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PACKAGE LEAFLET: INFORMATION FOR THE USER

Vaxigrip®

suspension for injection in pre-filled syringe

Trivalent influenza vaccine

(split virion, inactivated)

2026/2027 season

Read all of this leaflet carefully before you or your child are vaccinated 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.
- 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, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Vaxigrip is and what it is used for
- What you need to know before you or your child use Vaxigrip
- How to use Vaxigrip
- Possible side effects
- How to store Vaxigrip
- Contents of the pack and other information.

1. WHAT VAXIGRIP IS AND WHAT IT IS USED FOR

Vaxigrip 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 Vaxigrip, 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 close to 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 Vaxigrip 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. Due to this potential change in circulating strains on a yearly basis, as well as the duration of protection expected of the vaccine, vaccination is recommended 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.

Vaxigrip 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.

In addition, if you or your child are exposed to flu immediately before or after your vaccination, you or your child could still develop the illness as the incubation period for flu is a few days.

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 VAXIGRIP

To make sure that Vaxigrip 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 Vaxigrip:

- If you or your child are allergic to:
 - o the active substances or
 - o any of the other ingredients of this vaccine (listed in Section 6) or
 - o any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), neomycin, formaldehyde or octoxynol-9.

Warnings and precautions

Talk to your doctor or pharmacist before using Vaxigrip.

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 problems or bruise easily.

If you or your child have an acute illness with fever, the vaccination should be postponed until the fever is resolved.

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.

As with all vaccines, Vaxigrip 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.

Children

Vaxigrip is not recommended for use in children below 6 months of age.

Other medicines and Vaxigrip

Tell your doctor or pharmacist if you or your child are receiving, have recently received or might receive any other vaccines or any other medicines.

- Vaxigrip can be given at the same time as other vaccines by using separate injection sites.
- The immunological response may decrease in case of immunosuppressive treatments, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

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

Vaxigrip may be used in all stages of pregnancy.

Vaxigrip may be used during breast-feeding.

Your doctor or pharmacist will be able to decide if you should receive Vaxigrip.

Driving and using machines

Vaxigrip has no or negligible influence on the ability to drive and use machines.

Vaxigrip contains potassiumium and sodium

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

3. HOW TO USE VAXIGRIP

Dosage

Adults receive one 0.5 mL dose.

Use in children and adolescents

Children from 6 months to 17 years of age receive one 0.5 mL dose.

If your child is less than 9 years of age and has not been previously vaccinated against flu, a second dose of 0.5 mL 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 close to 6 months of age. Ask your doctor or pharmacist for more information.

How Vaxigrip is given

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

If you or your child use more Vaxigrip than you should

In some cases, more than the recommended dose has been inadvertently administered.

In these cases, when side effects were reported, they were in line with what is described following the administration of the recommended dose (see Section 4). If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If you experience an allergic reaction, contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away.

Allergic reactions

They can occur immediately after vaccine administration and may be life-threatening.

Symptoms may include:

- Rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, low blood pressure, rapid heart rate and weak pulse, cold, clammy skin, dizziness, weakness or fainting (anaphylactic reaction, angioedema, shock).

Other symptoms may include:

- Areas of itchy, red, swollen and cracked skin (atopic dermatitis), redness and warmth of the face, hot flush, blood in the white of the eye (ocular hyperaemia), redness and irritation of the eye (conjunctivitis), throat irritation, sore throat, irritation inside the nose, runny nose, sneezing, stuffy nose or throat, numbness or pins and needles sensation in the mouth (oral paraesthesia), rash in the mouth (oral eruption), asthma.

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).

