Product Information as approved by the CHMP on 27 June 2024, pending endorsement by the European Commission

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

{Havrix and associated names (see Annex I) strength pharmaceutical form}
[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[To be completed nationally]

3. PHARMACEUTICAL FORM

[To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Havrix is indicated for active immunisation against hepatitis A virus (HAV) infection in children, adolescents and adults:

- Havrix 720 Junior: individuals aged 1 to 15 years included. It can also be used for adolescents aged up to and including 18 years.
- Havrix 1440 Adult: individuals aged 16 years and above.

The use of this vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

Posology

Primary vaccination

Havrix 720 Junior (0.5 ml suspension)
A single dose of Havrix 720 Junior is used for immunisation of children and adolescents aged 1 to 15 years included.
It could also be acceptable to use a single dose of Havrix 720 Junior for immunisation of adolescents aged 16 to 18 years included, if necessary (see section 5.1).

Havrix 1440 Adult (1.0 ml suspension)
A single dose of Havrix 1440 Adult is used for immunisation of adults and adolescents 16 years of age and above.

For optimal antibody response, primary immunisation should be given at least 2, preferably 4 weeks prior to expected exposure to hepatitis A virus (see section 5.1).

Booster vaccination

After primary vaccination with either Havrix 720 Junior or Havrix 1440 Adult, a booster dose is recommended in order to ensure long-term protection. This booster dose should preferably be given between 6 months and 12 months after primary vaccination, however, it can be administered for up to 5 years after primary vaccination (see section 5.1).

Interchangeability

Havrix is interchangeable with other inactivated hepatitis A vaccines.

Elderly population

There are limited data with inactivated hepatitis A vaccines in elderly individuals.

Paediatric population

The safety and efficacy of Havrix 720 Junior in children less than 1 year of age have not been established. Currently available data are described in section 5.1 but no recommendation on a posology can be made.

Method of administration

Havrix 720 Junior (0.5 ml suspension) should be administered intramuscularly in the deltoid region in children and adolescents and in the antero-lateral part of the thigh in young children if the deltoid muscle is not yet sufficiently developed (see section 6.6).

Havrix 1440 Adult (1.0 ml suspension) should be administered intramuscularly in the deltoid region in adolescents and adults (see section 6.6).

With any administration site, firm pressure should be applied to the injection site (without rubbing) for at least two minutes post injection.

Havrix should not be administered in the gluteal region.

Havrix should under no circumstances be administered intravascularly.

Havrix should not be administered subcutaneously or intradermally (see section 4.4).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to neomycin or to formaldehyde.
Hypersensitivity after previous administration of any hepatitis A vaccine.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

General recommendations

As with other vaccines, the administration of Havrix should be postponed in individuals suffering from acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
Close observation for at least 15 minutes is recommended following vaccination.

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such

as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Havrix will not prevent hepatitis infection caused by other agents such as hepatitis B virus, hepatitis C virus, hepatitis E virus or other pathogens known to infect the liver.

Individuals may be in the incubation period of a hepatitis A infection at the time of vaccination. It is not known whether Havrix will prevent hepatitis A in such cases.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

The immune response to Havrix could be impaired in immunocompromised individuals. Those individuals always require administration of a 2-dose vaccination schedule.

Havrix should be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to them. Exceptionally and if in accordance with official recommendations, the vaccine may be administered subcutaneously to these individuals. However, this route of administration may lead to suboptimal anti-HAV antibody response. With both routes of administration, firm pressure should be applied to the injection site (without rubbing) for at least two minutes post injection.

Excipients

Havrix 720 Junior contains 83 micrograms phenylalanine in each dose.
Havrix 1440 Adult contains 166 micrograms phenylalanine in each dose.
Phenylalanine may be harmful for individuals with phenylketonuria (PKU).

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially “potassium-free”.

4.5 Interaction with other medicinal products and other forms of interaction

Since Havrix is an inactivated vaccine, its concomitant use with other inactivated vaccines is unlikely to result in interference with the immune responses.

Havrix can be given concomitantly with any of the following vaccines: typhoid, yellow fever, cholera (injectable), tetanus or with monovalent and combination vaccines comprised of measles, mumps, rubella and varicella.

Havrix can be administered simultaneously with immunoglobulins. Seroconversion rates remain unchanged, although antibody titres may be lower than after Havrix administration alone.

