

TWINRIX (720/20) and TWINRIX JUNIOR (360/10)

Consumer Medicine Information (CMI) summary

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

1. Why am I being given TWINRIX?

TWINRIX is a combination vaccine 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.

For more information, see Section [1. Why am I using TWINRIX?](#) in the full CMI.

2. What should I know before I am given TWINRIX?

Do not use if you 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 I use TWINRIX?](#) in the full CMI.

3. What if I am 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 I am taking other medicines?](#) in the full CMI.

4. How is TWINRIX given?

- TWINRIX will be injected into your 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).
- The dose using TWINRIX (720/20) is 1 mL.
- The dose using TWINRIX JUNIOR (360/10) is 0.5 mL.

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

5. What should I know when I'm given TWINRIX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse or pharmacist you visit that you are using TWINRIX.• Check with your doctor if you have an allergy to yeast, you are or think you may be pregnant, or if you intend to become pregnant, you are breastfeeding, you have any medical conditions, such as a severe heart or lung disease, a bleeding disorder, a liver or kidney problem, an immune deficiency condition (e.g. are HIV positive), or a nervous system illness
Things you should not do	<ul style="list-style-type: none">• Do not have TWINRIX if you have/ your child has had an allergic reaction to TWINRIX, or any ingredient contained in this vaccine (e.g. neomycin sulphate), or you have a severe infection with a high temperature.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how TWINRIX affects you. TWINRIX should not normally interfere with your ability to drive a car or operate machinery. In some people vaccination can cause dizziness or light-headedness.
Looking after your medicine	<ul style="list-style-type: none">• TWINRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. If you need to store TWINRIX always store in the refrigerator between +2°C and +8°C in the original pack until it is time for it to be given. The pack should never be frozen. Freezing destroys the vaccine.

For more information, see Section [5. What should I know while using TWINRIX?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been most commonly reported include irritability, headache, pain and redness at injection site and fatigue. There is a rare risk of serious allergic reactions. Contact your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following, 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. 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 (720/20) and TWINRIX JUNIOR (360/10)

Active ingredient(s): *Hepatitis A virus and Hepatitis B surface protein (yeast)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TWINRIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TWINRIX.**

Where to find information in this leaflet:

1. [Why am I being given TWINRIX?](#)
2. [What should I know before I am given TWINRIX?](#)
3. [What if I am taking other medicines?](#)
4. [How is TWINRIX given?](#)
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1. [Why am I being given TWINRIX?](#)
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1. Why am I being given TWINRIX?

TWINRIX is a combination vaccine 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. TWINRIX can be given to adults, adolescents, children and infants.

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. Hepatitis A occurs in Australia but is not common.

Vaccination is recommended for travellers to all developing countries, including people in the armed forces, or for those groups at a higher risk of exposure to the disease such as nursing staff, healthcare workers in contact with patients in childrens wards, infectious diseases wards, emergency rooms, intensive care units, day-care staff particularly where children have not been

toilet trained, staff and residents of homes for the intellectually disabled, sewerage workers, food handlers, homosexual men, people in contact with an infected person, people with chronic liver disease, liver transplants or people that receive blood products.

Hepatitis B

The 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. But others will get symptoms, which may not be seen 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 for the intellectually disabled
- 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.

2. What should I know before I am given TWINRIX?

Warnings

Do not use TWINRIX if:

- you are allergic to TWINRIX, or any of the ingredients listed at the end of this leaflet (e.g. neomycin sulphate). Always check the ingredients to make sure you can use this medicine. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.

Tell your doctor, nurse or pharmacist before the vaccine is given:

- if you have/ your child has had TWINRIX before and became unwell
- 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 about this before being vaccinated.

Check with your doctor if:

- you have/ your child has an allergy to baker's yeast, medicines or substances, such as dyes, foods or preservatives.
- you have/ your child has any medical conditions, such as:
 - a severe heart or lung disease
 - a liver or kidney problem
 - an immune deficiency condition (eg. HIV positive)
 - a nervous system illness
 - or a bleeding disorder
- you / your child take any medicines for any condition
- you have / your child has received another vaccine recently or are taking any prescription or OTC (over-the-counter) medicines.

Fainting can occur following, or even before, any needle injection, therefore, tell the doctor or nurse if you/your child fainted with a previous injection.

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 pregnant or intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving TWINRIX during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 I am taking other medicines?

Tell your doctor or pharmacist if you 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 or vaccines may interfere with TWINRIX and affect how it works, in particular medicines which suppress the immune system, such as steroids or cyclosporin.

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 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?

How much is given

- The dose using TWINRIX (720/20) is 1 mL.
- The dose using TWINRIX JUNIOR (360/10) is 0.5 mL.
- The doctor or nurse will give TWINRIX as an injection. If you have any concerns about how this vaccine is to be given, talk to your doctor or pharmacist.

