Package leaflet: Information for the user

Eribulin Baxter 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 Eribulin Baxter is and what it is used for

Eribulin Baxter 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 Eribulin Baxter

Do not use Eribulin Baxter
- if you are allergic to eribulin mesilate or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or nurse before using Eribulin Baxter:
- if you have liver problems
- if you have a fever or an infection
- if you experience numbness, tingling, prickling sensations, sensitivity to touch or muscle weakness
- if you 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 Eribulin Baxter

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

Pregnancy, breast-feeding and fertility

Eribulin Baxter 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 risk 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 Eribulin Baxter.

Eribulin Baxter must not be used during breast-feeding because of the possibility of risk to the child.

Driving and using machines

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

Eribulin Baxter contains ethanol anhydrous

This medicine contains 78.9 mg (0.1 mL) of ethanol anhydrous in each vial. The amount in 2 mL of this medicine is equivalent to 2 mL beer or less than 1 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Eribulin Baxter contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially `sodium-free'.

3. How to use Eribulin Baxter

Eribulin Baxter will be given to you by a qualified healthcare professional as an injection into a vein, over a period of 2 to 5 minutes. The dose you will receive is based on your body surface area (expressed in squared metres, or m^2) which is calculated from your weight and height. The usual dose of Eribulin Baxter is 1.23 mg/m^2, but this may be adjusted by your doctor based on your blood test results or other factors. To ensure that the whole dose of Eribulin Baxter is given it is recommended that a saline solution is flushed into the vein after Eribulin Baxter is given.

How often will you be given Eribulin Baxter?

Eribulin Baxter 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.

Stop taking Eribulin Baxter and seek medical attention straight away if you experience any of the following serious symptoms:

- Fever, with a racing heart beat, 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) are:

- 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) are:

- 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) are:

- Blood clots
- Abnormal liver function tests (hepatoxicity)
- 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 1000 people) are:

- 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eribulin Baxter

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.

Store below 30°C.

If Eribulin Baxter is diluted for infusion:
Chemical and physical in-use stability of the diluted solution has been demonstrated for 24 hours at 15-25°C and 72 hours at 2°C -8°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C -8°C, unless dilution has taken place in controlled and validated aseptic conditions.

If Eribulin Baxter as an undiluted solution has been transferred into a syringe:
Chemical and physical in-use stability of the undiluted solution in a syringe has been demonstrated for 4 hours at 15-25°C and 24 hours at 2°C -8°C.

Eribulin Baxter vials are for single-use only. Discard unused portions of Eribulin Baxter.

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

What Eribulin Baxter looks like and contents of the pack
Eribulin Baxter is a clear, colourless aqueous solution for injection essentially free from visible particles provided in a glass vial containing 2 mL of solution. Each carton contains 1 vial.

Marketing Authorisation Holder
Baxter Healthcare Limited
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Manufacturer
Baxter Oncology GmbH
Kantstraße 2
33790 Halle/Westfalen
Germany

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Detailed information on this medicine is available on the website of the UK Medicines and Healthcare products Regulatory Agency (MHRA)