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Use of Havrix (*hepatitis A virus (inactivated, adsorbed), suspension for injection*) to be harmonised in the EU

On 27 June 2024, the European Medicines Agency (EMA) completed a review of Havrix and associated names and recommended changes to the prescribing information in order to harmonise the way the medicine is used in the EU.

What is Havrix?

Havrix is a vaccine used to protect adults and children against infection caused by the hepatitis A virus. The vaccine contains the inactivated (killed) hepatitis A virus and cannot cause the disease. Different formulations of Havrix are available for use in children (Havrix 720 junior) and adults (Havrix 1440 adults).

Havrix is authorised in all EU Member States with the exception of Croatia, plus Norway and Iceland.

The company that markets Havrix is GlaxoSmithKline Biologicals group of companies.

Why was Havrix reviewed?

Havrix has been authorised in the EU via national procedures. This has led to inconsistency across Member States in the way the medicine can be used, as seen in the differences in the prescribing information (summary of product characteristics (SmPC), labelling and package leaflet) in the countries where the medicine is marketed.

On 21 August 2023, GlaxoSmithKline Biologicals group of companies referred the matter to EMA in order to harmonise the product information for Havrix in the EU.

What is the outcome of the review?

After considering the available data on the use of Havrix, the Agency concluded that the SmPC should be harmonised. The areas harmonised include:

4.1 Therapeutic indications

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Havrix can be used in adults, adolescents and children aged 1 year and older to protect against infection caused by the hepatitis A virus.

- Havrix 720 junior is used in children aged from 1 to 15 years and can also be used for adolescents aged up to, and including, 18 years;
- Havrix 1440 adults is used in adults and adolescents aged 16 years and older.

Havrix should be used according to official recommendations.

4.2 Posology and method of administration

For primary vaccination, adults, adolescents and children should receive a single dose of the vaccine, injected into the muscle of their upper arm. For young children, the vaccine should be given in the front, outer part of the thigh if the muscle in their upper arm is not sufficiently developed.

Primary vaccination should be given at least two, and preferably four, weeks before the patient is expected to come into contact with the virus.

A booster dose of Havrix is recommended and should be given between 6 and 12 months after primary vaccination but can be given up to 5 years afterwards.

Havrix should not be injected in the gluteal (buttocks) region and should under no circumstances be injected intravascularly (into a blood vessel). The vaccine should also not be injected subcutaneously (under the skin) and intradermally (into the skin)

Havrix can be used interchangeably (substituted) with other inactivated hepatitis A vaccines.

Section 4.4, special warnings and precautions for use, includes information to outline that, exceptionally and if in accordance with official recommendations, Havrix may be given subcutaneously in patients with thrombocytopenia (low levels of platelets, components that help the blood to clot) or a bleeding disorder.

4.3 Contraindications

Havrix must not be used in patients who are allergic to the active substance in the vaccine or any of its other ingredients. In addition, it must not be used by patients who are allergic to neomycin (an antibiotic) or formaldehyde (a preservative used in some medicines and vaccines) and patients who have had an allergic reaction to any hepatitis A vaccine.

Other changes

Other harmonised sections of the SmPC include section 4.4 (special warnings and precautions for use), section 4.5 (interaction with other medicinal products and other forms of interaction), section 4.6 (fertility, pregnancy and lactation), 4.7 (effects on ability to drive and use machines), section 4.8 (undesirable effects), section 4.9 (overdose), section 5.1 (pharmacodynamic properties), section 5.2 (pharmacokinetic properties) and section 5.3 (pre-clinical safety data).

The package leaflet will be updated accordingly.

The amended information for doctors and patients is available here.

More about the procedure

The review of Havrix was initiated on 14 September 2023 at the request of the marketing authorisation holder, GlaxoSmithKline Biologicals group of companies, under Article 30 of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision to implement these changes on 26 August 2024.