

GSK (logo)

Package leaflet: Information for the user

Havrix Junior Monodose Vaccine

Hepatitis A Vaccine (Inactivated, adsorbed). 720 ELISA Units/ 0.5 ml
Suspension for Injection in a pre-filled syringe

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 children and adolescents so you may be reading it for your child.

What is in this leaflet

- 1 What Havrix Junior Monodose is and what it is used for
- 2 What you need to know before you receive Havrix Junior Monodose
- 3 How Havrix Junior Monodose is given
- 4 Possible side effects
- 5 How to store Havrix Junior Monodose
- 6 Contents of the pack and other information

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

What Havrix Junior Monodose is used for

Havrix Junior Monodose is a vaccine used to protect children and adolescents aged 1 year to 15 years included against the infection caused by the hepatitis A virus.

Havrix Junior Monodose can also be given to adolescents aged 16 to 18 years included, if necessary.

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 Junior Monodose works

- Havrix Junior 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 Junior Monodose may not fully protect all individuals who are vaccinated.

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 Junior Monodose

Havrix Junior 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 Junior 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 Junior Monodose is given.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you receive Havrix Junior 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 Junior Monodose

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

Driving and using machines

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

Havrix Junior Monodose contains phenylalanine, sodium and potassium.

This vaccine contains 0.083 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 less than 1 mmol sodium (23 mg) and less than 1 mmol potassium (39 mg) per dose, that is to say essentially "sodium and potassium free".

3 How Havrix Junior Monodose is given

How the vaccine is given

- The doctor or nurse will give Havrix Junior Monodose as an injection into a muscle. It is usually into the upper arm for children and adolescents.
- In young children, the injection may be given into the thigh muscle.
- Havrix Junior 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 Junior Monodose (0.5 ml 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 Junior 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 Junior 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 Junior Monodose were as follows:

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 (feeling sick)
- generally feeling unwell
- fever of 37.5°C or more
- swelling at the injection site

Uncommon (these may occur with up to 1 in 100 doses of vaccine):

- blocked or runny nose
- vomiting (being sick)
- diarrhoea
- rash
- hard lump at the injection site

Side effects that occurred after Havrix Junior 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 Junior Monodose

- Keep this medicine 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 this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will dispose of vaccine no longer required.

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 (total 0.25 mg Al³⁺).
- The other ingredients are polysorbate 20, amino acids for injection (containing phenylalanine), disodium phosphate anhydrous, potassium dihydrogen phosphate, sodium chloride, potassium chloride, water for injections and less than 10ng trace of neomycin sulphate.

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. Upon storage, a fine white deposit with a clear colourless supernatant may be observed.

The vaccine is available in a pack of 1 pre-filled syringe.

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:

Denmark, Estonia, Finland, Greece, Iceland, Italy	HAVRIX
Norway, Sweden	Havrix
Austria, Belgium, Luxembourg	HAVRIX JUNIOR 720
Bulgaria	ХАВРИКС 720 инжектионна суспензия (доза за деца)
Cyprus, Malta, Netherlands	HAVRIX JUNIOR
Czech Republic, Ireland	HAVRIX JUNIOR MONODOSE
France	HAVRIX NOURRISSONS ET ENFANTS 720 U/0,5 ml
Germany	Havrix 720 Kinder
Hungary, Poland	HAVRIX 720 JUNIOR
Latvia	HAVRIX 720 ELISA units/0,5 ml vienības/0,5 ml suspensija injekcijām
Lithuania	Havrix 720 ELISA vienetų/0,5 ml injekcinė suspensija
Portugal	HAVRIX 720 Júnior
Romania	HAVRIX JUNIOR 720 suspensie injectabilă
Slovak Republic	HAVRIX 720 Junior monodose
Slovenia	HAVRIX 720 ELISA enot suspenzija za injiciranje za otroke
Spain	HAVRIX 720 suspensión inyectable en jeringa precargada

This leaflet was last revised in August 2024

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.

The following information is intended for medical or healthcare professionals only:

As with all vaccinations, appropriate medication (e.g. adrenaline) should be readily available for immediate use in case of anaphylaxis.

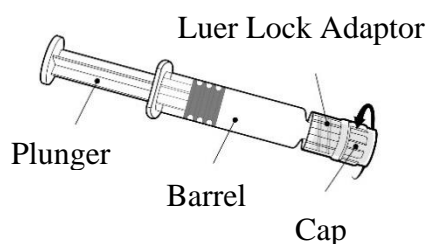
When concomitant administration is considered necessary the vaccines must be given at different injection sites.

Havrix Junior Monodose must not be mixed with other vaccines in the same syringe.

Shake well before use to obtain a slightly opaque white suspension, discard if the contents of the syringe appear otherwise.

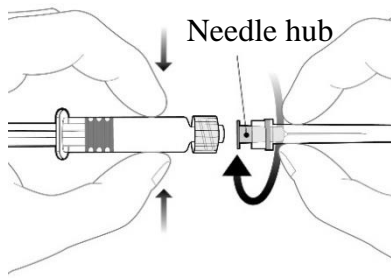
Stability data indicate that Havrix is stable at temperatures up to 25°C for 3 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Instructions for the pre-filled syringe



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

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