

For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) I.P.

VAXIGRIP®

Suspension for Injection in multidose vial

COMPOSITION

Each 0.5 ml dose contains 15 µg of haemagglutinin of each of the three recommended strains (as per the WHO recommendations).

Excipients:

Thiomersal2 micrograms per 0.5 ml dose

Excipients include buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride, water for injections.

THERAPEUTIC INDICATIONS

VAXIGRIP® is indicated for prophylaxis against influenza. Use of VAXIGRIP® and the best time for vaccination should be according to official recommendations. VAXIGRIP® is intended to protect against the 3 strains of influenza virus contained in the vaccine after about 2-3 weeks following the injection. The vaccine will not protect against common cold, even though some of the symptoms are similar to influenza.

DOSAGE AND ADMINISTRATION

Adults and children aged from 36 months receive one 0.5 ml dose.. If the child is less than 9 years and has not been previously vaccinated against influenza, a second dose should be given after at least 4 weeks.

Method and/or route(s) of administration

Vaccine should be administered by intramuscular or deep subcutaneous route.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS

- Allergy to the active substance or any other in gradient ,excipient including thiomersal.
- Allergy to any component that may be present in very small amounts, such as eggs (ovalbumin or chicken proteins), neomycin, formaldehyde, or octoxinol-9. -Febrile or acute illness (vaccination should be postponed).

Pregnancy and lactation

Inactivated influenza vaccines can be used in all stages of pregnancy. Larger data sets on safety are available for the second and third trimesters, compared with the first trimester. However, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. VAXIGRIP® may be used during breast feeding.

WARNING AND PRECAUTIONS

Immunodeficiency due to disease or treatment -bleeding problems or bruises easily.

- As with other vaccines, VAXIGRIP® may not fully protect all persons who are vaccinated.

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

Headache, Muscle pain, Malaise, unusual tiredness or weakness, Injection site reactions: pain, redness, swelling, hardening, itchiness.

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

Headache, unusual crying, irritability, drowsiness, Muscle pain, Diarrhoea, Decrease or loss of appetite, Malaise, fever, shivering, Injection site reactions: pain, redness, swelling, hardening

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

Joint pain, Increased sweating, Injection site reactions: bruising, itchiness, Shivering, fever, malaise, unusual tiredness or weakness.

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

Dizziness, Insomnia, Vomiting, Fever, shivering, Injection site reactions: bruising, itchiness, discomfort, hardening, warmth

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

Swelling of the glands in the neck, armpit or groin, Sleepiness, dizziness, Nausea, diarrhoea
Flu-like syndrome, injection site reaction: discomfort, warmth.

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

Swelling of the glands in the neck, armpit or groin, Diarrhoea, injection site reactions: haemorrhage, warmth, Children/adolescents aged 6 months to 17 years

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

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

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, CTS No.117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400 072

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