

Summary Public Assessment Report

Avaxim Junior hepatitis A virus, inactivated antigen

SE/H/1880/02/DC

Summary Public Assessment Report

Avaxim Junior
hepatitis A virus, inactivated antigen

Suspension for injection, pre-filled syringe, 80 E

This is a summary of the public assessment report (PAR) for Avaxim Junior. It explains how Avaxim Junior was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Avaxim Junior.

For practical information about using Avaxim Junior, patients should read the package leaflet or contact their doctor or pharmacist.

What is Avaxim Junior and what is it used for?

Avaxim Junior is a vaccine that helps to protect against hepatitis A infection.

- It is used in children aged from 1 year up and including 15 years of age.

Hepatitis A infection is caused by a virus that attacks the liver.

- It may be caught from food or drink that contains the virus.
- Symptoms include yellowing of the skin and eyes (jaundice) and feeling generally unwell.

How does Avaxim Junior work?

Avaxim Junior is a vaccine. Vaccines are used to protect against infectious diseases.

- When an injection of Avaxim Junior is given, the body's natural defenses produce protection (antibodies) against hepatitis A infection.
- This vaccine protects against hepatitis A - but it cannot cause a hepatitis A infection.
- This vaccine will not protect against other viruses that attack the liver (such as hepatitis B, hepatitis C or hepatitis E viruses).

How is Avaxim Junior used?

The pharmaceutical form of Avaxim Junior is suspension for injection, pre-filled syringe for intramuscular use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Avaxim Junior have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Avaxim Junior is effective in the active immunisation against infection caused by

hepatitis A virus in children from 1 year up and including 15 years of age.

What are the possible side effects of Avaxim Junior?

For the full list of all side effects reported with Avaxim Junior, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Avaxim Junior approved?

It was noted that Avaxim Junior induced protective level of antibodies against infection caused by hepatitis A virus in children from 1 year up and including 15 years of age (open label single arm studies). The effectiveness study in Belarus demonstrated that Avaxim Junior was stopping successfully Hep A epidemic among children. Therefore, the Medical Products Agency in Sweden decided that Avaxim Junior's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Avaxim Junior?

A risk management plan has been developed to ensure that Avaxim Junior is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Avaxim Junior, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Avaxim Junior

The full PAR for Avaxim Junior can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Avaxim Junior, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-03.