

SPMSD - Pays : GB - Format à plat : 104 x 500 mm - Plié : 104 x 83.3 mm

3 Référence Pantone U :
Black (Texte)
185 (Bandeau Supérieur)
Process Blue (Bandeau Inférieur)



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4. POSSIBLE SIDE EFFECTS

Like all medicines, Inactivated Influenza Vaccine (Split Virion) BP can cause side effects, although not everybody gets them.

During clinical trials, the following side effects have been observed. Their frequencies have been estimated as Common: affects 1 to 10 users in 100.

- headache
- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- fever, generally feeling unwell (malaise), shivering, fatigue
- local reactions: redness, swelling, pain, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

These reactions usually disappear within 1-2 days without treatment.

Next to the above common side effects, the following side effects occurred after the vaccine came on the market:

- allergic reactions:
 - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases
 - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems.
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (convulsions) associated with fever, neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré Syndrome)
- temporary reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia), temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP

Keep out of the reach and sight of children.

Do not use Inactivated Influenza Vaccine (Split Virion) BP after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Inactivated Influenza Vaccine (Split Virion) BP contains

The active substances are: Influenza virus (inactivated, split) of the following strains*:
 A/California/7/2009 [H1N1]pdm09-derived strain used [NYMC X-179A] 15 micrograms HA**
 A/Texas/50/2012 [H3N2]-derived strain used [NYMC X-223A] .. 15 micrograms HA**
 B/Massachusetts/2/2012 15 micrograms HA**
 Per 0.5 ml dose
 * propagated in fertilised hens'eggs from healthy chicken flocks
 ** haemagglutinin

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern hemisphere) and EU decision for the 2014/2015 season.

The other ingredients are a buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride and water for injections.

What Inactivated Influenza Vaccine (Split Virion) BP looks like and contents of the pack

Inactivated Influenza Vaccine (Split Virion) BP is a suspension for injection presented in a pre-filled syringe of 0.5 ml in box of 1, 10, 20 or 50. Not all pack sizes may be marketed. The vaccine, after shaking gently, is a slightly whitish and opalescent liquid.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder in the UK is:
 Sanofi Pasteur MSD Limited
 Mallards Reach, Bridge Avenue - Maidenhead - Berkshire, SL6 1QP

The Marketing Authorisation Holder in Ireland is:
 Sanofi Pasteur MSD Limited

Block A, Second Floor, Cookstown Court, Old Belgard Road
 Tallaght, Dublin 24.

The Manufacturer is: SANOFI PASTEUR - 2, avenue Pont Pasteur - 69007 Lyon, FRANCE

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name
Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxemburg, Norway, Portugal, Slovakia, Spain, Sweden, The Netherlands	Vaxigrip
Ireland, United Kingdom	Inactivated Influenza Vaccine (Split Virion) BP

This leaflet was last approved in 07/2014.

The following information is intended for medical or healthcare professionals only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

The vaccine should be allowed to reach room temperature before use.

Shake before use.

The vaccine should not be used if foreign particles are present in the suspension.

It should not be mixed with other medicinal products in the same syringe.

This vaccine is not to be injected directly into any blood vessel.

For children, when one dose of 0.25 ml is indicated, push the plunger stopper exactly to the edge of the mark of the syringe to eliminate half of the volume. The remaining volume should be injected.

See also section 3. HOW TO USE INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP



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PACKAGE LEAFLET: INFORMATION FOR THE USER

Inactivated Influenza Vaccine (Split Virion) BP, suspension for injection in pre-filled syringe

Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you or your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP IS AND WHAT IT IS USED FOR
2. BEFORE YOU OR YOUR CHILD USES INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP
3. HOW TO USE INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP
6. FURTHER INFORMATION

1. WHAT INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP IS AND WHAT IT IS USED FOR

Inactivated Influenza Vaccine (Split Virion) BP is a vaccine.

This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of Inactivated Influenza Vaccine (Split Virion) BP should be based on official recommendations.

When a person is given the vaccine Inactivated Influenza Vaccine (Split Virion) BP, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you or your child might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child was not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Inactivated Influenza Vaccine (Split Virion) BP will protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection. The incubation period for flu is a few days, so if you or your child is exposed to flu immediately before or after your vaccination, you or your child could still develop the illness.

The vaccine will not protect you or your child against the common cold, even though some of the symptoms are similar to flu.

2. BEFORE YOU OR YOUR CHILD USES INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP

To make sure that Inactivated Influenza Vaccine (Split Virion) BP is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Inactivated Influenza Vaccine (Split Virion) BP

- If you or your child is allergic (hypersensitive) to:
 - the active substances, or
 - any of the other ingredients of Inactivated Influenza Vaccine (Split Virion) BP, see section 6 "Further information", or
 - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), neomycin, formaldehyde or octoxinol-9,
- If you or your child has an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child has recovered.

Take special care with Inactivated Influenza Vaccine (Split Virion) BP

You should tell your doctor before vaccination if you or your child has a poor immune response (immunodeficiency or taking medicines affecting the immune system).

Your doctor will decide if you or your child should receive the vaccine.

If, for any reason, you or your child has a blood test within a few days following a flu vaccination, please tell your doctor. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

As with all vaccines, Inactivated Influenza Vaccine (Split Virion) BP may not fully protect all persons who are vaccinated.

Using other medicines

- Please tell your doctor or pharmacist if you or your child is taking or has recently taken any other vaccines or any other medicines, including medicines obtained without a prescription.
- Inactivated Influenza Vaccine (Split Virion) BP can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be stronger.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.

Flu vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of flu vaccines do not indicate that the vaccine would have harmful effects on the pregnancy or the baby.

Inactivated Influenza Vaccine (Split Virion) BP may be used during breast-feeding. Your doctor/pharmacist will be able to decide if you should receive Inactivated Influenza Vaccine (Split Virion) BP.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Inactivated Influenza Vaccine (Split Virion) BP has no or negligible influence on the ability to drive or use machines.

3. HOW TO USE INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP

Dosage

Adults receive one 0.5 ml dose.

Use in children

Children from 36 months and older receive one 0.5 ml dose.

Children from 6 months to 35 months may receive either one 0.25 ml dose or one 0.5 ml dose in accordance with existing national recommendations.

If your child has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route(s) of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

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