

TWINRIX & TWINRIX JUNIOR

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor, nurse or pharmacist.

1. Why are my child or I being given TWINRIX?

TWINRIX is used to prevent hepatitis A and hepatitis B infection. In this leaflet, TWINRIX refers to the use of both TWINRIX for adults and TWINRIX JUNIOR for children. TWINRIX is a combination vaccine containing the ingredients inactivated hepatitis A virus and Hepatitis B surface antigen.

For more information, see Section [1. Why are my child or I being given TWINRIX?](#) in the full CMI.

2. What should I know before my child or I are given TWINRIX?

Do not receive this vaccine if you or your child have ever had an allergic reaction to TWINRIX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before my child or I are given TWINRIX?](#) in the full CMI.

3. What if my child or I are taking other medicines?

Some medicines may interfere with TWINRIX and affect how it works.

A list of these medicines is in Section [3. What if my child or I are taking other medicines?](#) in the full CMI.

4. How is TWINRIX given?

- TWINRIX will be injected into the upper arm muscle in adults and older children, and into the thigh muscle in infants. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).
- TWINRIX is generally given as a total of three doses over 6 months. Each dose 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.

More instructions can be found in Section [4. How is TWINRIX given?](#) in the full CMI.

5. What should I know while my child or I are being given TWINRIX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse or pharmacist you visit that you are receiving TWINRIX.• Tell your doctor if you or your child do not feel well during or after a dose of TWINRIX.• Keep your follow-up visits with the doctor or clinic.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine after the expiry date.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how TWINRIX affects you.
Looking after your vaccine	<ul style="list-style-type: none">• TWINRIX will normally be stored at the doctor's surgery or in the pharmacy.• If you need to store TWINRIX, store in the refrigerator between 2°C and 8°C. Do not freeze.

For more information, see Section [5. What should I know while my child or I are being given TWINRIX?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported include soreness, redness, swelling, bruising, hard lump or itching around the injection site, immediate injection site pain, stinging and burning feeling, sweating, chills, flushing or generally feeling unwell, fever, headache, fatigue, dizziness, disturbed sleep, fainting, ringing in the ears, muscle aches and pains, painful joints, neck stiffness, feeling sick or vomiting, gut pain, diarrhoea, loss of appetite, cough, sore throat, and respiratory infections. Serious side effects include feelings of numbness, weakness and/or fatigue in limbs, tingling in fingers or toes, sudden headache, drooping eyelids or sagging facial muscles, generalised stiffness, neck stiffness, visual changes, dislike of bright lights, swollen glands, unusual bleeding, difficulty passing urine, and allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TWINRIX & TWINRIX JUNIOR

Active ingredients: *Inactivated Hepatitis A virus and Hepatitis B surface antigen*

Consumer Medicine Information (CMI)

This leaflet provides important information about TWINRIX. In this leaflet, TWINRIX refers to the use of both TWINRIX for adults and TWINRIX JUNIOR for children. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about TWINRIX.**

Where to find information in this leaflet:

1. [Why are my child or I being given TWINRIX?](#)
2. [What should I know before my child or I are given TWINRIX?](#)
3. [What if my child or I are taking other medicines?](#)
4. [How is TWINRIX given?](#)
5. [What should I know while my child or I are being given TWINRIX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why are my child or I being given TWINRIX?

TWINRIX is a combination vaccine containing inactivated Hepatitis A virus and Hepatitis B surface antigen. TWINRIX is used to prevent hepatitis A and hepatitis B infection. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Hepatitis A and hepatitis B are infectious diseases, which cause the liver to become inflamed (swollen). These diseases are caused by viruses - hepatitis A and hepatitis B viruses.

Hepatitis A

Symptoms of hepatitis A usually begin 3 to 6 weeks after coming into contact with the virus. These consist of nausea (feeling sick), fever, aches and pains. After a few days the skin and/or the whites of the eyes may become yellowish (jaundice). The severity and type of symptoms can vary. Hepatitis A is often milder in young children.

Most people recover completely but the illness is usually severe enough to keep adults off work for about a month

The hepatitis A virus can be passed from person to person in food and drink, or by swimming in water contaminated by sewage. Hepatitis A is very common in many parts of the world and the risk of infection is greatest in those areas where hygiene and sanitation are poor. Areas include Asia, India, Africa, Central and South America, the Pacific Islands, the Middle East, and the Mediterranean Basin. Vaccination is recommended for travellers to these areas, including people in the armed forces.