When concomitant administration of injectable vaccines or of immunoglobulins is considered necessary, the products must be given with different syringes and needles and at different injection sites.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of data on pregnant women (between 300-1 000 pregnancy outcomes) indicates no malformative or foeto/ neonatal toxicity.
Animal studies do not indicate reproductive toxicity (see section 5.3).
The use of Havrix may be considered during pregnancy, if necessary.

Breast-feeding

It is unknown whether Havrix is excreted in human milk. Although the risk can be considered as negligible, Havrix should be used during breast-feeding only when clearly needed.

Fertility

There are no data on the effects of Havrix on human fertility. Effects on human fertility have not been evaluated in animal studies.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

The most common local undesirable effects, both in children and adults, are pain and redness at the injection site.
The most common general undesirable effects are, in children, irritability and in adults, fatigue and headache.

Tabulated list of adverse reactions

Clinical trial data

The safety profile presented in the table below is based on data from 5 331 subjects including 1 664 children (up to 18 years of age) vaccinated with Havrix 720 Junior and 3 667 adults (from 16 years of age) vaccinated with Havrix 1440 Adult,in clinical trials (total vaccinated cohort). A total of 3 193 doses of Havrix 720 Junior and 7 131 doses of Havrix 1440 Adult were administered during clinical trials. A total number of 3 971 doses of Havrix 1440 Adult were administered concomitantly with Engerix-B in 2 064 adult subjects.

Adverse reactions reported are listed according to the following frequency:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1 000 to <1/100)
Rare (≥1/10 000 to <1/1 000)
Very rare (<1/10 000)

Within each frequency grouping the adverse reactions are presented in the order of decreasing seriousness.

System organ class	**Frequency**	**Adverse reactions**
Infections and infestations	Uncommon	Upper respiratory tract infection [(2)], rhinitis
Metabolism and nutrition disorders	Common	Appetite lost
Psychiatric disorders	Very common	Irritability [(1)]
Nervous system disorders	Very common	Headache [(3)]
	Common	Drowsiness [(1)]
	Uncommon	Dizziness [(2)]
	Rare	Hypoaesthesia [(2)], paraesthesia [(2)]

Gastrointestinal disorders	Common	Gastrointestinal signs and symptoms [2] [5], diarrhoea [4], nausea
	Uncommon	Vomiting
Skin and subcutaneous tissue disorders	Uncommon	Rash [1]
	Rare	Pruritus [2]
Musculoskeletal and connective tissue disorders	Uncommon	Myalgia [2], musculoskeletal stiffness [2]
General disorders and administration site conditions	Very common	Injection site pain and injection site erythema, fatigue [2]
	Common	Malaise, fever (≥37.5° C), injection site reaction (such as injection site induration[4] and injection site swelling)
	Uncommon	Influenza like illness [2]
	Rare	Chills [2]

[1] only with Havrix 720 Junior
[2] only with Havrix 1440 Adult
[3] reported with a frequency of common with Havrix 720 Junior
[4] reported with a frequency of uncommon with Havrix 720 Junior
[5] gastrointestinal = including nausea, vomiting, diarrhoea (symptoms not separately recorded)

Post-marketing data

The following additional adverse reactions have been identified during post-marketing surveillance with both Havrix 720 Junior and Havrix 1440 Adult.

System organ class	**Frequency**	**Adverse reactions**
Immune system disorders	Rare	Anaphylaxis, allergic reactions including anaphylactoid reactions and serum sickness-like reaction
Nervous system disorders	Rare	Convulsions
Vascular disorders	Rare	Vasculitis
Skin and subcutaneous tissue disorders	Rare	Angioneurotic oedema, erythema multiforme, urticaria
Musculoskeletal and connective tissue disorders	Rare	Arthralgia

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Cases of overdose have been reported during post-marketing surveillance. Adverse events reported following overdosage were similar to those reported with normal vaccine administration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hepatitis A vaccines, ATC code J07BC02

Mechanism of action

Havrix confers immunisation against HAV by stimulating specific immune responses evidenced by the induction of antibodies against HAV.

Pharmacodynamic effects

The immunogenicity of Havrix was assessed in 39 studies in more than 6 000 subjects including adults, adolescents and children.

Immune response

In clinical studies, 99% of vaccinees seroconverted 30 days after the primary dose.

