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GSK (logo)

Package leaflet: Information for the user

Havrix Monodose Vaccine suspension for injection in pre-filled syringe

Hepatitis A (inactivated) vaccine (adsorbed)

Read all of this leaflet carefully before you or your child 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, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adolescents as of 16 years of age so you may be reading it for your child.

What is in this leaflet:

1 What Havrix Monodose is and what it is used for

What Havrix Monodose is used for

Havrix Monodose is a vaccine used to protect adolescents from 16 years of age and adults against the infection caused by the hepatitis A virus.

What hepatitis A is

- Hepatitis A is a disease of the liver caused by hepatitis A virus.
- The hepatitis A virus can be passed from person to person, or by contact with contaminated water, food and drinks.
- Symptoms of hepatitis A range from mild to severe and can include fever, malaise, loss of appetite, diarrhoea, nausea, abdominal discomfort, dark-coloured urine and jaundice (a yellowing of the eyes and skin). Most people recover completely but sometimes the disease can be severe requiring hospitalisation and rarely can lead to acute liver failure.

How Havrix Monodose works

- Havrix Monodose helps your body to produce its own protection (antibodies) against the virus. These antibodies help protect you against the disease.
- As with all vaccines, Havrix Monodose may not fully protect all individuals who are vaccinated.

2 What you need to know before you receive Havrix Monodose

Havrix Monodose should not be given if:
- you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6) or to neomycin or to formaldehyde,
- you have already had an allergic reaction to any hepatitis A vaccine.

Signs of an allergic reaction may include itchy skin rash, being short of breath and swelling of the face or tongue.

Havrix Monodose should not be given if any of the above applies. If you are not sure, talk to your doctor, pharmacist or nurse before Havrix Monodose is given.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you receive Havrix Monodose if:

- you have a severe infection with a high temperature (fever). The vaccine can be given after you have recovered. A minor infection such as a cold should not be a problem but talk to your doctor first,
- you have a weakened immune system due to diseases and/or treatments. Your doctor will see whether more injections are needed,
- you have bleeding problems or bruise easily.

Fainting can occur before or after any needle injection. Therefore tell the doctor, pharmacist or nurse if you fainted with a previous injection.

Other medicines and Havrix Monodose
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other vaccines or medicines.

Havrix Monodose can be administered at the same time as some other vaccines and immunoglobulins. A different injection site should be used for each injection.

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

Driving and using machines
Havrix Monodose has no or negligible influence on the ability to drive and use machines.

Havrix Monodose contains phenylalanine, polysorbate 20, sodium and potassium.
This vaccine contains 0.166 mg 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.

This vaccine contains 0.050 mg of polysorbate 20 in each dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially “potassium-free”.

3 How Havrix Monodose is given

How the vaccine is given
- The doctor or nurse will give Havrix Monodose as an injection into a muscle. It is usually into the upper arm.
- Havrix Monodose may exceptionally be injected under the skin if you suffer from thrombocytopaenia or if you have serious bleeding disorders.

How much is given
- You will receive 1 dose of Havrix Monodose (1ml suspension) on a date agreed with your doctor or nurse.
- A second dose (booster) is recommended to be administered between 6 and 12 months after the first dose, but can be given for up to five years after the first dose, in order to ensure long term protection.

If you receive more Havrix Monodose than you should
Overdose is very unlikely because the vaccine is provided in a single dose vial or syringe and is administered by a doctor or nurse. Few cases of accidental administration were reported and the reported side effects were similar to those reported with normal vaccine administration (listed in section 4).

If you think you have missed a dose of Havrix Monodose
Contact your doctor who will decide if a dose is required and when to give it.

4 Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- allergic reactions – the signs can 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 and loss of consciousness.
  These reactions may occur before leaving the doctor's surgery.

Tell your doctor straight away if you notice any of the serious side effects listed above.

