

Package Leaflet: Information for the User

Havrix® Junior Monodose® Vaccine

Hepatitis A Vaccine (Inactivated, adsorbed). 720 ELISA Units/ 0.5 ml Suspension for Injection in a pre-filled syringe

Read all of this leaflet carefully before you start receiving this vaccine 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, nurse or pharmacist.
- This vaccine has been prescribed for your child only. Do not pass it on to others. It may harm them.
- If you get any side-effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Havrix Junior Monodose is and what it is used for

Havrix Junior Monodose is a vaccine containing the inactivated hepatitis A virus. It is used to boost the body’s immune system to stop infection from hepatitis A in children and adolescents from 1 year up to and including 15 years of age.

How Havrix Junior Monodose works

- The virus is not alive so this vaccine cannot cause hepatitis A infection.
- When your child is given Havrix Junior Monodose their body will make antibodies (the body’s natural defence system) against the hepatitis A virus.
- After 2 to 4 weeks, these antibodies will have been produced and will protect your child against hepatitis A infection.
- To ensure long term protection from hepatitis A of up to 40 years, your child should receive a second (booster) vaccination 6 to 12 months after their first dose. As long as the booster is given within 5 years, they should still be fully protected. Once the booster vaccination is given, they are not expected to need an additional dose of Havrix.
- Having this vaccine will only protect against hepatitis A and not against any other type of hepatitis virus or any other illness that can cause hepatitis (inflammation of the liver).

Some general information on hepatitis A infection is given at the end of this leaflet.

2 What you need to know before your child receives Havrix Junior Monodose

Do not take Havrix Junior Monodose:

- if your child is allergic to any of the ingredients of this medicine (listed in section 6)
- if your child is allergic to any other hepatitis A vaccine, any antibiotic, or neomycin; an antibiotic used to treat skin infections
- if your child has a severe infection with a high temperature. The presence of a minor infection such as a cold should not be a problem. Talk to your doctor first.

Do not give your child Havrix if any of the above apply to them. If you are not sure, talk to their doctor, nurse or pharmacist before they have Havrix.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before Havrix Junior Monodose is given if:

- your child already has the hepatitis A virus or is living with someone who has caught the hepatitis A virus recently
- your child is undergoing haemodialysis or has an impaired immune system
- if your child has a condition in which they bleed or bruise easily (e.g. haemophilia).

If any of the above apply to your child, Havrix Junior Monodose can still be given, but your child may not develop enough antibodies after a single injection to protect them against infection.

In these cases, the doctor or nurse may decide that extra doses of Havrix Junior Monodose should be given and may take a blood test to measure the antibody levels in the blood before or after the vaccine is given.

Sometimes, an antibody injection will be given to try and protect your child until the vaccine starts to work. This can be given at the same time as they have the vaccine but will be injected into the opposite arm.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you/your child fainted with a previous injection.

Other medicines and Havrix Junior Monodose

Tell your doctor or nurse if your child is taking, about to be given or has recently taken, any other medicine. Havrix Junior Monodose can be given at the same time as other routine childhood vaccines. These vaccines will be given at different injection sites.

Pregnancy and breastfeeding

If your child is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before receiving this vaccine.

Havrix Junior Monodose contains neomycin, potassium and sodium.

Please tell your doctor if your child has had an allergic reaction to neomycin (antibiotic).

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium- free’. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium- free’.

3 How Havrix Junior Monodose is given

- Havrix Junior Monodose is for use in children and adolescents from 1 year up to and including 15 years of age.
- Adolescents 16 years and above should receive the Havrix Monodose Vaccine
- A single dose of 0.5 ml is injected into the muscle in the upper arm.
- The first dose of vaccine should protect your child from infection with hepatitis A virus within 2 to 3 weeks. Protection should last for up to 5 years.
- To ensure that protection continues for at least 40 years, a second (booster) dose of the vaccine should be given 6 to 12 months after the first injection.
- Having two doses within 1 year is the best way to ensure protection, and that protection will last for at least 40 years.
- If the date for the booster injection is missed but a second dose is given within 5 years of the first dose, protection against hepatitis A infection should still continue for at least 40 years.

4 Possible side effects

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

Allergic reactions (these may occur with up to 1 in 10,000 doses of the vaccine)

If your child has an allergic reaction, see your doctor straight away. The signs may include:

- face swelling
- low blood pressure
- difficulty breathing
- skin going blue
- loss of consciousness.

