

Package leaflet: Information for the user

Eribulin STADA 0.44 mg/ml solution for injection

eribulin

Read all of this leaflet carefully before you start using this medicine 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you use <Product name>
3. How to use <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> contains the active substance eribulin and is an anti-cancer medicine which works by stopping the growth and spread of cancer cells.

It is used in adults for locally advanced or metastatic breast cancer (breast cancer that has spread beyond the original tumour) when at least one other therapy has been tried but has lost its effect.

It is also used in adults for advanced or metastatic liposarcoma (a type of cancer that arises from fat tissue) when previous therapy has been tried but has lost its effect.

2. What you need to know before you use <Product name>

DO NOT use <Product name> if you

- are allergic to eribulin mesilate or any of the other ingredients of this medicine (listed in section 6)
- are breast-feeding

Warnings and precautions

Talk to your doctor or nurse before using <Product name> if you

- have liver problems
- have a fever or an infection
- experience numbness, tingling, prickling sensations, sensitivity to touch or muscle weakness
- have heart problems

If any of these affects you, tell your doctor, who may wish to stop treatment or reduce the dose.

Children and adolescents

Do not give this medicine to children between the ages of 0 to 18 years because it does not work.

Other medicines and <Product name>

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

<Product name> may cause serious birth defects and should not be used if you are pregnant unless it is thought clearly necessary after carefully considering all the risks to you and the baby. It may also cause future permanent fertility problems in men if they take it and they should discuss this with their doctor before starting treatment. Women of childbearing age should use effective contraception during and up to 3 months after treatment with <Product name>.

<Product name> must not be used during breast-feeding because of the possibility of risk to the child.

Driving and using machines

<Product name> may cause side effects such as tiredness (very common) and dizziness (common). Do not drive or use machines if you feel tired or dizzy.

<Product name> contains ethanol (alcohol)

This medicine contains 40 mg of ethanol in each ml solution for injection. The amount in each ml is equivalent to less than 1 ml beer or 0.4 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use <Product name>**Method of administration**

<Product name> will be given to you by a qualified healthcare professional as an injection into a vein, over a period of 2 to 5 minutes.

Dosage

The dose you will receive is based on your body surface area (expressed in squared metres, or m²) which is calculated from your weight and height.

The usual dose of <Product name> is 1.23 mg/m², but this may be adjusted by your doctor based on your blood test results or other factors. To ensure that the whole dose of <Product name> is given it is recommended that a saline solution is flushed into the vein after <Product name> is given.

How often will you be given <Product name>?

<Product name> is usually given on Days 1 and 8 of every 21-day cycle. Your doctor will determine how many cycles of treatment you should receive. Depending on the results of your blood tests, the doctor may need to delay administration of the medicine until the blood tests return to normal. The doctor may also then decide to reduce the dose you are given.

If you have any further questions about the use of this medicine, ask your doctor.

4. Possible side effects

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

If you experience any of the following serious symptoms, stop taking <Product name> and seek medical attention straight away:

- Fever, with a racing heartbeat, rapid shallow breathing, cold, pale, clammy or mottled skin and/or confusion. These may be signs of a condition called sepsis – a severe and serious reaction to an infection. Sepsis is uncommon (may affect up to 1 in 100 people) and can be life-threatening and may result in death.
- Any difficulty breathing, or swelling of your face, mouth, tongue or throat. These could be signs of an uncommon allergic reaction (may affect up to 1 in 100 people).
- Serious skin rashes with blistering of the skin, mouth, eyes and genitals. These may be signs of a condition called Stevens Johnson syndrome/toxic epidermal necrolysis. The frequency of this condition is not known but it can be life-threatening.

Other side effects

Very common side effects (may affect more than 1 in 10 people)

- decrease in the number of white blood cells or red blood cells
- tiredness or weakness
- nausea, vomiting, constipation, diarrhoea
- numbness, tingling or prickling sensations
- fever
- loss of appetite, weight loss
- difficulty breathing, cough
- pain in the joints, muscles and back
- headache
- hair loss

Common side effects (may affect up to 1 in 10 people)

- decrease in the number of platelets (which may result in bruising or taking longer to stop bleeding)
- infection with fever, pneumonia, chills
- fast heart rate, flushing
- vertigo, dizziness
- increased production of tears, conjunctivitis (redness and soreness of the surface of the eye), nosebleed
- dehydration, dry mouth, cold sores, oral thrush, indigestion, heartburn, abdominal pain or swelling
- swelling of soft tissues, pains (in particular chest, back and bone pain), muscle spasm or weakness
- mouth, respiratory and urinary tract infections, painful urination
- sore throat, sore or runny nose, flu-like symptoms, throat pain
- liver function test abnormalities, altered level of sugar, bilirubin, phosphates, potassium, magnesium or calcium in the blood
- inability to sleep, depression, changed sense of taste
- rash, itching, nail problems, dry or red skin
- excessive sweating (including night sweats)
- ringing in the ears
- blood clots in the lungs
- shingles
- swelling of the skin and numbness of the hands and feet

Uncommon side effects (may affect up to 1 in 100 people)

- blood clots
- abnormal liver function tests (hepatotoxicity)
- kidney failure, blood or protein in the urine
- widespread inflammation of the lungs which may lead to scarring
- inflammation of the pancreas
- mouth ulcers

Rare side effects (may affect up to 1 in 1 000 people)

- a serious disorder of blood clotting resulting in the widespread formation of blood clots and internal bleeding

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly [via the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 and the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

If <Product name> is diluted for infusion, the diluted solution should be used immediately. If not used immediately in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C unless dilution has taken place in controlled and validated aseptic conditions.

If <Product name> as an undiluted solution has been transferred into a syringe, it should be stored at 25°C for no longer than 24 hours, or at 2- 8°C for no longer than 96 hours.

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 <Product name> contains

- The active substance is eribulin. Each 2 ml vial contains eribulin mesilate equivalent to 0.88 mg eribulin.
- The other ingredients are ethanol and water for injections, with hydrochloric acid (diluted) and sodium hydroxide possibly present in very small amounts.

What <Product name> looks like and contents of the pack

<Product name> is a clear, colourless aqueous solution for injection provided in glass vials containing 2 ml of solution. Each carton contains either 1 or 6 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised 2023-09-20