Package leaflet: Information for the user

Twinrix Paediatric, Suspension for injection in pre-filled syringe
Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)

Read all of this leaflet carefully before you start/ your child starts 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 or your pharmacist.
- This vaccine has been prescribed for you/ your child only. Do not pass it on to others.
- If you get / your child gets any side effects, talk to your doctor or pharmacist. 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 and children so you may be reading it for your child.

What is in this leaflet

1. What Twinrix Paediatric is and what it is used for

Twinrix Paediatric is a vaccine used in infants, children and adolescents from 1 year up to and including 15 years to prevent two diseases: hepatitis A and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Hepatitis A:** Hepatitis A is an infectious disease, which can affect the liver. This disease is caused by the hepatitis A virus. The hepatitis A virus can be passed from person to person in food and drink, or by swimming in water contaminated by sewage. Symptoms of hepatitis A begin 3 to 6 weeks after coming into contact with the virus. These consist of nausea (feeling sick), fever and aches and pains. After a few days the whites of eyes and skin may become yellowish (jaundice). The severity and type of symptoms can vary. Young children may not develop jaundice. Most people recover completely but the illness is usually severe enough to keep people off work for about a month.

- **Hepatitis B:** Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

2. What you need to know before you receive Twinrix Paediatric

Twinrix Paediatric should not be given if
- you are allergic to:
  - the active substances, or any of the ingredients of this medicine (listed in section 6).
  - neomycin.

  Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

- you have previously had an allergic reaction to any vaccine against hepatitis A and hepatitis B diseases.
- you have a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

Warnings and precautions
Talk to you doctor or pharmacist before you receive Twinrix Paediatric if:
- you have experienced any health problems after previous administration of a vaccine.
- you have a poor immune system due to illness or drug treatment.
- you have a bleeding problem or bruise/ bruises easily.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

Other medicines and Twinrix Paediatric
Twinrix Paediatric can be given with a Human Papillomavirus (HPV) vaccine at a separate injection site (another part of your body, e.g. the other arm) during the same visit.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.
It is not known if Twinrix Paediatric passes into breast milk, however the vaccine is not expected to cause problems in breast-fed babies.

Twinrix Paediatric contains neomycin and sodium
Please tell your doctor if you have had an allergic reaction to neomycin (antibiotic).
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Twinrix Paediatric is given

You will receive a total of three injections over 6 months. Each injection is given on a separate visit. The first dose will be given on an elected date. The remaining two doses will be given one month, and six months after the first dose.

- First dose: at an elected date
- Second dose: 1 month later
- Third dose: 6 months after the first dose

Your doctor will advise on the possible need for extra doses, and future booster dosing.

If you miss a scheduled injection, talk to your doctor and arrange another visit.

Make sure you finish the complete vaccination course of three injections. If not, you may not be fully protected against the diseases.

The doctor will give Twinrix Paediatric as an injection into your upper arm muscle or into the thigh muscle of your child.

The vaccine should never be given into a vein.

If you have any further questions on the use of this vaccine, ask your doctor or pharmacist.

4. Possible side effects

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

Side effects that may occur are the following:

Side effects occured during clinical studies or routine use of the vaccine or with individual hepatitis A and hepatitis B vaccines or with the adult formulation of Twinrix.

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

Common (these may occur with up to 1 in 10 doses of the vaccine): drowsiness, headache, nausea, loss of appetite, swelling or bruising at the injection site, generally feeling unwell, tiredness, fever equal to or greater than 37.5°C, irritability.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine): diarrhoea, vomiting, stomach pain, rash, aching muscles, upper respiratory tract infection.

Rare (these may occur with up to 1 in 1,000 doses of the vaccine): swollen glands in the neck armpit or groin (lymphadenopathy), dizziness, loss of skin sensitivity to pain or touch (hypoaesthesia), feeling of pins and needles (paraesthesia), hives, itching, joint pain, low blood pressure, flu-like symptoms such as high temperature, sore throat, runny nose, cough and chills.