How is it given

TWINRIX will be injected into your 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). Each dose of TWINRIX is for single use only. Any residual vaccine must be discarded.

The vaccine should never be given intravenously.

When is it given

Adults

TWINRIX (720/20) 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

For adults, TWINRIX (720/20) can also be given as a total of three doses over 3 weeks (a 0, 7, 21 day schedule). However, the body's immune response to this rapid schedule may be reduced compared to the above

schedule. Therefore, this rapid schedule should only be used under special circumstances (e.g. adult travellers wanting to be vaccinated within one month of departure). A booster dose is recommended at 12 months.

Children (1 to 15 years inclusive)

TWINRIX (720/20) is generally given as a total of two doses 6 to 12 months apart. Each dose is given on a separate visit. The first dose will be given on an elected date. The second dose will be given 6 to 12 months after the first dose.

First dose: at an elected date

Second dose: 6 to 12 months after the first dose.

In children who are travelling to areas where there is a risk of exposure to hepatitis B, TWINRIX Junior (360/10) should be given as a total of 3 doses over 6 months (a 0, 1, 6 month schedule).

In children who are travelling to areas where there is a risk of exposure to hepatitis B, TWINRIX Junior (360/10) should be given as a total of 3 doses over 6 months (a 0, 1, 6 month schedule).

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.

If a dose is missed

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 being given TWINRIX?

Things you should do

Keep your follow up visits with the doctor or clinic. It is important that the 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.

Call your doctor straight away if:

- you or your child do not feel well during or after having had a dose of TWINRIX.

TWINRIX helps protect most people from hepatitis A and hepatitis B, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Most of the time they are not serious; however,

sometimes they can be. Some side effects may need medical treatment.

Remind any doctor, nurse or pharmacist you visit that you have been given TWINRIX.

Things you should not do

- Do not miss follow up doses.

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 lightheadedness.

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 medicine

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

- Keep TWINRIX in the refrigerator stored between +2 C and +8 C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children
- Keep TWINRIX in the original pack until it is time for it to be given.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Ask your pharmacist what to do with any left over TWINRIX that has expired or has not been used.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

Do not use this medicine if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines 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, a hard lump, bruising or itching around the injection site • Immediate injection site pain, stinging and burning feeling • Fatigue, headache, unusual tiredness, drowsiness, dizziness or feeling generally unwell • Fever • Fainting or chills • Ringing in the ears <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • Feeling sick or vomiting, stomach pains or diarrhoea, • Loss of appetite <p>Musculoskeletal disorders:</p> <ul style="list-style-type: none"> • Muscle aches and pains, painful joints, neck stiffness <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • Disturbed sleep <p>Respiratory and mouth disorders:</p> <ul style="list-style-type: none"> • Cough, sore throat, respiratory infections <p>Skin disorders:</p> <ul style="list-style-type: none"> • Sweating, flushing 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>[Insert appropriate action]</p>

Serious side effects

Serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • Feelings of numbness, weakness and/or fatigue in limbs, tingling in fingers or toes • Generalised stiffness, difficulty passing urine • Swollen glands, unusual bleeding, bleeding or bruising more easily than normal • Sudden headache, neck stiffness, dislike of bright lights, convulsions (fits) <p>Eye disorders:</p> <ul style="list-style-type: none"> • Visual changes • Drooping eyelids or sagging facial muscles <p>As with all vaccines given by injection there is a very small risk of serious allergic reaction. This may occur days to weeks after vaccination:</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 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 to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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

7. Product details

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

What TWINRIX contains

Active ingredient	Killed hepatitis A virus and the surface protein of the hepatitis B virus (from genetically engineered yeast cells). The vaccine is not infectious, and will not give you hepatitis A or hepatitis B.
Other ingredients (inactive ingredients)	Aluminium hydroxide hydrate Aluminium phosphate, Sodium chloride Amino acid supplement Formaldehyde Neomycin sulphate Polysorbate 20 Dibasic sodium phosphate heptahydrate Monobasic sodium phosphate Trometamol Water.
Potential allergens	The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Do not take this medicine if you are allergic to any of these ingredients.

What TWINRIX looks like

TWINRIX comes in prefilled syringes. It is a white, slightly milky liquid. Two different vaccine dosages are available:

- TWINRIX (720/20): 720 ELISA units of killed hepatitis A virus and 20 micrograms of the hepatitis B surface protein (AUST R 140575)
- TWINRIX JUNIOR (360/10): 360 ELISA units of killed hepatitis A virus and 10 micrograms of the hepatitis B surface protein.
(AUST R 140576).

Who distributes Twinrix

GlaxoSmithKline Australia Pty Ltd
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www.gsk.com.au

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