



sanofi



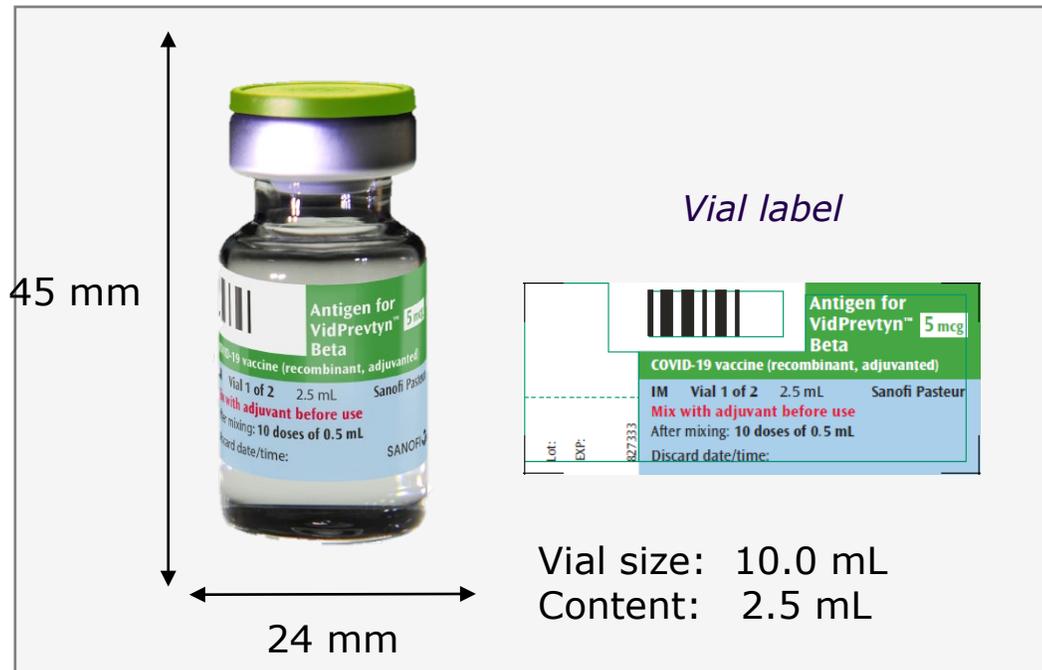
Vidprevtyn Beta Product Characteristics



Product Presentation: antigen & adjuvant vials

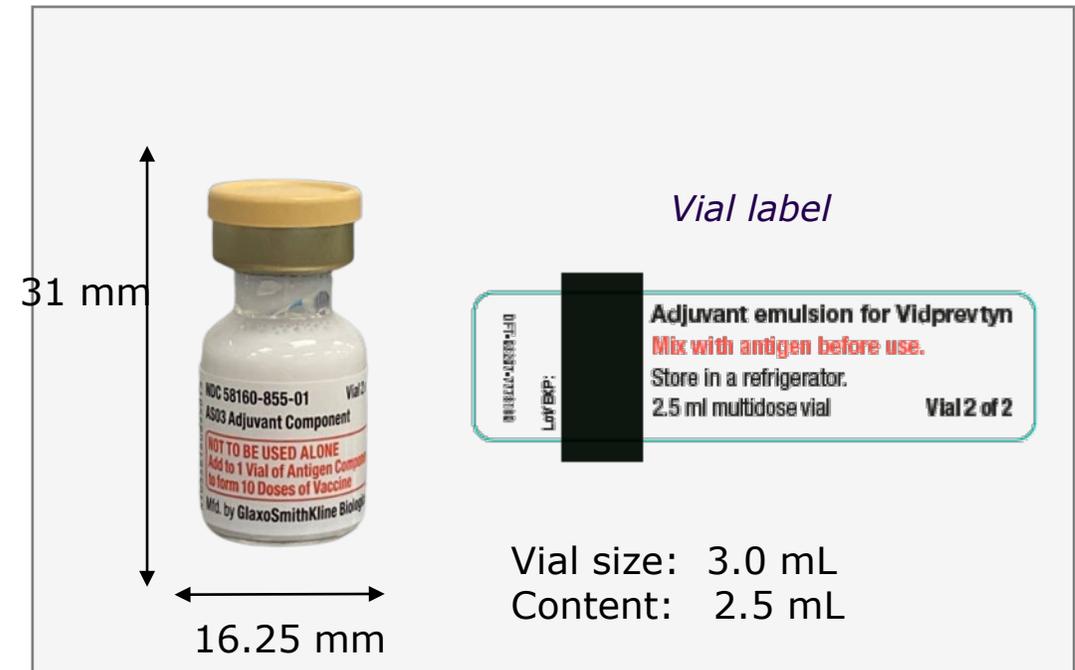
2 multidose vials (antigen vial and adjuvant vial) must be mixed before use. After mixing, the vaccine vial contains 10 doses of 0.5 mL.

