

GSK (logo)

Package leaflet: Information for the user

Havrix Junior 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 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.

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, polysorbate 20, 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 0.025 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 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 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 Junior Monodose contains

- The active substance is hepatitis A virus (inactivated) adsorbed on aluminium hydroxide. Each 0.5 ml dose of the vaccine contains 720 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 Junior Monodose looks like and contents of the pack

Suspension for injection.

Havrix Junior Monodose is a turbid injectable liquid.

Havrix Junior 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) Junior 720 EI.U/0,5 ml
Belgium, Cyprus, Luxembourg	Havrix Junior 720
Bulgaria	HAVRIX 720 suspension for injection (Junior monodose) Х а в р и к с 720 и н ж е к ц и о н н а с у с п е н з и я (д о з а з а д е ц а)
Czechia	Havrix Junior monodose
Denmark, Finland, Iceland, Norway	Havrix
Estonia	Havrix, 720 ELISA ühikut/ml süstesuspensioon
France	HAVRIX NOURRISSONS ET ENFANTS 720 U/0,5 ml
Germany	Havrix 720 Kinder
Greece, Italy	HAVRIX
Hungary	Havrix 720 Junior

Ireland	Havrix Junior Monodose
Latvia	Havrix 720 ELISA vienības/0,5 ml suspensija injekcijām
Lithuania	Havrix 720 ELISA vienetai/0,5 ml injekcinė suspensija
Malta	Havrix Junior Monodose Vaccine
Netherlands	Havrix Junior
Poland	HAVRIX 720 JUNIOR
Portugal	Havrix 720 Júnior
Romania	HAVRIX JUNIOR 720 VACCIN HEPATITIC A
Slovak Republic	HAVRIX 720 Junior monodose
Slovenia	HAVRIX 720 PAEDIATRIC
Spain	Havrix 720 Junior suspensión inyectable en jeringa precargada
Sweden	Havrix 720 ELISA U/0,5 ml

This leaflet was last revised in March 2025

Other sources of information

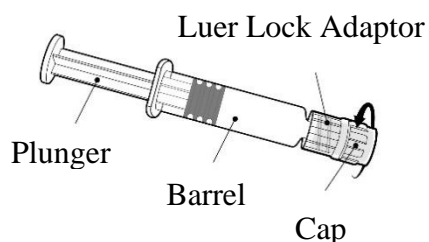
Detailed information on this medicine is available on the website of Health Products Regulatory Authority (HPRA).

The following information is intended for healthcare professionals only:

Havrix Junior 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 Junior Monodose, the pre-filled syringe should be well shaken to obtain a slightly opaque white suspension. Discard the vaccine if the content appears otherwise.

Instructions for the pre-filled syringe



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

Unscrew the syringe cap by twisting it anticlockwise.

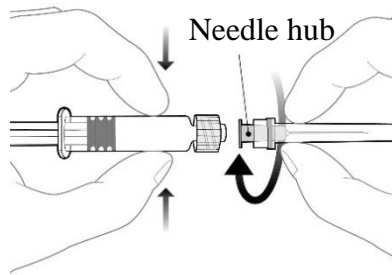
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Market: IE

Agency Approval Date

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Text Issue and Draft No.: Issue No.: 9 Draft No.: 1



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.

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