Some groups of people, however, are at a higher risk of exposure to the disease. Vaccination is recommended for these people:

- nursing staff and healthcare workers in contact with patients in children's wards, infectious
- diseases wards, emergency rooms and intensive care units
- day-care centre staff particularly where children have not been toilet trained
- staff and residents of homes or institutions
- sewerage workers
- food handlers
- homosexual men
- people in contact with an infected person
- people with chronic liver disease or liver transplants, or people who receive certain blood products.

Hepatitis B

The hepatitis B virus is found in body fluids such as blood, semen vaginal secretions, or saliva of infected people. You can catch the virus if it can enter your bloodstream. Ways this can happen are through:

- injection (e.g. needlestick injury, or sharing needles for IV drug use)
- sexual intercourse
- sores, cuts or tiny wounds coming into contact with infected fluids (e.g. from a human bite, sharing razors or toothbrushes, or working with human blood or body fluids)
- an infected mother passing the virus onto her baby during or shortly after birth.

Some people infected with hepatitis B may not look or feel sick, yet others will get symptoms. Symptoms may not appear for 6 weeks to 6 months after infection.

Sometimes people will only have mild flu-like symptoms, but other people can become very ill. They may be extremely tired, and have dark urine, pale faeces, yellowish skin and/or eyes (jaundice), and other symptoms possibly requiring hospitalisation. There is a risk of serious liver disease, such as cirrhosis (liver scarring) and liver cancer for all chronic hepatitis B carriers.

Some groups of people are at a higher risk of exposure to hepatitis B. Vaccination is recommended for these people:

- some healthcare workers
- abusers of injectable drugs
- people with many sexual partners
- homosexual men
- haemodialysis patients or people who receive certain blood products
- people with chronic liver disease or hepatitis C
- people in contact with a hepatitis B carrier or an infected person
- staff and residents of institutions or homes
- inmates and prison staff at some correctional institutions
- some travellers to areas where the incidence of hepatitis B is high.

There is no specific treatment for hepatitis A or hepatitis B. Vaccination is the best way to protect against infection.

TWINRIX will not protect against hepatitis caused by other agents or viruses (such as hepatitis C or hepatitis E). If a person is already infected with hepatitis A or hepatitis B virus at the time of vaccination, TWINRIX may not prevent the disease in these people.

TWINRIX is not recommended for prevention of hepatitis after exposure, for example in the case of needlestick injuries.

2. What should I know before my child or I are given TWINRIX?

Warnings

You should not receive TWINRIX if:

- you have/your child has had an allergic reaction to TWINRIX, or any of the ingredients listed at the end of this leaflet.
Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue. Always check the ingredients to make sure you can receive this vaccine
- you have/your child has had an allergic reaction to any other hepatitis A or hepatitis B vaccine
- you have/ your child has had TWINRIX before and became unwell. Tell your doctor, nurse or pharmacist before the vaccine is given
- you have/ your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.

Check with your doctor if you/your child:

- have/has an allergy to baker's yeast
- have/has any other medical conditions, such as:
 - a liver or kidney problem
 - an immune deficiency condition (e.g. HIV positive)
 - a nervous system illness
 - a bleeding disorder
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are or think you may be pregnant or if you intend to become pregnant. Your doctor or nurse will discuss with you the possible risks and benefits of receiving TWINRIX during pregnancy.

Talk to your doctor if you are breast feeding. It is not known if TWINRIX passes into breast milk, however the vaccine is not expected to cause problems for breast-fed babies.

3. What if my child or I are taking other medicines?

Tell your doctor, nurse or pharmacist if you/child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TWINRIX and affect how it works, such as:

- steroids, ciclosporin - medicines used to suppress the immune system.

Having other vaccines

Tell your doctor, nurse or pharmacist if you/your child have received another vaccine recently.

Some vaccines may be affected by other vaccines or medicines.

Your doctor, nurse or pharmacist will be able to tell you what to do if TWINRIX is to be given with another vaccine or medicine.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TWINRIX.

4. How is TWINRIX given?

The doctor or nurse will give TWINRIX as an injection.

If you have any concerns about how this vaccine/medicine is to be given, talk to your doctor, nurse or pharmacist.