These signs usually start very soon after the injection has been given to your child. See a doctor straight away if they happen after leaving the clinic.

Other side effects include:

Very Common (these may occur with 1 in 10 doses or more of the vaccine)

- Irritability
- Headache
- Pain and redness at the injection site
- Tiredness

Common (these may occur with up to 1 in 10 doses of the vaccine)

- Loss of appetite
- Drowsiness
- Diarrhoea
- Feeling sick (nausea) and being sick (vomiting)
- Swelling at the injection site
- Hard lump at the injection site
- Feeling generally unwell (malaise)
- High temperature (fever of 37.5°C or greater)

The following information is intended for medical or healthcare professionals only:

As with all vaccinations, appropriate medication (e.g. adrenaline) should be readily available for immediate use in case of anaphylaxis.

When concomitant administration is considered necessary the vaccines must be given at different injection sites.

Havrix Junior Monodose must not be mixed with other vaccines in the same syringe.

Shake well before use to obtain a slightly opaque white suspension, discard if the contents of the syringe appear otherwise.

Stability data indicate that Havrix is stable at temperatures up to 25°C for 3 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

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Uncommon (these may occur with up to 1 in 100 doses of the vaccine)

- Upper respiratory tract infection
- Stuffy, runny nose (rhinitis)
- Dizziness
- Rash
- Muscle pain and stiffness
- Flu-like symptoms such as high temperature, sore throat, runny nose, cough and chills

Rare (these may occur with up to 1 in 1,000 doses of the vaccine)

- Loss of skin sensitivity to pain or touch (hypoesthesia)
- Feeling of pins and needles (paraesthesia)
- Itching
- Chills

After the marketing of Havrix Junior Monodose, the following additional side effects have been reported on a few occasions:

- Serious life threatening allergic reactions (anaphylaxis, anaphylactoid reactions and mimicking serum sickness)
- Fits or seizures
- Inflammation of some blood vessels (vasculitis)
- Swelling of the face, mouth or throat (angioneurotic oedema)
- Erythema multiforme (symptoms are red, often itchy spots, which starts on the limbs and sometimes on the face and the rest of the body)
- Hives
- Joint pain and inflammation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Havrix Junior Monodose

- Keep this medicine out of the sight and reach of children.
- Store between 2°C and 8°C in a refrigerator.
- Do not freeze.
- Store in the original package with this leaflet in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will dispose of vaccine no longer required.

6 Contents of the pack and other information

What Havrix Junior Monodose contains

- The active ingredient is inactivated hepatitis A virus. Each 0.5 ml dose of the vaccine contains 720 ELISA units of hepatitis A viral protein, adsorbed on aluminium hydroxide, hydrated (total 0.25 mg Al³⁺).
- The other ingredients are polysorbate 20, amino acids for injection, disodium phosphate anhydrous, potassium dihydrogen phosphate, sodium chloride, potassium chloride, water for injections and a trace of neomycin sulphate.

What Havrix Junior Monodose looks like and contents of the pack
Havrix Junior Monodose is a cloudy white injectable liquid vaccine in a pre-filled syringe that contains a single 0.5 ml dose. The vaccine is available in a pack of 1 pre-filled syringe.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:
GlaxoSmithKline (Ireland) Ltd.
12 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer:
GlaxoSmithKline Biologicals
89, rue de l’Institut
1330 Rixensart
Belgium

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General information on hepatitis A
Hepatitis A virus causes an infection of the liver. You can catch the virus by eating or drinking contaminated food or water. The virus is present in the bowel movement (motion) of infected people, even when they may have no signs of the infection. You can catch hepatitis A infection in any country but the risk is highest in places and countries where sanitation and food and water hygiene are poor.

After catching the virus, it can be up to 6 weeks before signs of illness are seen. Some people have the virus and never get ill but they can still infect other people during this time.

The main signs of the illness include sickness, yellowing of the skin and eyes (jaundice), fever and headache. These signs are all due to an inflammation of the liver while it is infected with the virus.

Most patients get better, usually after a couple of weeks or months, but a few people may take up to a year to make a full recovery. While recovering, people affected with hepatitis A may be unable to work. They may not be able to drink alcohol and may need to avoid certain foods according to their doctors’ advice. Severe complications are very rare but sometimes the liver stops working and hospital care is needed until the infection gets better.

There are many other types of virus that can cause hepatitis. The signs may be the same as in hepatitis A infection but the viruses are not always caught through food and drink.

