

PACKAGE LEAFLET: INFORMATION FOR THE USER

Inactivated Influenza Vaccine (Split Virion) BP, suspension for injection in prefilled syringe.

Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you or your child receive this vaccine because it contains important information for you or your child

- 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 only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Inactivated Influenza Vaccine (Split Virion) BP is and what it is used for
2. What you need to know before you or your child use 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. Contents of the pack and other 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). 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 were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child run 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 is intended to 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 are 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. What you need to know before you or your child use 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 are allergic (hypersensitive) to:
 - the active substances, or
 - any of the other ingredients of this vaccine (listed in Section 6), 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 have an illness with a high or moderate temperature or an acute illness, the vaccination should be postponed until after you or your child have recovered.

Warnings and precautions

Talk to your doctor or pharmacist before using Inactivated Influenza Vaccine (Split Virion) BP

You should tell your doctor before vaccination if you or your child have:

- a poor immune response (immunodeficiency or taking medicines affecting the immune system),
- bleeding problem or bruising easily.

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

If, for any reason, you or your child have 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.

Other medicines and Inactivated Influenza Vaccine (Split Virion) BP

Tell your doctor or pharmacist if you or your child are taking or have recently taken any other vaccines or any other medicines.

- 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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have baby, ask your doctor or pharmacist for advice before using this medicine.

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.

Driving and using machines

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

Inactivated Influenza Vaccine (Split Virion) BP contains potassium and sodium

This medicine contains less than 1 mmol potassium (39 mg) and sodium (23 mg) per dose, i.e. essentially 'potassium-free' and 'sodium-free'.

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 receive one 0.25 ml dose.

If this is required by national recommendations, a 0.5 ml dose may be given.

If your child is under 9 years and 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.

If you or your child use more Inactivated Influenza Vaccine (Split Virion) BP than you should

In some cases, more than the recommended dose was used.

In these cases, when side effects were reported, the information was in line with what is described in Section 4.

4. Possible Side effects

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

Allergic reactions

See a doctor IMMEDIATELY if you or your child experience:

- Severe allergic reactions:
 - That may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, dizziness, that may lead to collapse (shock).
 - Swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema)
- Allergic reactions such as

skin reactions that may spread throughout the body including itching, hives, rash, redness (erythema).

These side effects are rare (may affect up to 1 in 1,000 people) except urticaria which is uncommon (may affect up to 1 in 100 people) in children from 3 years to 8 years old.

Other side effects reported

Very common (may affect more than 1 in 10 people) in adults and elderly:

- Headache ⁽¹⁾
- Muscular pain ⁽¹⁾
- Generally feeling unwell ⁽¹⁾⁽²⁾, unusual tiredness or weakness ⁽¹⁾⁽²⁾
- Injection site reactions ⁽¹⁾: pain, redness, swelling, hardness, itchiness ⁽²⁾

Very common (may affect more than 1 in 10 people) in paediatric* population:

- Headache ⁽¹⁾⁽⁵⁾⁽⁶⁾, unusual crying ⁽¹⁾⁽⁴⁾, irritability ⁽¹⁾⁽⁴⁾, drowsiness ⁽¹⁾⁽⁴⁾
- Muscular pain ⁽¹⁾⁽⁵⁾⁽⁶⁾
- Diarrhoea ⁽¹⁾⁽⁴⁾
- Decrease or loss of appetite ⁽¹⁾⁽⁴⁾
- Generally feeling unwell ⁽¹⁾⁽⁵⁾⁽⁶⁾, fever ⁽¹⁾⁽⁴⁾, shivering ⁽¹⁾⁽⁶⁾
- Injection site reactions ⁽¹⁾: pain, redness, swelling, hardness ⁽⁴⁾⁽⁵⁾

Common (may affect up to 1 in 10 people) in adults and elderly:

