

Package Leaflet: Information for the User

Havrix[®] Monodose[®] Vaccine

Hepatitis A Vaccine (Inactivated, adsorbed). 1440 ELISA Units/1 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 you 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.

What is in this leaflet:

- 1 What Havrix Monodose is and what it is used for
- 2 What you need to know before you receive Havrix Monodose
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1 What Havrix Monodose is and what it is used for

Havrix Monodose is a vaccine containing inactivated hepatitis A virus. It is used to boost the body's immune system to stop infection from hepatitis A in adults and adolescents (16 years of age and above).

How Havrix Monodose works

- The virus is not alive so this vaccine cannot cause hepatitis A infection.
- When you are given Havrix Monodose vaccine your 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 you against hepatitis A infection.
- To ensure long term protection from hepatitis A of up to 40 years, you should receive a second (booster) vaccination 6 to 12 months after your first dose. As long as you receive the booster within 5 years, you should still be fully protected. Once you have had your booster vaccination, you 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 you receive Havrix Monodose

Do not take Havrix Monodose:

- if you are allergic to any of the ingredients of this medicine (listed in section 6)
- if you are allergic to any other hepatitis A injection, any antibiotic, or neomycin; an antibiotic used to treat skin infections

- if you have 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 have Havrix if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist.

Warnings and precautions

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

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

If any of the above apply to you Havrix Monodose can still be given, but you may not develop enough antibody after a single injection to protect you against infection.

In these cases, the doctor or nurse may decide that extra doses of Havrix 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 injection of antibody will be needed to try to protect you until the vaccine starts to work. This can be given at the same time as 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 Monodose

Tell your doctor or nurse if you are taking, about to take or have recently taken, any other medicine. Other vaccines can be given at the same time as Havrix Monodose. These vaccines will be given at different injection sites.

Pregnancy and breastfeeding

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

Driving and using machines

Havrix Monodose should not affect your ability to drive or operate machinery.

Havrix Monodose contains neomycin, potassium and sodium.

Please tell your doctor if you have 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 Monodose is given

- Havrix Monodose is for use in adults and adolescents (16 years of age and above).
- Havrix Monodose is not recommended in children and adolescents under 16 years of age. Children and adolescents under 16 years should receive the Havrix Junior Monodose Vaccine.
- Havrix Monodose (1 ml) is injected into the muscle in the upper arm.

- The first dose of vaccine should protect you from infection with hepatitis A virus within 2 to 3 weeks after the injection. Protection should last for at least 1 year.
- 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 make sure that you are protected, and that protection will last for up to 40 years without interruption.
- 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 up to 40 years.
- If a second dose is not given within 5 years of the first dose, the doctor may decide that vaccination should start again, with 2 doses of vaccine within 1 year.

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 you have an allergic reaction, see your doctor straight away. The signs may include:

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

These signs usually start very soon after the injection has been given to you. 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)

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 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 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 Monodose contains

- The active ingredient is inactivated hepatitis A virus. Each 1 ml dose of the vaccine contains 1440 ELISA units of hepatitis A viral protein, adsorbed on aluminium hydroxide, hydrated (total 0.5 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 Monodose looks like and contents of the pack

Havrix Monodose is a cloudy white injectable liquid vaccine in a pre-filled syringe that contains a single 1 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.

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 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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