

EVOLTRA

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 using EVOLTRA?

EVOLTRA contains the active ingredient clofarabine. EVOLTRA is used to treat young patients with Acute Lymphoblastic Leukaemia (ALL) when previous treatments have not worked or have stopped working. For more information, see Section [1. Why am I using EVOLTRA?](#) in the full CMI.

2. What should I know before I use EVOLTRA?

Do not use if you have ever had an allergic reaction to EVOLTRA 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 EVOLTRA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EVOLTRA 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 do I use EVOLTRA?

- EVOLTRA is given as a slow injection (or infusion) into a vein. EVOLTRA should only be given by a nurse or doctor.

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

5. What should I know while using EVOLTRA?

Things you should do	<ul style="list-style-type: none">• If you are a female and can get pregnant, you must use effective contraception during treatment with EVOLTRA and for 6 months following completion of treatment. Call your doctors straight away if you become pregnant while you are being treated with EVOLTRA.• If you are breast-feeding, you must stop breast-feeding before starting the treatment, and must not breast-feed during your treatment and for 2 weeks after completion of treatment.• If you are a man, you must also use effective contraception and do not father a child while receiving EVOLTRA, and for 3 months following completion of treatment.• Drink plenty of water while you are being treated with EVOLTRA to avoid dehydration.• Avoid people with infections, and check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain, or find it painful or difficult to urinate.• Check with your doctor immediately if you notice any unusual bleeding or bruising, black stools, blood in urine or stools, or pinpoint red spots on your skin.• Be careful when using a toothbrush, toothpick or dental floss. Check with your doctor before having any dental work.• Avoid contact sports or other situations where you may bruise or get injured.
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 EVOLTRA affects you. You may feel dizzy or light-headed while you are receiving a cycle of EVOLTRA.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. Be careful when drinking alcohol while you are being given this medicine.
Looking after your medicine	<ul style="list-style-type: none">• EVOLTRA will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

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

EVOLTRA

Active ingredient: *clofarabine* (CLOE-fa-ra-been)

Consumer Medicine Information (CMI)

This leaflet provides important information about using EVOLTRA. **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 EVOLTRA.**

Where to find information in this leaflet:

- [1. Why am I using EVOLTRA?](#)
- [2. What should I know before I use EVOLTRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EVOLTRA?](#)
- [5. What should I know while using EVOLTRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EVOLTRA?

EVOLTRA contains the active ingredient clofarabine. EVOLTRA belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine.

This medicine is thought to work by interfering with the growth and/or repair of some cells that are multiplying rapidly, such as cancer cells, which are eventually destroyed.

EVOLTRA is used to treat young patients with Acute Lymphoblastic Leukaemia (ALL) when previous treatments have not worked or have stopped working. ALL is caused by abnormal growth of some types of white blood cells.

There is not enough information to recommend the use of this medicine for children under the age of one year, or adults over the age of 65 years.

2. What should I know before I use EVOLTRA?

Warnings

Do not use EVOLTRA if:

- you are allergic to clofarabine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have or have had any of the following medical conditions:
 - severe kidney problems
 - severe liver problems

Check with your doctor if you:

- have an infection or high temperature. Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.
- have allergies to any other medicines, foods, preservatives or dyes.

- have or have had any other medical conditions, especially the following:
 - any blood disorders, or conditions which cause a reduced number of red blood cells, white blood cells, or platelets
 - bone marrow disease
 - kidney disease
 - liver disease
 - hypotension (low blood pressure)
 - gout
 - bowel problems such as colitis (inflammation of the colon)
 - lowered immunity due to diseases including HIV/AIDS
 - heart disease.
- have been given EVOLTRA before, and you became unwell. You may be given another medicine instead.
- if you are on a controlled sodium diet as it could affect how you will be given your medicine. EVOLTRA contains 180mg of sodium chloride in each vial. This is equivalent to 3.08 mmol (or 70.77mg) of sodium. You need to allow for this if you are on a controlled sodium diet.

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

EVOLTRA should not be used during pregnancy unless clearly necessary.

If you are a female and can get pregnant, you must use effective contraception during treatment with EVOLTRA and for 6 months following completion of treatment. EVOLTRA may cause harm to unborn babies when used by pregnant women. **If you are pregnant or become pregnant during treatment with EVOLTRA, call your doctor immediately.**

If you are breast-feeding, you must stop breast-feeding before starting the treatment, and must not breast-feed during your treatment and for 2 weeks after completion of treatment.

Males

- **Use effective contraception and do not father a child while receiving EVOLTRA, and for 3 months following completion of treatment.**
- EVOLTRA may cause birth defects if either the male or female is using it at the time of conception. Your doctor can discuss this with you.

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 may interfere with EVOLTRA and affect how it works. These may include:

- other medicines used to treat cancer
- some vaccines
- medicines which can affect the kidneys
- medicines which can affect the liver
- medicines which can affect blood pressure or the heart.