1 Antigen (sanofi): Vial 10 doses Beta 5µg: Green Cap



The antigen solution is a colourless, clear liquid.

2 Adjuvant (GSK): Vial 10 doses Gold Cap



The adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.

1 Co-pack= 1 Antigen box & 1 Adjuvant box (=100ds)



**Co-pack =100 doses =
1 box Antigen & 1 box Adjuvant**
Pack size (mm): 138*92*57

 Co-Pack Box closed with a security label
Serialization aligned with Falsified Medicine Directive (FMD)



QR code link to electronic Product information
(on the co-pack)



2D barcode encoding vaccine product code (GTIN), batch number, expiry date, serial number
(on the co-pack)



Batch Number & Expiry Date
printed on the co-pack box

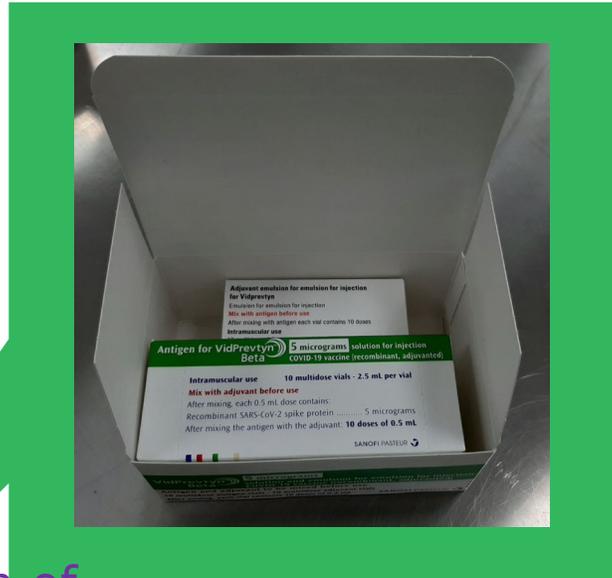


10 sheets of 20 stickers (tear off)
including 2D barcode
(inside the co-pack above antigen & adjuvant box)



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

Vidprevtyn Beta Co-packaging



Assembly of pack and addition of antigen box and adjuvant box to the pack

Addition of stickers



Co-pack
100 ds
(EU footprint)



