VAXIGRIP

INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

2013/2014 STRAINS

Registration certificate №: П N014493/01

PHARMACEUTICAL FORM

Suspension for intramuscular or subcutaneous route.

COMPOSITION

0.5 ml of suspension contents:
Active ingredient: Influenza viruses, propagated in eggs, split, inactivated, containing antigens equivalent to the following strains:
A/California/7/2009 (H1N1)pdm09-derived strain* .....15 µg of haemagglutinin;
A/Victoria/361/2011 (H3N2)-like strain** .....15 µg of haemagglutinin;
B/Massachusetts/02/2012*** .....15 µg of haemagglutinin.

* NYMC X-179A derived from A/California/7/2009
** NYMC X-223A derived from A/Texas/50/2012
*** B/Massachusetts/02/2012
] Vaccine strains

The other ingredients are: buffer solution (sodium chloride, potassium chloride, dihydrate disodium phosphate, monopotassium phosphate and water for injections) - up to 0.5 ml.
The vaccine complies with the W.H.O. recommendations (northern hemisphere) and E.U. decision for the 2013/2014 year season.
VAXIGRIP does not contain more than 0.05 microgram ovalbumin per adult dose (0.5 ml).

DESCRIPTION

Slightly opalescent and whitish liquid.

IMMUNOBIOLOGICAL PROPERTIES

VAXIGRIP forms specific resistance to epidemiologically actual influenza viruses of types A and B, contained in this vaccine. The immunity arises from about 2 to 3 weeks after the injection. The duration of post vaccinal immunity is usually 6-12 months.

INDICATIONS

This vaccine is recommended for the prevention of influenza in adults and in kids from 6 months of age, particularly in subjects showing a high risk of associated complications.

CONTRA-INDICATIONS

Hypersensitivity to any component of the vaccine, as well as to eggs or chicken meat, to neomycin, to formaldehyde, to octoxinol 9.
Febrile illness, acute or exacerbation of a chronic disease (in this case the vaccination shall be postponed).

PREGNANCY AND LACTATION

Limited data from vaccinations in pregnant women do not indicate that adverse foetal and maternal outcomes were attributable to the vaccine. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.
VAXIGRIP may be used during lactation.

METHOD OF ADMINISTRATION AND DOSAGE

Intramuscular route or deep subcutaneous injection. Do not administer by the intravascular route!
The vaccine should be brought to room temperature and shaken before use.
Dosage: For adult and children from 36 months - one 0.5 ml dose; for children from 6 to 35 months - one 0.25 ml dose.
For children (aged under 9 years) who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.
For the use of 0.5 ml prefilled syringe for the immunization of children requiring a half-dose (0.25 ml): push the plunger exactly to the edge of the mark so that the half of the volume should be eliminated. The remaining vaccine should be injected.
For the use of 0.5 ml ampoule for the immunization of children requiring a half-dose (0.25 ml): take up 0.25 ml from the ampoule with a graduated syringe. The fraction of suspension remaining in the ampoule must not be injected or kept.

UNDESIRABLE EFFECTS

Adverse events that occurred during clinical trials were as follows:
Common (from 1/100 to 1/10):
Systemic reactions: fever, malaise, shivering, fatigue, headache, sweating, myalgia (muscular pain), arthralgia (joint pain).
Local reactions: redness, swelling, pain, bruise (ecchymosis), induration in site of injection.
These reactions usually disappear within 1-2 days without treatment.
In post-marketing surveillance, the following adverse events have also been reported, very rarely:
From vascular and lymphatic system: transient thrombocytopenia, lymphadenopathy, vasculitis which may result (in isolated cases) in transient kidney problems.
From nervous system: paraesthesia, Guillain-Barre syndrome, neuritis, neuralgia, convulsions, encephalomyelitis.
Allergic reactions: urticaria, pruritus, cutaneous eruption, dyspnoea, angioedema, shock.

SPECIAL PRECAUTIONS

Due to the seasonal nature of influenza, it is recommended to perform vaccination against influenza every year during autumnal and winter seasons when risk of catching influenza is greatest.
The vaccine will only help to prevent influenza if it is caused by one of the three strains of virus contained in the vaccine, or other strains closely related to them.
VAXIGRIP will not prevent influenza if you or your child are incubating the disease before vaccination or if it is caused by another virus.
The vaccine will not protect against influenza-like illnesses caused by other germs.
Previous injections of influenza vaccine are unlikely to have given you protection against the current strains of influenza virus which are most common this year.
Your doctor has to be informed if you or your child has: immunodeficiency, allergy, unusual side effects after previous vaccination and if you or your child is taking or has recently taken any other medicines.
The vaccine should not be used if foreign particles are present in the suspension or if suspension has unusual colour.
The vaccine is unlikely to affect your ability to drive or use machines.
Your doctor has to be informed about any side effects including not listed in this leaflet.
Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 could be observed. The Western Blot technique disproves the results.
Appropriate medical treatment should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS

VAXIGRIP can be given at the same time (concomitantly) as other vaccines by using different injection sites and different syringes. The vaccine should not be mixed with any other medicinal product in the same syringe.
The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

PRESENTATIONS

0.5 ml in syringe, 1 syringe in blister, 1 blister with a leaflet in box.
0.5 ml in ampoule, per 10 ampoules in strip pack, 2 strip packs (20 ampoules) with a leaflet in box.

SHELF LIFE

12 months.
Do not use after the expiry date indicated on the package.
The expiry date refers to the last day of that month.

STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C), protected from light. Do not freeze.
Keep out of the reach and sight of children.

PHARMACY PURCHASING TERMS

Syringes: On prescription only.
Ampoules: For medical institutions only.
Inform on all the events of unusual graft reactions:
FGBU «Scientific center of expertise of medications» (119002, Moscow, per. Sivtzev Vrazshek, 41, tel. (499) 241-66-64) and the Representative office of company-manufacturer «Sanofi-aventis group» (115035, Moscow, ul. Tverskaya, 22, tel. (495) 935-86-91).

MANUFACTURER

Sanofi Pasteur S.A., 2, avenue Pont Pasteur, 69007 Lyon – France.

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