**Package Leaflet: Information for the User**

# Havrix Monodose Vaccine

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

**Read all of this leaflet carefully before you receive 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. Do not pass it on to others. It may harm them.
- If you get 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 Monodose is and what it is used for

Havrix Monodose is a vaccine containing hepatitis A virus. It is used to boost the body's immune system to help protect against hepatitis A infection 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, 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

**Havrix Monodose should not be given if:**

- you are allergic (hypersensitive) to any of the ingredients of Havrix (listed in section 6)
- you are allergic (hypersensitive) to any other hepatitis A injection or neomycin, an antibiotic that may be present in very small amounts
- you are between ages 1-15 years, as another product, Havrix Junior Monodose is recommended for this age group

- you have 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 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**

Check with your doctor, nurse or pharmacist before Havrix Monodose is given if:

- you are on dialysis for a kidney problem
- you already have the hepatitis A virus or are living with someone who has caught the hepatitis A virus recently
- you have any problem with the way your body fights disease (immunosuppression).

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

Check with the doctor, nurse or pharmacist before Havrix Monodose is given if you have a bleeding problem or bruise easily.

**Other medicines or vaccines 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 breast-feeding**

- Women who are pregnant may sometimes be vaccinated.
- Talk to your doctor or nurse if you think you are, or might be pregnant.
- Talk to your doctor or nurse if you are breast-feeding. It is sometimes possible to have the vaccine when you are breast-feeding.

**Driving and using machines**

Havrix Monodose should not affect your ability to drive or operate machinery. However, some of the effects mentioned under Section 4 “Possible side effects” may temporarily affect the ability to drive or use machines.

**Havrix Monodose contains neomycin, potassium, sodium and phenylalanine.**

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 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 166 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 Monodose is given

- Havrix Monodose is for use in adults and adolescents 16 years of age and above.
- Children (1 to 15 years of age) should be given Havrix Junior Monodose.
- Havrix Monodose (1 ml) is injected into the muscle in the upper arm.
- 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 you from infection with hepatitis A virus within 2 to 4 weeks after the injection. Protection should last for at least 1 year.
- The best way to ensure that protection continues for at least 40 years is to receive a second (booster) dose of the vaccine. This should be given 6 to 12 months after the first injection.
- 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 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 you have 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 you. 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):

- Headache
- Pain and redness at the injection site
- Fatigue

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

- Loss of appetite
- Stomach upset e.g. diarrhoea and 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):

- Upper respiratory tract infection, runny or blocked nose
- Dizziness
- Vomiting
- Aching muscles, muscular stiffness not caused by exercise
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

**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
- 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 you have problems moving your 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 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 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 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 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.
- 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 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 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 Monodose Vaccine**
Reference number 10592/0037

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.