Side effects that occurred during clinical trials with Havrix Monodose were as follows:

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

- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- generally feeling unwell
- fever of 37.5°C or more
- swelling or hard lump at the injection site

Uncommon (these may occur with up to 1 in 100 doses of vaccine):
- upper respiratory tract infection
- blocked or runny nose
- dizziness
- 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 1 000 doses of the vaccine):
- decrease or loss of skin sensitivity to pain or touch
- pins and needles
- itching
- chills

Side effects that occurred after Havrix Monodose was put on the market, were as follows:
- fits or convulsions
- inflammation of the blood vessels leading to narrowing or blockage (vasculitis)
- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing
- hives, red, often itchy spots which starts on the limbs and sometimes on the face and the rest of the body
- joint pain

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, Website: www.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 vaccine out of the sight and reach of children.
- Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C)
- Do not freeze.
- Store in the original package in order to protect from light.
  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 substance is hepatitis A virus (inactivated) adsorbed on aluminium hydroxide. Each 1 ml dose of the vaccine contains 1440 ELISA Units of hepatitis A virus.

- The other ingredients are amino acids for injections (containing phenylalanine), disodium phosphate, monopotassium phosphate, polysorbate 20 (E432), potassium chloride, sodium chloride, water for injections (see section 2).

What Havrix Monodose looks like and contents of the pack

Suspension for injection.
Havrix Monodose is a turbid injectable liquid.
Havrix Monodose is available in 1-dose pre-filled syringe with or without needles, pack sizes of 1, 5, 10 and 25.

Not all pack sizes may be marketed.

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

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Havrix (Hepatitis A-Impfstoff) 1440 EI.U/1 ml
Belgium, Germany, Hungary, Luxembourg, Netherlands	Havrix 1440
Bulgaria	HAVRIX 1440 suspension for injection (Adult dose) Хаврикс 1440 инжекционна суспензия (доза за възрастни)
Cyprus	Havrix Adults 1440
Czechia, Denmark, Finland, Iceland, Norway	Havrix
Estonia	Havrix, 1440 ELISA ühikut/ml süstesuspensioon
France	HAVRIX 1440 U/1ml ADULTES

Greece, Italy	HAVRIX
Ireland	Havrix Monodose
Latvia	Havrix 1440 ELISA vienības/ml suspensija injekcijām
Lithuania	Havrix 1440 ELISA vienetų/ml injekcinė suspensija
Malta	Havrix Monodose Vaccine
Poland	HAVRIX ADULT
Portugal	Havrix 1440 Adulto
Romania	HAVRIX ADULT 1440 VACCIN HEPATITIC A
Slovak Republic	HAVRIX 1440 Dosis adulta
Slovenia	HAVRIX 1440
Spain	Havrix 1440 Adulto suspensión inyectable en jeringa precargada
Sweden	Havrix 1440 ELISA U/1 ml

This leaflet was last revised in March 2025

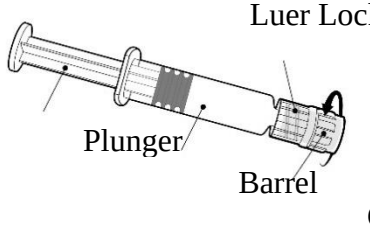
Other sources of information

Detailed information on this medicine is available on the website of Health Products Regulatory Authority (HPRA).

The following information is intended for healthcare professionals only:

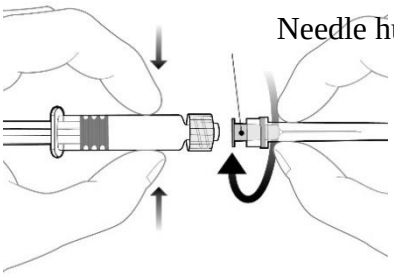
Havrix Monodose is a turbid liquid suspension. During storage, a fine white deposit with a colourless supernatant may form.
The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. Before use of Havrix Monodose, the pre-filled syringe should be well shaken to obtain a slightly opaque white suspension. Discard the vaccine if the content appears otherwise.

<u>Instructions for the pre-filled syringe</u>



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.