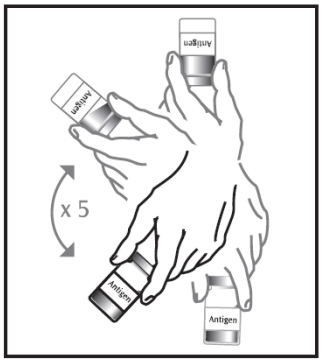
VidPrevtyn Beta is supplied as 2 separate vials: an antigen vial and an adjuvant vial.
Prior to administration, the two components must be mixed as per steps below.

Step 1: Place the vials at room temperature (up to 25 °C) for a minimum of 15 minutes before mixing, **protecting them from light.**

Step 2: Invert (without shaking) each vial and inspect them visually for any particulate matter or discoloration. If either of these conditions exist, do not administer the vaccine.

Step 3: After removing the flip-off caps, cleanse both vial stoppers with antiseptic swabs.

Step 4  **Vial 2 of 2**	Using a sterile 21-gauge or narrower needle and a sterile syringe, withdraw the entire contents from the adjuvant vial (yellow cap) into a syringe. Invert the adjuvant vial to facilitate the withdrawal of the full contents.

Step 5  **Vial 1 of 2**	Transfer the full syringe contents into the antigen vial (green cap).
Step 6  **Vial 1 of 2**	Remove the syringe with the needle from the antigen vial. Mix the contents by inverting the vial 5 times. Do not shake. The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.

Step 7: Record the discard date and time (6 hours after mixing) on designated area of vial label.

The volume of the vaccine after mixing is at least 5 mL. It contains 10 doses of 0.5 mL.
An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered.

After mixing, administer immediately or store the vaccine at 2 °C to 8 °C, **protected from light**, and use within 6 hours. After this time period, discard the vaccine.

Preparation of individual doses

Prior to each administration, mix the vial thoroughly by inversion 5 times. Do not shake.
Visually inspect it for any particulate matter and discoloration (see Step 6 for the aspect of the vaccine). If either of these conditions exists, do not administer the vaccine.

Using appropriate syringe and needle, withdraw 0.5 mL from the vial containing the mixed vaccine and administer intramuscularly.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant, the scientific conclusions of PRAC are as follows:

In view of available data on dizziness from clinical trials, spontaneous reports, including in some cases a close temporal relationship, the PRAC considers a causal relationship between SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant and dizziness is at least a reasonable possibility. The PRAC concluded that the product information of products containing SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.