- Joint pain ⁽¹⁾
- Increased sweating ⁽¹⁾
- Injection site reactions: bruising ⁽¹⁾, itchiness ⁽³⁾
- Shivering ⁽¹⁾, fever ⁽¹⁾, generally feeling unwell ⁽³⁾, unusual tiredness or weakness ⁽³⁾

Common (may affect up to 1 in 10 people) in paediatric* population:

- Dizziness ⁽⁶⁾
- Insomnia ⁽¹⁾⁽⁴⁾
- Vomiting ⁽¹⁾⁽⁴⁾
- Fever ⁽⁵⁾⁽⁶⁾, shivering ⁽⁵⁾
- Injection site reactions: bruising ⁽¹⁾, itchiness, discomfort ⁽⁶⁾, hardness ⁽⁶⁾, warmth ⁽⁶⁾

Uncommon (may affect up to 1 in 100 people) in adults and elderly:

- Swelling of the glands in the neck, armpit or groin ⁽²⁾
- Sleepiness ⁽³⁾, Dizziness ⁽³⁾
- Feeling sick (nausea) ⁽²⁾, Diarrhoea ⁽¹⁾
- Flu-like illness ⁽²⁾
- Injection site reactions ⁽²⁾: discomfort, warmth

Uncommon (may affect up to 1 in 100 people) in paediatric* population:

- Swelling of the glands in the neck, armpit or groin ⁽⁵⁾
- Diarrhoea ⁽⁵⁾
- Injection site reactions ⁽⁵⁾: haemorrhage, warmth

* Children/adolescents from 6 months to 17 years old

Rare (may affect up to 1 in 1000 people) in adults and elderly:

- Numbness or pins and needles sensation (paraesthesia), decrease of sensitivity (hypoesthesia) ⁽²⁾, numbness, pain and weakness of the arm (brachial radiculitis) ⁽³⁾, pain situated on the nerve route (neuralgia) ⁽³⁾
- Swelling of the glands in the neck, armpit or groin ⁽³⁾

Not known frequency (frequency cannot be estimated from the available data)

- Swelling of the glands in the neck, armpit or groin ⁽⁴⁾⁽⁶⁾
- Numbness or pins and needles sensation (paraesthesia) ⁽⁷⁾
- Pain situated on the nerve route (neuralgia) ⁽⁵⁾⁽⁶⁾
- Fits (convulsions)
- 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 ⁽²⁾⁽³⁾⁽⁵⁾⁽⁶⁾, Guillain-Barré Syndrome ⁽²⁾⁽³⁾⁽⁵⁾⁽⁶⁾)
- Blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems
- 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).

⁽¹⁾ These side effects usually occurred within the 3 days following vaccination and disappeared within 1 to 3 days without treatment. Most of these side effects were of mild to moderate intensity.

⁽²⁾ In adults

⁽³⁾ In elderly

⁽⁴⁾ In 6 to 35 months old

⁽⁵⁾ In 3 to 8 years old

⁽⁶⁾ In 9 to 17 years old

⁽⁷⁾ In 6 months to 17 years old

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In Ireland

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

In the UK

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inactivated Influenza Vaccine (Split Virion) BP

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

Do not use this vaccine 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.

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

6. Contents of the pack and other 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 - like strain.....15 micrograms HA**
A/Switzerland/9715293/2013 (H3N2) - like strain15 micrograms HA**
B/Phuket/3073/2013.....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 2015/2016 season.

The other ingredients are: a buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride, 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 prefilled 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
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:

<u>Member State</u>	<u>Name</u>
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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 revised in 07/2015.

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.

Instructions for administration of 0.25 ml in children from 6 months to 35 months

When one dose of 0.25 ml is indicated, in order to eliminate half of the volume of the 0.5 ml syringe, the syringe should be held in an upright position and the plunger stopper should be pushed until it reaches the fine black line printed on the syringe. The remaining volume of 0.25 ml should be injected.

See also Section 3. How to use Inactivated Influenza Vaccine (Split Virion) BP