In a subset of adult clinical studies where the kinetics of the immune response were studied, early and rapid seroconversion was demonstrated following administration of the primary dose of Havrix 1440 Adult in 79% of vaccinees at day 13, 86.3% at day 15, 95.2% at day 17 and 100% at day 19.

Limited data are available from clinical studies involving infants below 1 year of age. In those studies, Havrix 720 Junior was administered at 2, 4 and 6 months of age or as 2 doses given 6 months apart from 4 to 6 months of age. Humoral antibodies against HAV were detected in most vaccinees one month following the administration of the last vaccine dose; infants with pre-existing antibodies of maternal origin had a markedly diminished response compared to initially seronegative infants (see section 4.2).

In clinical studies involving children 1-18 years of age, specific humoral antibodies against HAV were detected in more than 93% of vaccinees at day 15 and 99 % of vaccinees one month following administration of the primary dose of Havrix 720 Junior.

In clinical studies in which adolescents 16-18 years of age received Havrix 720 Junior, humoral antibodies against HAV were detected in more than 94% of vaccinees at day 15 and in 100% of vaccinees one month following administration of the primary dose of Havrix 720 Junior.

Immune response in patients with chronic liver disease

In two clinical trials, 300 subjects with chronic liver disease (chronic hepatitis B, chronic hepatitis C or other) were vaccinated with 2 doses of Havrix 1440 Adult given at an interval of 6 months. The vaccine provided detectable antibody titres in at least 95% of the vaccinees, one month after the second dose.

Persistence of the immune response

In order to ensure long-term protection, a booster dose should be given between 6 and 12 months after the primary dose of Havrix 720 Junior or Havrix 1440 Adult. In clinical trials, all vaccinees were seropositive one month after the booster dose.
However, if the booster dose has not been given between 6 and 12 months after the primary dose, the administration of this booster dose can be given up to 5 years after the primary dose. In a comparative trial in adults, a booster dose given up to 5 years after the primary dose has been shown to induce similar antibody levels as a booster dose given between 6 and 12 months after the primary dose.

Long-term persistence of hepatitis A antibody titres following 2 doses of Havrix 1440 Adult given 6 to 12 months apart has been evaluated. In two clinical trials in adults, 96.7% and 100% of vaccinees were still seropositive at year 17.5 (study HAV-112) and year 17 (study HAV-123), respectively.
Data available up to 17 and 17.5 years allow prediction that at least 95% and 90% of subjects will remain seropositive (≥15 mIU/ml) 30 and 40 years after vaccination, respectively.
Current data do not support the need for further booster vaccination among immunocompetent subjects after a 2-dose vaccination course.

It can be expected that the duration of protection in children following 2 doses of Havrix 720 Junior is comparable with the above predicted duration of protection in adults.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

No special hazard for humans was observed from protection studies in chimpanzees.
A reproductive toxicity study in rats has been conducted with another hepatitis A and hepatitis B combination vaccine (HAB). This combination vaccine has the same active ingredient as Havrix. Rats were administered intramuscularly with $1/5^{th}$ of the human dose of HAB (200 µL intramuscular injection containing 144 Elisa units of Hepatitis A virus (inactivated), 4 micrograms Hepatitis B surface antigen and 0.09 mg aluminium as aluminium salts). It was not associated with maternal toxicity and no adverse or vaccine-related effects on pre- or post-natal development of the foetuses/pups were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

This vaccine should not be mixed with other vaccines.
[To be completed nationally]

6.3 Shelf life

[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

6.5 Nature and contents of container

[To be completed nationally]

6.6 Special precautions for disposal and other handling

[To be completed nationally]

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

PRE-FILLED SYRINGE, PACK OF 1, 10

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

Hepatitis A (inactivated) vaccine (adsorbed)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

[To be completed nationally]

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

[To be completed nationally]

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

[To be completed nationally]

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

[To be completed nationally]

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

[To be completed nationally]

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

VIALS, PACK OF 10, 100

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

Hepatitis A (inactivated) vaccine (adsorbed)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

[To be completed nationally]

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

[To be completed nationally]

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

[To be completed nationally]

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

[To be completed nationally]

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

[To be completed nationally]

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED SYRINGE

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

[See Annex I - To be completed nationally]

HAV vaccine
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

[To be completed nationally]

4. BATCH NUMBER

[To be completed nationally]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

[To be completed nationally]

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

[See Annex I - To be completed nationally]

HAV vaccine
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

[To be completed nationally]

4. BATCH NUMBER

[To be completed nationally]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

[To be completed nationally]

6. OTHER

PACKAGE LEAFLET

Package leaflet: Information for the user

Havrix 720 Junior, suspension for injection
[See Annex I - To be completed nationally]

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 720 Junior is and what it is used for

What Havrix 720 Junior is used for
Havrix 720 Junior 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 720 Junior 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 720 Junior works
- Havrix 720 Junior 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 720 Junior may not fully protect all individuals who are vaccinated.

