



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 Monodose is and what it is used for
2. Before having Havrix Monodose
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The name of this vaccine is Havrix Monodose (hepatitis A) Vaccine

- The active ingredient in Havrix 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, water for injections and a trace of neomycin B sulphate.

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 Monodose is and what it is used for?

Havrix Monodose is a vaccine containing hepatitis A virus. 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 (your body's natural defence system) against the hepatitis A virus. These antibodies will protect you against hepatitis A infection from about 2 to 4 weeks after the injection. To ensure long term protection, you should receive a booster vaccination 6 to 12 months after your primary dose. However, as long as you receive the booster within 5 years, you should still be fully protected. Once you have had your booster vaccination, you should remain protected for up to 25 years and 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 you 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 Monodose is a cloudy white injectable liquid vaccine in a prefilled syringe that contains a single 1 ml dose. Each 1 ml dose of the vaccine contains 1440 ELISA units of hepatitis A viral protein. The vaccine is available in packs of 1 or 10 prefilled syringes.

2. Before having Havrix Monodose

Do not have Havrix Monodose if the answer is "Yes" to any of the following:

- Have you ever had an allergic reaction to any vaccine intended to protect against hepatitis A infection?
- Do you think you may be allergic to Havrix Monodose or any of the ingredients listed above?
- Have you ever had a severe allergic reaction to neomycin or any other antibiotic?
- Are you aged 15 years or younger? A lower dose vaccine is available for people who are 15 years and younger.

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

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

- Do you have a severe fever (high temperature)?

Take special care with Havrix Monodose

If you answer "Yes" to any of the following questions, talk to your doctor or nurse before the vaccine is given. You can still have Havrix Monodose, but you may not develop enough antibody after a single injection to protect you against infection. Sometimes, you may also need to have an injection of antibody to try to protect you until the vaccine starts to work. This can be given at the same time as you have the vaccine but will be injected into the opposite arm.

- Are you on dialysis for kidney disease?
- Do you have a poor immune system (for example, have you been told that your immunity to infections is low or are you taking steroid tablets or other medicines that can lower your immunity to infections)?

In these cases, your 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 your blood before or after you have the vaccine.

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

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

Pregnancy

Women who are pregnant may sometimes be vaccinated. Talk to your doctor or nurse if you are, or if you think that you might be, pregnant.

Breast-feeding

Women who are breast feeding may sometimes be vaccinated. Talk to your doctor or nurse if you are breast feeding.

Driving and using machines

Having this vaccine should not affect your ability to drive or operate machinery.

Taking/using other medicines

Please tell your doctor or nurse if you are taking, or have recently taken, any other medicine. You can be given other vaccines at the same time as Havrix Monodose. You will be given these vaccines at different injection sites.

3. How Havrix Monodose is given

Havrix Monodose (1ml) is injected into the muscle in your 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 you are protected for up to 25 years you should have a second (booster) dose of the vaccine 6 to 12 months after the first injection. Having 2 doses within 1 year is the best way to make sure that you are protected, and that protection will last for up to 25 years without interruption.

If you miss the date for your booster injection but you have a second dose within 5 years of the first dose, you should still be protected from hepatitis A infection for up to 25 years.

If you do not manage to have a second dose within 5 years of the first dose, your doctor may decide that you should start again and have 2 doses of the vaccine within 1 year.

The vaccine is for people aged 16 years and over. Children (1 to 15 years of age) should be given Havrix Junior Monodose.

4. Possible side effects

Like all medicines, including all vaccines, Havrix 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, you 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 you develop any of these or any other worrying effects after leaving the clinic, 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 you notice any of the following: pins and needles, loss of feeling or numbness, problems moving your 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 you 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.

Very rarely some people have joint or muscle pain following vaccination. If you notice any side effects not mentioned in this leaflet, please tell your doctor or nurse.

5. Storing Havrix Monodose

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

However, if you have been given a prescription for Havrix 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 has not passed.

Keep Havrix 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. Whilst 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 other viruses are not always caught through food and drink. Havrix Monodose can help to protect you against infection with the hepatitis A virus only.