PACKAGE LEAFLET: INFORMATION FOR THE USER

Epaxal®

15219

Suspension for injection in a prefilled syringe
Hepatitis A vaccine (inactivated, virosome)

Read all of this leaflet carefully before you start using this medicine.
– Keep this leaflet. You may need to read it again.
– If you have further questions, ask your doctor or pharmacist.
– This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
– If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this package insert:

1. WHAT EPAXAL IS AND WHAT IT IS USED FOR

Epaxal is a suspension for injection presented in prefilled syringe
Epaxal is used to vaccinate against hepatitis A (infectious jaundice) for adults and children from 1 year of age. The immune system is activated by means of killed hepatitis A virus, bound to virosomes (vaccine particles) consisting of fats (lipids) and proteins. Protection against hepatitis A infection is achieved in 80–97% of vaccinated individuals after 14 days, in 92–100% after 28 days and in 78–100% after 1 year.

2. BEFORE YOU USE EPAXAL

Do not use Epaxal
– If you are hypersensitive to any of the vaccine components
– If you are hypersensitive to eggs, chicken protein, or formaldehyde

If you have an acute infection with a fever, your vaccination should be postponed. Please tell your doctor if you think you have a fever.

Take special care with Epaxal
Before vaccination with Epaxal, please tell your doctor if you have any problems with your immune system, as this may affect the way the vaccine works. If you have had your spleen removed (splenectomy) or your immune system does not work properly (immunodeficiency), you should be given a second dose of vaccine, not earlier than 1 month after the first dose. Your doctor will decide if this is necessary.
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available, in case of a rare allergic reaction following the administration of the vaccine.
Epaxal may contain traces of polymyxin B.
Experience in vaccinating children under the age of 1 and people over 60 is limited.

Using other medicines together with Epaxal
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Epaxal can be administered simultaneously with other vaccines (influenza, typhoid fever, yellow fever, polio, diphtheria, tetanus and meningococcal vaccine A + C) and malaria prophylaxis. However, Epaxal must not be mixed with other injectable vaccines in the same syringe.

Pregnancy and breast-feeding
There is little experience in vaccinating pregnant women with Epaxal. Therefore consult your doctor before being vaccinated with Epaxal if you are pregnant.
It is unknown whether the vaccine is secreted in breastmilk. You should therefore consult with your doctor before being vaccinated with Epaxal when breastfeeding.

Driving and using machines
The vaccine does not usually affect your ability to drive a car or operate machinery. However, please be aware that some side effects such as dizziness and headache may temporarily affect your ability to drive and carry out precision work.

3. HOW TO USE EPAXAL

Adults and children from 1 year of age: 1 dose of 0.5 ml is injected intramuscularly into the upper arm. In patients with blood clotting problems the vaccine may be administered subcutaneously (under the skin) in the upper arm.
Booster vaccination: To ensure long-term protection a second (booster) dose of 0.5 ml is administered. This prolongs the protective effect for at least 30 years for almost all users. For optimal protection this dose should preferably be given 6 to 12 months after the first dose, but

may be given up to 10 years later as was demonstrated in a study involving 26 healthy travelers 24 to 73 years old.
Shake before use.

Epaxal can be interchanged with other inactivated hepatitis A-vaccines for the first or second (booster) dose.

If you receive more Epaxal than you should
An unintentional second dose should not cause any side effects.

4. POSSIBLE SIDE EFFECTS

Like any medicines, Epaxal can cause side effects, although not everybody gets them.
Serious allergic reactions are always a possibility after receiving a vaccine.
These reactions may include difficulty in breathing, blue discolouration of the tongue or lips, low blood pressure (causing dizziness) and collapse. When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery. If any of these symptoms occur after leaving the place where your injection was given, you must consult a doctor immediately.
Very common (more than 1 of 10 persons): headache, fatigue, local pain.
Common (more than 1 of 100, but less than 1 of 10 persons): hardening of the skin, redness, swelling, feeling sick, fever, nausea, loss of appetite, mild and short-lived diarrhoea.
Uncommon (more than 1 of 1000, but less than 1 of 100 persons): dizziness, skin rash/itching, vomiting, arthralgia (joint pain).
Very rare (less than 1 of 10 000 persons): serious allergic reaction (anaphylactic shock).

Occasionally:
- A short-lived and mild rise in levels of liver enzymes was observed on single occasions at the time of vaccination.
- As observed with other vaccines, occasional inflammatory diseases of the central and peripheral nervous system may occur, including a paralysis travelling upward up to breathing paralysis, e.g. Guillain-Barré-Syndrome.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EPAXAL

Store in a refrigerator (2 °C–8 °C). Store in the original package in order to protect from light.
Do not freeze.
Keep out of the reach and sight of children.
Do not use Epaxal after the expiry date which is stated on the label and on the carton after Exp. The expiry date refers to the last day of that month.
Do not use Epaxal if you notice a cloudy appearance or particles in the vaccine.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Epaxal contains
- *The active substance* is inactivated hepatitis A virus (strain RG-SB) >24 IU adsorbed to virosomes (the adjuvant system) which consist of hemaglutinin from the influenza virus (A/Singapore/6/86; H1N1) 10 micrograms, phospholipids 100 micrograms (lecithin 80 micrograms + cephalin 20 micrograms). Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.
- *The other ingredients* are sodium chloride 4.5 mg, water for injections to make 0.5 ml.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially «sodium-free».

What Epaxal looks like and content of the pack
Epaxal consists of a clear, colorless liquid (solution for injection, suspension), distributed in prefilled syringes.
Package sizes: 1x0.5 ml, 10x0.5 ml. Not all pack sizes may be marketed.

Marketing authorization holder:
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