

Evoltra

Clofarabine (CLOE-fa-ra-been)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EVOLTRA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking EVOLTRA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EVOLTRA is used for

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.

This medicine 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

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.

Before you are given EVOLTRA

When you must not be given it

Do not receive treatment with EVOLTRA if you have an allergy to:

- any medicine containing clofarabine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

Do not receive treatment with EVOLTRA if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines, EVOLTRA is not recommended for use during pregnancy. If there is any need to consider EVOLTRA during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Do not breast-feed if you are being treated with this medicine.

If you are breast-feeding, you must stop breast-feeding before starting the treatment,

and must not breast-feed either during or after your treatment. Your doctor can advise you when it is safe to breast-feed.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are being given EVOLTRA or shortly after you have stopped treatment with EVOLTRA.

EVOLTRA may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use effective methods of contraception during and after treatment with EVOLTRA. Your doctor can discuss this with you.

Do not receive treatment with EVOLTRA if you have or have had any of the following medical conditions:

- severe kidney problems
- severe liver problems

Tell 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.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any 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.

Tell your doctor if you have been given EVOLTRA before, and you became unwell.

You may need to be given another medicine instead.

Tell your doctor 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.

If you have not told your doctor about any of the above, tell him/her before you are given EVOLTRA.

Taking other medicines

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

Some medicines and EVOLTRA may interfere with each other. 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.

Your doctor and pharmacist have more information on medicines/vaccinations to be careful with or avoid while being treated with EVOLTRA.

How EVOLTRA is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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 (overdose)

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. However, if you experience any side effects after being given EVOLTRA, tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given EVOLTRA

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of EVOLTRA.

Things you must do

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.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given EVOLTRA.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are being given EVOLTRA.

If you become pregnant while you are being treated with EVOLTRA, tell your doctor immediately.

Drink plenty of water while you are being treated with EVOLTRA to avoid dehydration.

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.

Things to be careful of

Be careful driving or operating machinery until you know how EVOLTRA affects you.

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

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with EVOLTRA.

Like other medicines that treated cancer, EVOLTRA, may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Nausea and vomiting
- Diarrhoea
- Headache
- Unusual tiredness or weakness
- Anxiety or nervousness
- Fever
- Flushing, itching and inflamed skin
- Skin rashes or flaking
- Inflammation of mucus (moist) linings, such as the mouth
- Infections
- Hair loss
- Decreased or lost appetite, weight loss

The above list includes the more common side effects of EVOLTRA.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- High fever
- Breathing difficulties, rapid breathing or breathlessness, cough
- Nosebleeds, bleeding gums, mouth ulcers
- Changes in your heart beat
- Dizziness, light-headedness or fainting
- Hearing problems
- Fluid retention (oedema)
- Severe nausea and vomiting
- Severe diarrhoea
- Feeling thirsty and producing concentrated (dark) urine
- Blood in the urine
- Vomiting blood, stomach ache
- Bruising, hair loss, changes to skin colour
- Increased sweating or dry skin
- Feeling numb
- Yellowing of the eyes and skin (jaundice)
- Pain in the chest wall or bones
- Neck or back pain, pain in the muscles or joints

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

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.

After being given EVOLTRA

Storage

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.

Product description

What it 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.

Ingredients

Active ingredients:

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

Other ingredients:

- Sodium chloride
- Water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Australia

New Zealand Sponsor:

sanofi-aventis new zealand Ltd
Level 8, 56 Cawley Street
Ellerslie
Auckland
New Zealand

EVOLTRA is available in the following sizes:

- 20mg/20mL vials

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