Package leaflet: Information for the user

Eribulin STADA Arzneimittel AG 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 STADA Arzneimittel AG is and what it is used for

Eribulin STADA Arzneimittel AG 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 STADA Arzneimittel AG

Do not use Eribulin STADA Arzneimittel AG:
- 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 STADA Arzneimittel AG:
- 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 STADA Arzneimittel AG
Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility
Women of childbearing age should use effective contraception during and for at least 7 months after treatment with Eribulin STADA Arzneimittel AG. Men should not father a child while receiving treatment with Eribulin STADA Arzneimittel AG. Men should use an effective method of contraception while taking Eribulin STADA Arzneimittel AG and for at least 4 months after treatment.

Eribulin STADA Arzneimittel AG 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.

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

It may cause future permanent fertility problems in men if they take it and they should discuss this with their doctor before starting treatment.

Driving and using machines
Eribulin STADA Arzneimittel AG 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 STADA Arzneimittel AG contains ethanol (alcohol)
This medicine contains 79 mg alcohol (ethanol) in each vial which is equivalent to 40 mg/ml. The amount in each vial of this medicine is equivalent to less than 2 ml beer or 1 ml wine.

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

3. How to use Eribulin STADA Arzneimittel AG

Eribulin STADA Arzneimittel AG 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 STADA Arzneimittel AG 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 STADA Arzneimittel AG is given it is recommended that a saline solution is flushed into the vein after Eribulin STADA Arzneimittel AG is given.

How often will you be given Eribulin STADA Arzneimittel AG?
Eribulin STADA Arzneimittel AG 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 Eribulin STADA Arzneimittel AG and seek medical attention straightaway:

- 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 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 Eribulin STADA Arzneimittel AG

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 Eribulin STADA Arzneimittel AG is diluted for infusion, the diluted solution should be used immediately. If not used immediately the undiluted solution should be stored at 2 to 8°C for no longer than 48 hours.

If Eribulin STADA Arzneimittel AG 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 to 8°C for no longer than 96 hours.

From a microbiological point of view, the product 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.

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 STADA Arzneimittel AG contains
- The active substance is eribulin. One ml contains eribulin mesilate equivalent to 0.44 mg 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 and sodium hydroxide.

What Eribulin STADA Arzneimittel AG looks like and contents of the pack
Eribulin STADA Arzneimittel AG 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 and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

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