Package Leaflet: Information for the User

Havrix Junior Monodose Vaccine

Suspension for injection in a pre-filled syringe
Hepatitis A (inactivated) vaccine (adsorbed)

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child. Do not pass it on to others. It may harm them.
- If your child gets any side effects talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

Havrix Junior Monodose is a vaccine containing the hepatitis A virus. It is used to boost the body's immune system to help protect against hepatitis A infection 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, your child should receive a second (booster) vaccination 6 to 12 months after their first dose. As long as the booster is given within 3 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

Havrix Junior Monodose should not be given if:

- your child is allergic (hypersensitive) to any of the ingredients of Havrix (listed in section 6)
- your child is allergic to any other hepatitis A vaccine or neomycin, an antibiotic that may be present in very small amounts
- your child is aged 16 years or over, as another product, Havrix Monodose is recommended for this age group

- your child has a high temperature (fever). 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
Check with the doctor, nurse or pharmacist before Havrix Junior Monodose is given if:
- your child is on dialysis for a kidney problem
- your child already has the hepatitis A virus or is living with someone who has caught the hepatitis A virus recently
- your child has any problem with the way their body fights disease (immunosuppression).

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 (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if your child fainted with a previous injection.

Check with the doctor, nurse or pharmacist before Havrix Junior Monodose is given if your child has a bleeding problem or bruises easily.

Other medicines or vaccines 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 most other routine childhood vaccines. These vaccines will be given at different injection sites.

In particular talk to your doctor if:
- your child is taking a medicine that can affect the way in which their body fights disease. Your child should not have Havrix if they are taking this type of medicine

Pregnancy and breast-feeding
- Women who are pregnant may sometimes be vaccinated. If they are over 16, they should not receive the Havrix Junior Monodose, but should have the Havrix Monodose vaccine instead.
- Talk to their doctor or nurse if the person to be vaccinated thinks they are, or that they might be, pregnant.
- Talk to their doctor or nurse if the person to be vaccinated is breast-feeding. It is sometimes possible to have the vaccine if they are breast-feeding.

Havrix Junior Monodose contains neomycin, potassium, sodium and phenylalanine
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 1 ml dose, i.e. essentially ‘potassium-free’.
This medicine contains less than 1 mmol sodium (23 mg) per 1 ml dose, that is to say essentially ‘sodium-free’.

This vaccine contains 83 micrograms of phenylalanine in each dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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 Havrix Monodose.
- A single dose of 0.5 ml is injected into the muscle in the upper arm or thigh.
- The vaccine should never be given into the buttock.
- The vaccine should never be given into a vein.
- The first dose of vaccine should protect your child from infection with hepatitis A virus within 2 to 4 weeks. Protection should last for at least 1 year.
- The best way to ensure that protection continues for at least 10 years is to receive a second (booster) dose of the vaccine. This should be given 6 to 12 months after the first injection.
- If the date for the booster injection is missed but a second dose is given within 3 years of the first dose, protection against hepatitis A infection should still continue for at least 10 years.
- If a second dose is not given within 3 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 medicines, this vaccine can have side effects, although not everybody gets them.

Allergic reactions (these may occur with up to 1 in 10,000 doses of the vaccine)
See your doctor straight away, if your child has an allergic reaction. The signs may include:
- local or widespread rashes that may be itchy or blistering
- swelling of the eyes and face
- difficulty in breathing or swallowing
- a sudden drop in blood pressure
- a very fast heart beat
- 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 more than 1 in 10 doses of the vaccine):
- Irritability
- Pain and redness at the injection site

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Loss of appetite
- Headache
- Drowsiness
- Nausea
- Swelling or hard lump at the injection site
- Generally feeling unwell

- Fever

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Diarrhoea and vomiting
- Rash

Rare (these may occur with up to 1 in 1000 doses of the vaccine):
- Abnormal sensation such as of burning, prickling, tickling or tingling, pins and needles, loss of feeling or numbness
- Itching
- Fatigue
- Chills

Not known: frequency cannot be estimated from the available data
- Fits or seizures
- Inflammation of the blood vessels, often with skin rash
- Hives, red, often itchy spots which starts on the limbs and sometimes on the face and the rest of the body.
- Joint pain

Occasionally tests for liver function can become abnormal for a short time. Extremely rarely there may be reactions involving the nerves. You should tell your doctor immediately if your child has problems moving their arms or legs or difficulty with walking and moving about.

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

If your child gets 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Havrix Junior Monodose

- Keep 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 after the expiry date which is stated on the label and carton.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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.

- The other ingredients are polysorbate 20, amino acids for injection (containing phenylalanine), disodium phosphate, monopotassium phosphate, sodium chloride, potassium chloride and water for injections.

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 packs of 1 or 10 pre-filled syringes.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder:
SmithKline Beecham Ltd,
980 Great West Road, Brentford,
Middlesex
TW8 9GS

Manufacturer:
GlaxoSmithKline Biologicals s.a., Rixensart, Belgium.

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:
Product name **Havrix Junior Monodose**
Reference number 10592/0080

This is a service provided by the Royal National Institute of Blind People.
This leaflet was last revised in August 2021

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.