These medicines may be affected by EVOLTRA or may affect how well it works. You may need different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

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

4. How do I use EVOLTRA?

How much is given

- Your doctor will decide what dose of EVOLTRA you will receive. This depends on your condition and other factors, such as your weight, height and other chemotherapy medicines you are being given.
- Your doctor will monitor your health and may change your dose depending on your response to the treatment.
- EVOLTRA may be given alone or in combination with other drugs.
- Several courses of EVOLTRA may be needed depending on your response to treatment.
- Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of EVOLTRA you receive.

How it is given

- EVOLTRA is given as a slow injection (or infusion) into a vein. EVOLTRA should only be given by a nurse or doctor.

How long it is given

EVOLTRA infusion lasts for two hours and is usually given every day for five days. If you (or your child) weighs less than 20kg, the infusion time may be longer. Your doctor will decide how many of these cycles you will need.

If you receive too much EVOLTRA

As EVOLTRA is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Symptoms of an overdose may include the side effects listed below under Section [6. Are there any side effects?](#), but are usually of a more severe nature.

If you think that you have received too much EVOLTRA, you may need urgent medical attention.

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 using EVOLTRA?

Things you should do

- **Drink plenty of water while you are being treated with EVOLTRA to avoid dehydration.**
- Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.
- Keep follow up appointments with your doctor. It is important to have your follow-up cycles of EVOLTRA at the appropriate times to get the best effects from your treatment.
- EVOLTRA can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:
 - Avoid people with infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain, or find it painful or difficult to urinate.
 - Check with your doctor immediately if you notice any unusual bleeding or bruising, black stools, blood in urine or stools or pinpoint red spots on your skin.
 - Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, pharmacist or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
 - Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
 - Avoid contact sports or other situations where you may bruise or get injured.

Call your doctor straight away if you:

- become pregnant while you are being treated with EVOLTRA.

Remind any doctor, dentist or pharmacist you visit that you are using EVOLTRA.

Driving or using machines

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

You may feel dizzy or light-headed while you are receiving a cycle of EVOLTRA.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are being given this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- EVOLTRA will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place where the temperature stays below 25°C.

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.

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>Gut-related:</p> <ul style="list-style-type: none"> Nausea and vomiting Diarrhoea <p>Brain-related:</p> <ul style="list-style-type: none"> Headache Unusual tiredness or weakness Anxiety or nervousness Decreased or lost appetite, weight loss <p>Skin-related:</p> <ul style="list-style-type: none"> Flushing, itching and inflamed skin Skin rashes or flaking Inflammation of mucus (moist) linings, such as the mouth <p>Immune system-related:</p> <ul style="list-style-type: none"> Fever Infections <p>Other:</p> <ul style="list-style-type: none"> Hair loss 	<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>Gut-related:</p> <ul style="list-style-type: none"> Severe nausea and vomiting Severe diarrhoea Vomiting blood, stomach ache <p>Airway and mouth-related:</p> <ul style="list-style-type: none"> Breathing difficulties, rapid breathing or breathlessness, cough Nosebleeds, bleeding gums, mouth ulcers <p>Heart-related:</p> <ul style="list-style-type: none"> Changes in your heart beat Fluid retention (oedema) <p>Immune system-related:</p> <ul style="list-style-type: none"> High fever <p>Head or brain-related:</p>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> Hearing problems Dizziness, light-headedness or fainting <p>Kidney-related:</p> <ul style="list-style-type: none"> Feeling thirsty and producing concentrated (dark) urine Blood in the urine <p>Liver-related:</p> <ul style="list-style-type: none"> Yellowing of the eyes and skin (jaundice) <p>Hair or skin-related:</p> <ul style="list-style-type: none"> Bruising, hair loss, changes to skin colour Increased sweating or dry skin <p>Nerve-related:</p> <ul style="list-style-type: none"> Feeling numb <p>Aches and pains:</p> <ul style="list-style-type: none"> Pain in the chest wall or bones Neck or back pain, pain in the muscles or joints <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> Symptoms of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin 	

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.

The benefits and side effects of EVOLTRA may take some time to occur. Therefore, even after you have finished receiving your EVOLTRA treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

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 EVOLTRA contains

Active ingredient (main ingredient)	clofarabine
Other ingredients	sodium chloride

(inactive ingredients)	water for injections
Potential allergens	This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What EVOLTRA looks like

EVOLTRA is a concentrate for solution for infusion (sterile concentrate) that is prepared and diluted before it is used.

It is a clear, colourless solution supplied in a glass vial.

EVOLTRA contains 20 mg of clofarabine in each 20 mL vial.

(Aust R 154991).

Who distributes EVOLTRA

Australian Sponsor:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australia

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

New Zealand Sponsor:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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