10 x



2.5mL
antigen of 10 ds



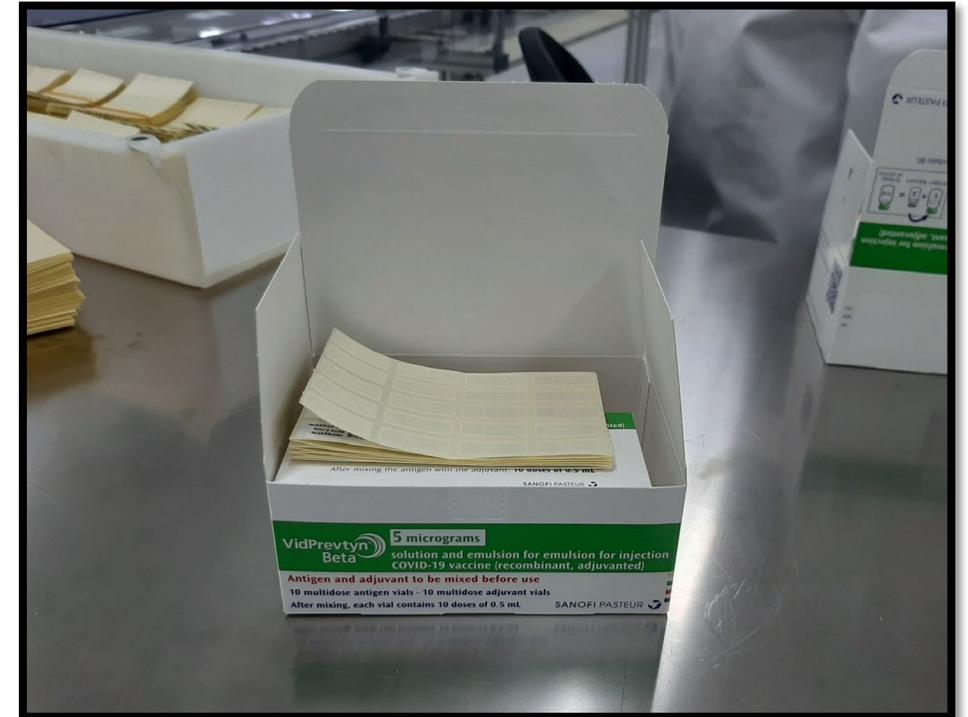
10 x



2.5mL
adjuvant of 10 ds

GMID available in Aug

Vidprevtyn Beta Co-packaging : Zoom

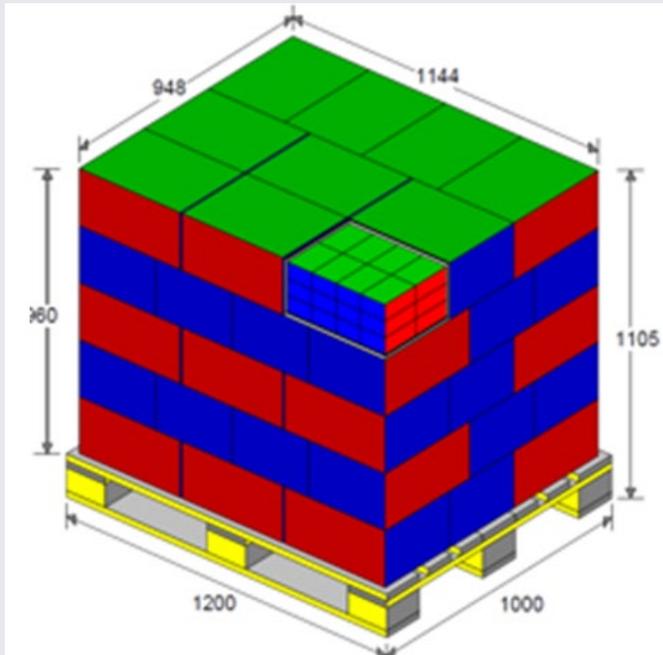


Final pallet



Confidential

Pallet specifications



1 Pallet = 120 000 doses / 1 200 co-pack

	Size	content	#doses
1 co-pack	138*92*57	= 1 box of 10 vials antigen +1 box of 10 vials adjuvant	100 doses
1 shipping case	380*282*178	=24 co-pack	2400 doses
1 pallet	1000*1200*1105	= 50 cases	120 000 doses

Paper Leaflet



1 booklet is grouping
10 separate leaflets

- ❑ No package leaflet included in the co pack
- ❑ Printed package leaflet in English
- ❑ 1 booklet is grouping 10 leaflets
- ❑ 1 leaflet is serving 1 co pack (100 doses) / 1 booklet is serving 10 Co pack
- ❑ For first deliveries, leaflets will be delivered after the products (printing time after MA)

INSTRUCTIONS FOR USE

Sanofi COVID-19 Vaccine Beta

Antigen solution
colourless, clear liquid



Adjuvant emulsion
whitish to yellowish homogeneous
milky liquid

PREPARATION & MIXING

1



1. Place the vials at room temperature for a minimum of **15 minutes protected from light**

2



2. Invert each vial and inspect them visually for any foreign particulate matter or discoloration

3



3. Remove the flip-off caps & cleanse both vial stoppers with antiseptic swabs

5



5. Transfer the full syringe contents into the antigen vial

4



4. Use a sterile **21-gauge** or narrower needle and a sterile syringe to withdraw the entire contents from the adjuvant vial

6



6. Mix the content by inverting the vial **5 times**

7



7. Record the appropriate date and time on designated area of vial label

PREPARATION OF INDIVIDUAL DOSES



The vial contains **10 doses** of **0.5 mL**. Store it between **2°C to 8°C, protected from light**, and use within **6 hours** and then discard.

An additional overfill is added to ensure that the **10 doses** can be delivered



Cleanse the vial stopper with antiseptic swabs and use a needle **23-gauge** or narrower for dosage and administration.

Withdraw **0.5 mL** from the vial containing the mixed vaccine. After each administration put the vial back between **2°C to 8°C, protected from light**

0.5 mL





Thank you



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