Additional side effects in adults and the elderly

Very common (may affect more than 1 in 10 people)

- Headache, muscular pain, generally feeling unwell (malaise)^(۱), pain at the injection site

(۱) Common in the elderly

Common (may affect up to 1 in 10 people)

- Fever⁽²⁾, shivering, reactions at the injection site: redness (erythema), hardness (induration), swelling

(۲) Uncommon in the elderly

Uncommon (may affect up to 1 in 100 people)

- Swelling of the glands in the neck, armpit or groin (lymphadenopathy)⁽³⁾, unusual weakness^(۴), tiredness, sleepiness^(۵), dizziness^(۵), increased sweating (hyperhidrosis)^(۶), joint pain^(۷), diarrhoea, feeling sick (nausea), reactions at the injection site: bruising, itching, warmth^(۸), discomfort

(۳) Rare in the elderly

(۴) Rare in adults

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

- Numbness or pins and needles sensation (paraesthesia), vomiting, decreased appetite, flu-like illness
- Decrease sensitivity (hypoaesthesia), abdominal pain, allergy at the injection site: only seen in adults

- Peeled off skin (exfoliation) at the injection site: only seen in the elderly

Additional side effects in children from 3 to 17 years of age

Very common (may affect more than 1 in 10 people)

- Headache, muscular pain, generally feeling unwell, shivering, reactions at the injection site: pain, redness, swelling, hardness^(۵)

(۵) Common in children from 9 to 17 years old.

Common (may affect up to 1 in 10 people)

- Fever, bruising at the injection site
- Uncommon (may affect up to 1 in 100 people)**
- Tiredness, dizziness, diarrhoea, reactions at the injection site, itching, warmth
- Swelling of the glands in the neck, armpit or groin, abdominal pain, vomiting, restlessness, moaning, joint pain, crying: only seen in children from 3 to 8 years of age.
- Reduction in the number of certain blood components called platelets; a low number of these can result in excessive bruising or bleeding (thrombocytopenia): only seen in a 3-year-old child.
- Unusual weakness, discomfort at the injection site: only seen in children from 9 to 17 years of age.

Additional side effects in children from 6 to 35 months of age

Very common (may affect more than 1 in 10 people)

- Irritability^(۵), vomiting^(۶), muscular pain^(۵), generally feeling unwell^(۵), fever, decrease of appetite^(۵), reactions at the injection site: tenderness, redness
- Unusual crying, drowsiness: only seen in children less than 24 months of age
- Headache: seen in children 24 months of age and older

(۵) Rare in children from 24 to 35 months old.

(۶) Uncommon in children from 24 to 35 months old.

(۵) Rare in children from 6 to 23 months old.

Common (may affect up to 1 in 10 people)

- Diarrhoea, reactions at the injection site: hardness (induration), bruising, swelling
- Shivering: only seen in children 24 months of age and older.

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

- Flu-like illness, reactions at the injection site: itching, rashes.

In children from 6 months to 8 years of age who receive 2 doses, side effects are similar after the first and after the second dose. Fewer side effects may happen after the second dose in children from 6 to 35 months of age. Most side effects usually occurred within the 3 days following vaccination and disappeared within 3 days without treatment. The intensity of most of these side effects was mild to moderate.

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)^(۵), 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^(۵) and Guillain-Barré Syndrome^(۵))

- 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 some blood components called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia).

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

Reporting of side effects

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

این واکسن شما را در برابر سرما خوردگی معمولی محافظت نمی نماید، اگر چه برخی از نشانه های آن مشابه آنفلوآنزا می باشد.

۲- آنچه لازم است قبل از تلقیح Vaxigrip به خود و فرزندان بدانید:

برای اطمینان از مناسب بودن Vaxigrip برای شما و یا فرزندان از برای است که در صورت دارا بودن هر یک از شرایط ذیل با واکسن و یا داکتر داروساز مشورت نمایید. در صورت عدم آگاهی نسبت به هر یک از موارد زیر، با پزشک یا دکتر داروساز بخاورید تا توضیحات لازم را به شما ارائه دهد.

از Vaxigrip استفاده نکند:
اگر شما یا فرزندان به موارد زیر حساسیت دارید:

- هر یک از سایر ترکیبات این واکسن (ذکر شده در پخش ۴، یا

- هر اجزایی که ممکن است در مقادیر بسیار کم وجود داشته باشد مانند تخم مرغ (آلبومین)، پروتئین مرغ، نئومایسین، فرمالدئید یا آکتوکلینول-۹.