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine): reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia), purple or red brown spots visible through the skin (thrombocytopenic purpura), swelling or infection of the brain (encephalitis), degenerative disease of the brain (encephalopathy), inflammation of nerves (neuritis), numbness or weakness of the arms and legs (neuropathy), paralysis, fits or seizures, swelling of the face, mouth or throat (angioneurotic oedema), purple or reddish-purple bumps on the skin (lichen planus), serious skin rashes (erythema multiforme), joint swelling, muscular weakness, infection around the brain which may give severe headache with stiff neck and sensitivity to light (meningitis), inflammation of some blood vessels (vasculitis), abnormal laboratory liver test results, multiple sclerosis, swelling of the spinal cord (myelitis), drooping eyelid and sagging muscles on one side of the face (facial palsy), a temporary inflammation of the nerves, causing pain, weakness and paralysis in the extremities and often progressing to the chest and face (Guillain-Barré syndrome),a disease of the nerves of the eye (optic neuritis), immediate injection site pain, stinging and burning feeling.
Serious allergic reactions (anaphylaxis, anaphylactoid reactions and mimicking serum sickness) may also occur very rarely (with up to 1 in 10,000 doses of the vaccine).
Signs of serious allergic reactions may be 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. Such reactions may occur before leaving the doctor's surgery. However, if you get any of these symptoms you should contact a doctor urgently.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Twinrix Paediatric

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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).
Store in the original package in order to protect from light.
Do not freeze. Freezing destroys the vaccine.

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 Twinrix Paediatric contains

- The active substances are:

Hepatitis A virus (inactivated)[1,2]	360 ELISA Units
Hepatitis B surface antigen[3,4]	10 micrograms

[1]Produced on human diploid (MRC-5) cells
[2]Adsorbed on aluminium hydroxide, hydrated 0.025 milligrams Al^{3+}
[3]Produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology
[4]Adsorbed on aluminium phosphate 0.2 milligrams Al^{3+}

- The other ingredients in Twinrix Paediatric are: sodium chloride, water for injections.

What Twinrix Paediatric looks like and contents of the pack

Suspension for injection in pre-filled syringe.

Twinrix Paediatric is a white, slightly milky liquid.

Twinrix Paediatric is available in 1-dose pre-filled syringe with or without separate needles, pack sizes of 1, 10 and 50.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline UK Limited
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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Twinrix Paediatric, Suspension for injection in pre-filled syringe**

Reference numbers 19494/0266

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in March 2023

(GlaxoSmithKline logo)

The following information is intended for healthcare professionals only:

Upon storage, a fine white deposit with a clear colourless layer above may be observed.

The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance.

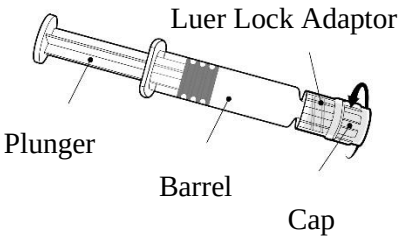
Re-suspension of the vaccine to obtain a uniform hazy white suspension

The vaccine should be re-suspended following the steps below.

1. Hold the syringe upright in a closed hand.
2. Shake the syringe by tipping it upside down and back again.
3. Repeat this action vigorously for at least 15 seconds.
4. Inspect the vaccine again:
    a. If the vaccine appears as a uniform hazy white suspension, it is ready to use – the appearance should not be clear.
    b. If the vaccine still does not appear as a uniform hazy white suspension - tip upside down and back again for at least another 15 seconds - then inspect again.

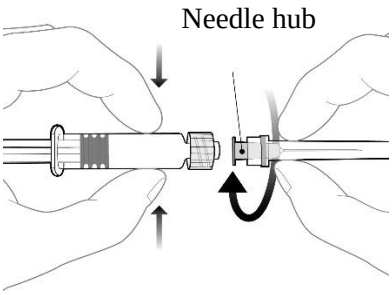
The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, do not administer the vaccine.

<u>Instructions for the pre-filled syringe after re-suspension</u>



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

Unscrew the syringe cap by twisting it anticlockwise.



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.