2. What you need to know before you receive Havrix 720 Junior

Havrix 720 Junior 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 720 Junior should not be given if any of the above applies. If you are not sure, talk to your doctor, pharmacist or nurse before Havrix 720 Junior is given.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you receive Havrix 720 Junior 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 720 Junior
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other vaccines or medicines.

Havrix 720 Junior 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 720 Junior.

Driving and using machines
Havrix 720 Junior has no or negligible influence on the ability to drive and use machines.

Havrix 720 Junior 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 720 Junior is given

How the vaccine is given
- The doctor or nurse will give Havrix 720 Junior 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 720 Junior 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 720 Junior (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 720 Junior 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 720 Junior
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 720 Junior 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 occured after Havrix 720 Junior 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Havrix 720 Junior

[To be completed nationally]

6. Contents of the pack and other information

What Havrix 720 Junior contains

[To be completed nationally]

What Havrix 720 Junior looks like and contents of the pack

[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[See Annex I - To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

[See Annex I - To be completed nationally]

This leaflet was last revised in

[To be completed nationally]

Other sources of information

Detailed information on this medicine is available on the website of

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The following information is intended for healthcare professionals only:

[To be completed nationally]

Package leaflet: Information for the user

Havrix 1440 Adult, suspension for injection
[See Annex I - To be completed nationally]

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 adolescents as of 16 years of age so you may be reading it for your child.

What is in this leaflet

1. What Havrix 1440 Adult is and what it is used for

What Havrix 1440 Adult is used for
Havrix 1440 Adult is a vaccine used to protect adolescents from 16 years of age and adults against the infection caused by the hepatitis A virus.

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 1440 Adult works
- Havrix 1440 Adult 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 1440 Adult may not fully protect all individuals who are vaccinated.

2. What you need to know before you receive Havrix 1440 Adult

Havrix 1440 Adult 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 1440 Adult should not be given if any of the above applies. If you are not sure, talk to your doctor, pharmacist or nurse before Havrix 1440 Adult is given.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you receive Havrix 1440 Adult 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 1440 Adult
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other vaccines or medicines.

Havrix 1440 Adult 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 1440 Adult.

Driving and using machines
Havrix 1440 Adult has no or negligible influence on the ability to drive and use machines.

Havrix 1440 Adult contains phenylalanine, sodium and potassium
This vaccine contains 0.166 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 1440 Adult is given

How the vaccine is given
- The doctor or nurse will give Havrix 1440 Adult as an injection into a muscle. It is usually into the upper arm.
- Havrix 1440 Adult 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 1440 Adult (1ml 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 1440 Adult 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 1440 Adult
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 1440 Adult were as follows:

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- headache
- pain and redness at the injection site
- fatigue

Common (these may occur with up to 1 in 10 doses of the vaccine):
- loss of appetite
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- generally feeling unwell
- fever of 37.5°C or more
- swelling or hard lump at the injection site

Uncommon (these may occur with up to 1 in 100 doses of vaccine):
- upper respiratory tract infection
- blocked or runny nose
- dizziness
- aching muscles, muscular stiffness not caused by exercise
- 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):
- decrease or loss of skin sensitivity to pain or touch
- pins and needles
- itching
- chills

Side effects that occurred after Havrix 1440 Adult 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Havrix 1440 Adult

[To be completed nationally]

6. Contents of the pack and other information

What Havrix 1440 Adult contains

[To be completed nationally]

What Havrix 1440 Adult looks like and contents of the pack

[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[See Annex I - To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

[See Annex I - To be completed nationally]

This leaflet was last revised in

[To be completed nationally]

Other sources of information

Detailed information on this medicine is available on the website of

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The following information is intended for healthcare professionals only:

[To be completed nationally]