

Patient Information Leaflet

Havrix® Junior Monodose® (Hepatitis A) Vaccine

Please read all of this leaflet before this vaccine is given.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

In this leaflet:

1. What Havrix Junior Monodose is and what it is used for
2. Before having Havrix Junior Monodose
3. How Havrix Junior Monodose is given
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The name of this vaccine is Havrix Junior Monodose (hepatitis A) Vaccine

- The active ingredient in Havrix Junior Monodose is inactivated hepatitis A virus.
- Other ingredients are aluminium hydroxide, 2-phenoxyethanol, polysorbate 20, amino acids for injection, disodium phosphate, monopotassium phosphate, sodium chloride, potassium chloride and water for injections.

The Product Licence holder is SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. The manufacturer is GlaxoSmithKline Biologicals s.a., Rixensart, Belgium.

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

Havrix Junior Monodose is a vaccine containing hepatitis A virus. The virus is not alive so this vaccine cannot cause hepatitis A infection. When a person is given Havrix Junior Monodose vaccine their body will make antibodies (the body's natural defence system) against the hepatitis A virus. These antibodies will protect the person against hepatitis A infection from about 2 to 4 weeks after the injection. To ensure long term protection, the child/teenager should receive a booster vaccination 6 to 12 months after their primary dose. However, as long as the child/teenager receives the booster within 3 years, they should still be fully protected. Once the child/teenager has had their booster vaccination, they are not expected to need an additional dose of Havrix.

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

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).

Havrix Junior Monodose is a cloudy white injectable liquid vaccine in a prefilled syringe that contains a single 0.5 ml dose. Each 0.5 ml dose of the vaccine contains 720 ELISA units of hepatitis A viral protein. The vaccine is available in packs of 1 or 10 prefilled syringes.

2. Before having Havrix Junior Monodose

Havrix Junior Monodose should not be given if the answer is "Yes" to any of the following:

- Has the child/teenager ever had an allergic reaction to any vaccine intended to protect against hepatitis A infection?
- Do you think the child/teenager may be allergic to Havrix Junior Monodose or any of the ingredients listed previously?
- Has the child/teenager ever had a severe allergic reaction to neomycin or any other antibiotic?
- Is the person to be vaccinated aged 16 years or over? A higher dose vaccine is recommended for people who are aged 16 years and over.

If you are not sure about the answers to any of these questions, ask your doctor or nurse.

Havrix Junior Monodose may have to be delayed if the answer to the following is "Yes":

- Does the child/teenager have a severe fever (high temperature)?

Take special care with Havrix Junior Monodose

If the answer is "Yes" to any of the following questions for the person who is going to receive the vaccine, talk to your doctor or nurse before the vaccine is given. Havrix Junior Monodose can still be given, but the person to be vaccinated may not develop enough antibody after a single injection to protect them against infection.

Sometimes, an injection of antibody will be needed to try to protect the person 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.

- Is the person to be vaccinated on dialysis for kidney disease?
- Does the person to be vaccinated have a poor immune system (for example, have they been told that their immunity to infection is low or are they taking steroid tablets or other medicines that can lower their immunity to infections)?

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.

Is it possible or has the person to be vaccinated already been told that they may have already been infected with hepatitis A virus but are not yet showing signs of the infection? For example, does the person to be vaccinated live with someone who has got hepatitis A recently? If so, the vaccine may not be able to prevent them showing signs of the illness.

In this case, the doctor or nurse may decide to give an injection of human antibodies to help prevent them from having the illness.

Pregnancy

Women who are pregnant may sometimes be vaccinated. Talk to your doctor or nurse if the person to be vaccinated thinks they are, or that they might be, pregnant.

Breast-feeding

Women who are breast-feeding may sometimes be vaccinated. Talk to your doctor or nurse if the person to be vaccinated is breast-feeding.

Taking/using other medicines

Please tell your doctor or nurse if the person to be vaccinated is taking, or has recently taken, any other medicine. Other vaccines can be given at the same time as Havrix Junior Monodose. These vaccines will be given at different injection sites.

3. How Havrix Junior Monodose is given

Havrix Junior Monodose (0.5 ml) is injected into the muscle in the upper arm.

The first dose of vaccine should protect people with normal immunity from infection with hepatitis A virus within 2-4 weeks after the injection. Protection should last for at least 1 year.

To ensure that protection continues for at least 10 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 the person is protected, and that protection will last for at least 10 years without interruption.

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.

The vaccine is for people aged 1 to 15 years. Persons who are aged 16 years and over should be given the higher strength vaccine (Havrix Monodose).

4. Possible side effects

Like all medicines, including all vaccines, Havrix Junior Monodose can have side effects.

Very rarely some people can have severe allergic reactions after having the vaccine, these usually happen very soon after the injection. These can involve difficulty breathing, tightness in the throat, rapidly spreading rashes, dizziness, loss of consciousness because of very low blood pressure, and a very fast heart beat. These severe reactions need urgent medical help.

Therefore, the person who has received Havrix Junior Monodose may be asked to stay in the surgery or vaccination area for a short time after the vaccine has been given to check that an immediate allergic reaction does not occur. Please tell your doctor or nurse if the person who has had Havrix Junior Monodose develops any of these or any other worrying effects after leaving the clinic, because it is urgent to get medical help.

Very rarely some people have had a fit (convulsion) after having the vaccine. If this happens tell your doctor immediately.

Extremely rarely there may be reactions involving the nerves. You should tell your doctor immediately if any of the following are noticed: pins and needles, loss of feeling or numbness, problems moving their arms or legs or difficulty with walking and moving about.

The commonest side effects are a mild soreness, redness or hardness at the site of the injection. This should last only a few days.

Less commonly the person who has had the vaccine may feel generally unwell, or have a rash, fever, tiredness, headache, sickness, diarrhoea or loss of appetite.

Occasionally tests for liver function can become abnormal for a short time.

If any side effects not mentioned in this leaflet are noticed, please tell your doctor or nurse.

5. Storing Havrix Junior Monodose

Your doctor or nurse will usually have supplies of Havrix Junior Monodose and will have stored it correctly.

However, if you have been given a prescription for Havrix Junior Monodose to collect from your pharmacist (chemist), you should store the vaccine carefully in its outer container, in a refrigerator between 2°C and 8°C. The vaccine should not be frozen. The doctor or nurse will check that the expiry date on the outer package label has not passed.

Keep Havrix Junior Monodose out of the reach and sight of children.

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Disease 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 stools (motions) 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 six 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 a headache, fever, sickness and jaundice (yellowing of the skin and eyes). 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 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 very special 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. Havrix Monodose can help to protect you against infection with the hepatitis A virus only.