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

5. HOW TO STORE VAXIGRIP

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 box 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 Vaxigrip contains

- The active substances are: influenza virus (split, inactivated) of the following strains*:
A/Missouri/11/2025 (H1N1)pdm09-like strain
(A/Switzerland/6849/2025, IVR-278) 15 micrograms HA**
A/Darwin/1454/2025 (H3N2)-like strain
(A/Michigan/105/2025, SAN-049A) 15 micrograms HA**
B/Tokyo/EIS13-175/2025-like strain
(B/Tokyo/EIS13-175/2025, wild type)..... 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 Organization) recommendations (Northern Hemisphere) and European Union decision for the 2026/2027 season.

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

Some components such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde or octoxynol-9 may be present in very small amounts (see section 2).

What Vaxigrip is and contents of the pack

The vaccine, after shaking gently, is a colourless opalescent liquid.

Vaxigrip is a 0.5 mL suspension for injection in pre-filled syringe, with attached needle, with separate needle or without needle, in boxes of 1 or 10. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sanofi Winthrop Industrie - 82 Avenue Raspail, 94250 Gentilly, France

This leaflet was last revised in: 08/2026

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 reaction following the administration of the vaccine.

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

Shake before use. Inspect visually prior to administration.

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 must not be injected directly into a blood vessel.

See also section 3. How to use Vaxigrip

Vaxigrip®

سوسپانسیون در سرنگ از پیش پر شده واکسن آنفلوآنزای سه ظرفیتی (ویریون اسمپلیت ، غیر فعال شده) سوشهای سال ۲۰۲۷-۲۰۲۶

خواهشمند است قبل از واکسینه شدن خود و یا فرزندان این بروشور را کامل و به دقت مطالعه کنید. زیرا حاوی اطلاعات مهمی برای شما می باشد.

- از آنجا که ممکن است مجددا به مطالعه بروشور نیاز داشته باشید، آن را نزد خود نگه دارید.
- در صورت نیاز به اطلاعات بیشتر، سوالات خود را از پزشک، دکتر داروساز و یا پرستار خود بپرسید.
- این واکسن فقط برای شما و یا فرزندان تجویز شده است. لطفاً از توصیه آن به دیگران جدا خودداری فرمایید.
- چنانچه شما و یا فرزندان دچار عوارض ناخواسته ای شدید، با پزشک، دکتر داروساز و یا پرستار خود مشورت نمایید. این توصیه شامل هر عارضه ناخواسته ی محتمل دیگری که در این بروشور ذکر نشده نیز می شود. (به قسمت ۴ بروشور مراجعه شود)

در این بروشور می خوانید:

- ۱- Vaxigrip چیست و موارد مصرف آن کدامند؟**
آنچه لازم است قبل از تلقیح Vaxigrip به خود یا فرزندان بدانید.
- ۲- نحوه مصرف Vaxigrip**
- ۳- عوارض ناخواسته محتمل**
- ۵- شرایط نگهداری Vaxigrip**
- ۶- محتویات جعبه و سایر اطلاعات**

۱- Vaxigrip چیست و موارد مصرف آن کدامند؟

Vaxigrip یک واکسن است.

این واکسن به شما و یا فرزندان از سن شش ماهگی کمک می کند تا در برابر آنفلوآنزا محافظت شوند. پس از تلقیح واکسن Vaxigrip به شخص، سیستم ایمنی (سیستم طبیعی دفاعی بدن) شروع به دفاع از خود (از طریق تولید پادتن) در مقابل بیماری می نماید. تجویز این واکسن در زمان بارداری علاوه بر محافظت از خانم باردار، از طریق انتقال پادتن از مادر به کودکان در طی بارداری، باعث محافظت از کودک از زمان تولد تا ۶ ماهگی می گردد (به قسمت ۴ و ۱ مراجعه شود).

هیچکدام از محتویات واکسن باعث بروز بیماری آنفلوآنزا نمی شوند.

مصرف Vaxigrip می بایست بر اساس توصیه های رسمی باشد.

