VAXIGRIP

2003/2004 STRAINS

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION)

Please read these instructions carefully before vaccination.
Keep this leaflet till completion of the vaccination schedule; you may need to read it again.
You have to follow carefully the advice of your doctor or nurse. If you need further information and advice, contact your doctor or nurse.
Make sure that the whole immunization schedule has been completed.
Otherwise, the protection may be insufficient.

COMPOSITION

The active substance is Influenza virus*, split, inactivated, containing antigens equivalent to :

- A/MOSCOW/10/99 (H_3N_2) like strain used RESVIR-17 derived from A/PANAMA/2007/99 . . . . . 15 micrograms**
- A/NEW CALEDONIA/20/99 (H_1N_1) like strain derived used IVR-116 . 15 micrograms**
- B/HONG KONG/330/2001 like strain used B/SHANGDONG/7/97 . . . . . 15 micrograms** for one 0.5 ml dose

* propagated in eggs
** haemagglutinin

The vaccine complies with the W.H.O. recommendations (northern hemisphere) and E.U. decision for the 2003/2004 year season.

– The other components include the following: buffer solution containing sodium chloride, dihydrate disodium phosphate, monopotassium phosphate, potassium chloride and water for Injections.

MARKETING AUTHORIZATION HOLDER

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1. WHAT IS VAXIGRIP AND WHEN SHOULD IT BE USED?

VAXIGRIP is a suspension for injection in prefilled syringe of 0.5 ml in box of 1 or 20 or in ampoule of 0.5 ml.
This vaccine is recommended for the prevention of influenza, particularly in subjects showing a high risk of associated complications.

2. WHAT INFORMATION IS REQUIRED BEFORE USING VAXIGRIP?

Do not use VAXIGRIP if you or your child have:
– an allergy to the active substances, to any of the excipients, to eggs, to chicken proteins, to neomycin, to formaldehyde, to octoxinol-9.
– a febrile illness or an acute infection (in this case it is preferable to postpone vaccination).

Take special care with VAXIGRIP:
Inform your doctor if you or your child:
– are immunodepressed,
– are allergic or have shown any abnormal reaction following a previous vaccination.
This vaccine should never be administered by the intravascular route.

Pregnancy and lactation:
This vaccine should only be given to pregnant women on medical advice.
The vaccine may be administered to women who are breast feeding.
Ask the advice of your doctor or pharmacist before using any medecine.

Effects on ability to drive and use machinary:
The vaccine is unlikely to produce an effect on the ability to drive vehicles and use machines.

List of excipients with known effect:
Sodium (chloride, dihydrate disodium phosphate form), potassium (chloride, monopotassium phosphate form).

Use with other medicinal products:
VAXIGRIP can be given at the same time as other vaccines by using different injection sites.
The immunological response may be diminished in case of immunosuppressive treatment.
Please inform your doctor or pharmacist of any ongoing treatment, or if any other medicinal products, even if non-prescription, have been taken recently.

3. HOW TO USE VAXIGRIP?

Posology:
Adult and children from 36 months: one 0.5 ml dose.
Children from 6 to 35 months: one 0.25 ml dose.
For children (aged under 8 years) who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Method of administration:
Intramuscular route or deep subcutaneous injection.
The vaccine should be brought to room temperature before use.
Shake before use to obtain a uniform suspension.
Presentation in syringe:
For the use of the 1 dose (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 volume should be injected.
Presentation in ampoule:
For children, when a 0.25 ml half-dose is indicated, take up half the contents of the ampoule with a graduated syringe. The fraction of suspension remaining in the ampoule must not be injected or kept.

Administration rate and time:
Due to the seasonal nature of influenza, it is recommended to perform vaccination against influenza every year, either at the beginning of autumn in temperate countries or at the beginning of the risk period in tropical countries.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

As with all medicinal products, VAXIGRIP may cause undesirable effects:
– local reactions: erythema (redness), swelling, pain, ecchymosis, induration;
– systemic reactions: fever, malaise, shivering, fatigue, headache, sweating, joint and muscular pain;
These reactions usually disappear within 1-2 days without treatment;
– rarely: neuralgia (pain located along the course of the nerve), paraesthesia (a sensory perception disorder where reactions to touch, pain, heat or movement are affected), convulsions and transient thrombocytopenia (an insufficient amount of platelets, which play an important role in blood clotting);
Allergic reactions:
– among these: urticaria, pruritus, erythematus (redness of the skin) rash (cutaneous eruptions), dyspnea, in rare cases leading to shock have been reported;
– vasculitis (inflammation of the blood vessels) with transient renal involvement, in very rare cases;
– rarely, neurological disorders, such as encephalomyelitis, neuritis and Guillain-Barré syndrome have been reported.
Please inform your doctor or pharmacist if you notice any other undesirable effects not mentioned in this leaflet.

5. HOW TO STORE VAXIGRIP?

Keep out of the reach and sight of children.
The product should be stored at + 2°C to + 8°C (in a refrigerator) and protected from light.
Do not freeze.
Do not use after the expiry date indicated on the label or the package.
This vaccine must not be used in the event of colouring or presence of foreign particles.

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