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 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, nurse or pharmacist.

This vaccine has been prescribed for your child. Do not pass it on to others. It may harm others.

If you get any side-effects, talk to your doctor or pharmacist or nurse.

This includes any possible side-effects not listed in this leaflet. See section 4.

What is this leaflet about?
1. What Havrix Junior Monodose is and what is it used for
2. What you need to know before your child receives Havrix Junior Monodose
3. How Havrix Junior Monodose is given
4. Possible side effects
5. What to do if you think there is an allergic reaction
6. Contents of the pack and other information

What Havrix Junior Monodose is and what is it used for
Havrix Junior Monodose is a vaccine containing the inactivated hepatitis A virus. It is used to boost the body's immune system to stop infection from hepatitis A in children and adolescents from 1 year up to and including 15 years of age.

How Havrix Junior Monodose works
• The virus is not alive so this vaccine cannot cause hepatitis A infection.
• When your child is given Havrix Junior Monodose, their 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 your child against hepatitis A infection.
• To ensure long-term protection from hepatitis A up to 40 years, your child should receive a second (booster) vaccination 6 to 12 months after their first dose.

• The first dose of vaccine should protect your child from infection with hepatitis A virus within 2 to 3 weeks. Protection should last for up to 5 years.
• To ensure that protection continues for at least 40 years, a second (booster) dose of the vaccine should be given 6 to 12 months after the first injection.
• Having two doses within 1 year is the best way to ensure protection, and that protection will last for at least 40 years. If the date for the booster injection is missed but a second dose is given within 5 years of the first dose, protection against hepatitis A infection should still continue for at least 40 years.

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

Possible side effects include:
• Common
  • Feeling sick (nausea) and being sick (vomiting)
  • Diarrhoea
  • Loss of appetite
  • Hard lump at the injection site
  • Irritability
  • Pain and redness at the injection site
  • Swellings (bumps or lumps) in the skin
  • Hard swelling after injection
  • Throat pain
  • Headache
  • Sore throat
  • Feeling tired
  • Skin rash (redness or spots)
  • Muscle aches or pains
  • Feeling sick (nausea) and being sick (vomiting)
  • Feeling unusually hot or cold
  • Swelling at the injection site
  • Hard lump at the injection site
  • Feeling generally unwell (malaise)
  • High temperature (fever of 37.5°C or greater)

• Rare
  • Loss of appetite
  • Drowsiness
  • Shivering
  • Feeling sick (nausea) and being sick (vomiting)
  • Swelling at the injection site
  • Hard lump at the injection site
  • Feeling generally unwell (malaise)
  • High temperature (fever of 37.5°C or greater)

Sometimes, an antibody injection will be given to try and protect your child until the vaccine starts to work. This can be given at the same time as they have the vaccine but will be injected into the opposite arm.

Vaccination can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child was vaccinated with a previous injection.

Other medicines and Havrix Junior Monodose
Tell your doctor or nurse if your child is taking, about to be given or has recently taken, any other medicines. Havrix Junior Monodose can be given at the same time as other routine childhood vaccines. These vaccines will be given at different injection sites.

Pregnancy and breastfeeding
If your child is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before receiving this vaccine.

Havrix Junior Monodose contains neomycin, potassium and sodium
Please tell your doctor if your child has had an allergic reaction to neomycin (antibiotic).

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium-free’. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

What you need to know before your child receives Havrix Junior Monodose
If any of the above apply to your child, Havrix Junior Monodose must not be mixed with other vaccines in the same syringe.

• If your child already has the hepatitis A virus or is living with someone who has caught the hepatitis A virus recently your child is undergoing haemodialysis or has an impaired immune system
• If your child has a condition in which they bleed or bruise easily (e.g. haemophilia)

In these cases, the doctor or nurse may decide that extra doses of Havrix Junior 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.

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Uncommon (these may occur with up to 1 in 100 doses of the vaccine)
• Upper respiratory tract infection
• Stuffy, runny nose (rhinitis)
• Dizziness
• Rash
• Muscle pain and stiffness
• 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)
• Loss of skin sensitivity to pain or touch (hypoesthesia)
• Feeling of pins and needles (paraesthesia)
• Itching
• Chills

After the marketing of Havrix Junior Monodose, the following additional side effects have been reported on a few occasions:
• Serious (life threatening allergic reactions (anaphylaxis, anaphylactoid reactions and mimicking serum sickness)
• Fits or seizures
• Inflammation of some blood vessels (vasculitis)
• Swelling of the face, mouth or throat (angioneurotic oedema)
• Asthma
• Joint pain and inflammation

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 report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

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.

Vaccines
Additional Information Panel
Folded dimensions: 210x25mm
2D Pharmacode value: N/A