آنفلوآنزا بیماری است که به سرعت می تواند منتشر گردد و عامل آن سوشهای مختلف ویروس است که هر ساله می توانند تغییر کنند. با توجه به تغییر سالانه سوش های در گردش و همچنین مدت زمان ایمنی ایجاد شده توسط واکسن، انجام واکسیناسیون هر ساله توصیه می شود.
شایع ترین زمان ابتلا به بیماری آنفلوآنزا در خلال ماههای سرد سال (مهر تا اسفند) می باشد. اگر شما یا فرزندان در پاییز واکسینه نشده اید تا بهار فرصت دارید تا واکسن دریافت کنید. زیرا تا آن زمان احتمال مبتلا شدن شما (یا فرزندان) به آنفلوآنزا وجود دارد. پزشک شما قادر است تا بهترین زمان واکسیناسیون را به شما توصیه نماید.

شما (یا فرزندان) حدود ۲ تا ۲ هفته پس از تلقیح Vaxigrip در مقابل سه سوش از ویروس که واکسن از آن تهیه شده است، محافظت خواهید شد.

همچنین اگر شما یا فرزندان بلافاصله پیش و یا پس از انجام واکسیناسیون در معرض آنفلوآنزا قرار گرفتید احتمال ابتلا به بیماری شما وجود دارد، زیرا که دوره کمون (Incubation) بیماری آنفلوآنزا روزی هشت می باشد.

با گزارش عوارض ناخواسته شما می توانید به ارائه اطلاعات بیشتر در مورد ایمنی این دارو کمک کنید.

۵- شرایط نگهداری Vaxigrip

دور از دسترس و دید کودکان قرار دهید.

این واکسن را پس از تاریخ نشانه استفاده کنید. تاریخ انقضاء بر روی جعبه بعد از کلمه EXP ذکر شده است. تاریخ دقیق انقضاء آخرین روز از ماه مورد اشاره (جدا شده بر روی جعبه) می باشد.

در پخشال (بین ۸-۲ درجه سانتیگراد نگهداری شود از پنج روزگی آن جدا جلوگیری نمایید. واکسن را جهت محافظت در مقابل نور، تا زمان مصرف از جعبه خارج نمایید.

هیچ دارویی نباید از طریق قفلابل و یا راهه های خلگی دفع گردد؛ دکتر داروساز خود در مورد نحوه دفع داروهای که دیگر استفاده نمی کنید سیال باید. این روشها را می برای حفاظت از محیط زیست می باشد.

- محتویات جعبه و سایر اطلاعات

۶- ترکیبات Vaxigrip

*ماده مؤثره: ویروس آنفلوآنزا(اسپلیت غیرفعال شده) از سوبه های ذیل

A/Missouri/11/2025 (H1N1)pdm09-like strain
(A/Switzerland/6849/2025, IVR-278) 15 micrograms HA**
A/Darwin/1454/2025 (H3N2)-like strain
(A/Michigan/105/2025, SAN-049A) 15 micrograms HA**
B/Tokyo/EIS13-175/2025-like strain
(B/Tokyo/EIS13-175/2025, wild type)..... 15 micrograms HA**
Per 0.5 mL dose

هر تخم مرغ زور در دسته نمرغان سالم، تکثیر شده است.

®® همالوئین

این واکسن بر اساس توصیه سازمان بهداشت جهانی (WHO) تولید نمیکره شمالی و تصمیم اتحادیه اروپا برای قبل از توزیع آن تهیه شده است.

توزیکبات جانبی شامل: محلول بافری شامل کلرید سدیم، کلرید بتاسیم، دی هیدرات فسفات دی سدیم، فسفات دی هیدروژن بتاسیم و آب برای تزریق.

برخی اجزا مانند تخم مرغ (آلبومین، پروتئین مرغ)، نئومایسین، فرمالدئید یا آکتوکلینول-۹ ممکن است به مقدار بسیار کم وجود داشته باشند. (مراجعه شود به قسمت ۴)

شکل ظاهری Vaxigrip محتویات داخل بسته بندی:

واکسن را پس از اینکه به آرامی تکان دادید، می بایست به صورت مایع بیرنگ متمایل به شیری در آید.

Vaxigrip یک سوسپانسیون تزریقی در سرنگهای از قبل پر شده ۰۵ میلی لیتری با یا بدون سوز که در جعبه های یکبارگیه های موجود می باشد، ممکن است نمایی این بسته بندی ها در بازار عرضه شده باشد.

درمانه مجوز فروش: