

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 administered to you or your child from 6 months of age helps to protect you or your child against influenza (flu).

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.

When given during pregnancy the vaccine helps to protect the pregnant women but also helps to protect her baby from birth to less than 6 months of age through the transmission of protection from mother to baby during pregnancy (see also Sections 2 and 3).

None of the ingredients in the vaccine can cause flu.

The use of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP should be based on official recommendations.

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.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection.

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.

Not all babies less than 6 months of age born to pregnant women vaccinated during pregnancy will be protected.

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, ask your doctor or pharmacist for advice before using this medicine.

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP can be used in all stages of pregnancy.

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

Adults receive one 0.5 ml dose.

Use in children and adolescents

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

Children from 6 months to 35 months of age 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 of age and has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

If you are pregnant, one 0.5 ml dose given to you during pregnancy may protect your baby from birth to less than 6 months of age. Ask your doctor or pharmacist for more information.

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)

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See a doctor if you or your child experience allergic reactions that may affect:

- The skin: such as itching, hives, rash, redness, areas of itchy, red, swollen, and cracked skin (dermatitis atopic), flushing
- The eyes: such as excess of blood in the white of the eye (ocular hyperaemia), redness and irritation of the eye (conjunctivitis allergic)
- The throat and the nose: such as throat irritation, sore throat, allergic irritation inside the nose, runny nose, sneezing, stuffy nose, sinus or throat
- The mouth: such as numbness or pins and needles sensation (paraesthesia oral), rash (oral mucosal eruption)
- Breathing: such as asthma, difficulty breathing (dyspnea).

These allergic reactions were reported as uncommon (may affect up to 1 in 100 people) to rare (may affect up to 1 in 1,000 people).

Other side effects reported

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

- Headache
- Muscular pain
- Generally feeling unwell ⁽¹⁾
- Pain at injection site

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

- Shivering, fever ⁽¹⁾
- Reactions at the injection site: redness, hardness, swelling

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

- Swelling of the glands in the neck, armpit or groin ⁽¹⁾
- Unusual weakness ⁽¹⁾, tiredness, sleepiness ⁽²⁾, dizziness ⁽²⁾, increased sweating ⁽¹⁾
- Joint pain ⁽¹⁾
- Feeling sick (nausea), diarrhea
- Reactions at the injection site: bruising, itching, warmth ⁽¹⁾, discomfort

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

- Numbness or pins and needles sensation (paraesthesia), decrease sensitivity (hypoesthesia) ⁽³⁾
- Vomiting, decreased appetite, abdominal pain ⁽³⁾
- Signs of flu-like illness ⁽³⁾
- Reactions at the injection site: peeled off skin (exfoliation) ⁽⁴⁾, allergy ⁽³⁾

⁽¹⁾ Less frequent in elderly ⁽²⁾ Less frequent in adults ⁽³⁾ In adults ⁽⁴⁾ In elderly

Very common (may affect more than 1 in 10 people) in children and adolescents from 3 to 17 years of age:

- Headache
- Muscular pain
- Generally feeling unwell, shivering ⁽⁶⁾
- Reactions at the injection site : pain , redness, swelling , hardness ⁽⁵⁾

Common (may affect up to 1 in 10 people) in children and adolescents from 3 to 17 years of age:

- Fever, shivering ⁽⁵⁾
- Reactions at the injection site: bruising ⁽⁵⁾, hardness ⁽⁶⁾

Uncommon (may affect up to 1 in 100 people) in children and adolescents from 3 to 17 years of age:

- Swelling of the glands in the neck, armpit or groin ⁽⁵⁾, unusual weakness ⁽⁶⁾, tiredness, dizziness ⁽⁶⁾, crying ⁽⁵⁾
- Diarrhea ⁽⁵⁾, abdominal pain ⁽⁵⁾
- Reactions at the injection site: bruising ⁽⁶⁾, itching, warmth⁽⁶⁾, discomfort ⁽⁶⁾

Very common (may affect more than 1 in 10 people) in children from 6 to 35 months of age:

- Headache ⁽⁷⁾, unusual crying ⁽⁸⁾, irritability ⁽⁸⁾, drowsiness ⁽⁸⁾
- Muscular pain ⁽⁷⁾
- Fever, loss of appetite ⁽⁸⁾
- Reactions at the injection site : tenderness , redness, hardness, bruising, swelling

Common (may affect up to 1 in 10 people) in children from 6 to 35 months of age:

- Vomiting ⁽⁸⁾, diarrhea
- Shivering ⁽⁷⁾

⁽⁵⁾ In 3 to 8 years old

⁽⁶⁾ In 9 to 17 years old

⁽⁷⁾ In 24 to 35 months old

⁽⁸⁾ In 6 to 23 months old

The frequency of the following side effects is not known (cannot be estimated from the available data) in the whole population except in the population for which the side effect is listed above:

- Swelling of the glands in the neck, armpit or groin
- Numbness or pins and needles sensation (paraesthesia)
- Pain situated on the nerve route (neuralgia)
- 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, Guillain-Barré Syndrome)
- 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).

⁽⁹⁾ Not reported in children from 6 to 35 months old

Most side effects usually occurred within the 3 days following vaccination, disappeared within 3 days without treatment. The intensity of these side effects was mild to moderate.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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/Michigan/45/2015 (H1N1)pdm09 - like strain (A/Michigan/45/2015, NYMC X-275)
..... 15 micrograms HA**
 - A/Singapore/INFIMH-16-0019/2016 (H3N2) - like strain (A/Singapore/INFIMH-16-0019/2016, IVR-186)) 15 micrograms HA**
 - B/Colorado/06/2017 - like strain (B/Maryland/15/2016, NYMC BX-69A) 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 2018/2019 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.

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The Manufacturer is:

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FRANCE

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

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

This leaflet was last revised in 04/2019.

The following information is intended for 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