How it is given

- For adults and children aged 16 years and over: TWINRIX is given as a 1 mL injection into the upper arm muscle.
- For adolescents and children aged 1 to 15 years: TWINRIX JUNIOR is given as a 0.5 mL injection into the upper arm muscle in older children and into the thigh muscle in infants.
- For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously (into the vein).

When it is given

- TWINRIX is generally given as a total of three doses over 6 months. Each dose 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
- TWINRIX may be given as a two-dose schedule, at 0 and 6 to 12 months for individuals aged between 1 and 15 years inclusive.

- **It is important to return at the recommended times for follow up doses.**
- Your doctor will advise on the possible need for extra doses, and future booster dosing.
- **Rapid Schedule:** If you are going to be travelling within 1 month or more after initiating the vaccination course, but insufficient time is available to complete the 0, 1, 6-month schedule, a rapid vaccination schedule of 0, 7, 21 days may be used. A fourth dose is recommended 12 months after the first dose.

If a dose is missed

If you miss a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you are given too much TWINRIX

If you think that you have/your child has been given too much TWINRIX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while my child or I are being given TWINRIX?

Things you must do

Keep your follow-up visits with the doctor or clinic. It is important that the 2 follow-up doses of TWINRIX are given at the correct times. This will ensure the best effect of the vaccine in protecting you against hepatitis A and hepatitis B.

Remind any doctor, nurse or pharmacist you visit that you are receiving TWINRIX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TWINRIX affects you.

TWINRIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or light headedness. Make sure you know how you react to TWINRIX before you drive a car or operate machinery, or do anything that could be dangerous if you feel dizzy or lightheaded.

Looking after your vaccine

TWINRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store TWINRIX always:

- store in the refrigerator between 2°C and 8°C
- **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE**
- store in original pack.

Follow the instructions in the carton on how to take care of your vaccine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to receive this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not receive this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • soreness, redness, swelling, bruising, hard lump or itching around the injection site • immediate injection site pain, stinging and burning feeling • sweating • chills • flushing • generally feeling unwell • fever <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • headache • fatigue • dizziness • disturbed sleep • fainting • ringing in the ears <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> • muscle aches and pains • painful joints • neck stiffness <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • feeling sick • vomiting • gut pain • diarrhoea • loss of appetite <p>Respiratory, thoracic and mediastinal disorders:</p> <ul style="list-style-type: none"> • cough • sore throat • respiratory infections 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> feelings of numbness weakness and/ or fatigue in limbs tingling in fingers or toes sudden headache <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> drooping eyelids or sagging facial muscles generalised stiffness neck stiffness <p>Eye disorders:</p> <ul style="list-style-type: none"> visual changes dislike of bright lights <p>Lymphatic disorders:</p> <ul style="list-style-type: none"> swollen glands unusual bleeding difficulty passing urine <p>Immune system disorders and allergic reactions:</p> <p>As with all vaccines given by injection there is a very small risk of serious allergic reaction:</p> <ul style="list-style-type: none"> swelling of limbs, face, eyes, inside of nose, mouth or throat shortness of breath, breathing or swallowing difficulties hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions unusual tiredness or weakness that is sudden and severe 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://pophealth.my.site.com/carmreportnz/s/>.

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

Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This vaccine is only available with a doctor's prescription.

What TWINRIX contains

Active ingredients (main ingredients)	<ul style="list-style-type: none"> Inactivated Hepatitis A virus Hepatitis B surface antigen
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> aluminium sodium chloride water for injection amino acids dibasic sodium phosphate monohydrate formaldehyde monobasic sodium phosphate neomycin sulphate polysorbate 20 trometamol

You should not be given this vaccine if you are allergic to any of these ingredients.

The vaccine is not infectious, and will not give you hepatitis A or hepatitis B.

TWINRIX is made without any human blood or blood products.

What TWINRIX looks like

TWINRIX is a white, slightly milky liquid in a prefilled syringe.

TWINRIX: 720 ELISA units of killed hepatitis A virus and 20 micrograms of the hepatitis B surface protein prefilled syringe in a pack of 1 x 1 mL (TT50-5871).

TWINRIX JUNIOR: 360 ELISA units of killed hepatitis A virus and 10 micrograms of the hepatitis B surface protein prefilled syringe in a pack of 1 x 0.5 mL (TT50-5871/1).

Who distributes TWINRIX

GlaxoSmithKline NZ Ltd
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