1065047190

Package leaflet: Information for the user

Eribulin 0.44 mg/ml solution for injection

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 is and what it is used for

The name of your medicine is Eribulin Zentiva 0.44 mg/ml solution for injection (called Eribulin throughout this leaflet). Eribulin 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 are given Eribulin

Do not use Eribulin 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 you are given Eribulin 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 Eribulin
Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility
Eribulin 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 potential must use highly effective contraception during treatment with Eribulin and for 7 months after treatment.
Eribulin must not be used during breast-feeding because of the possibility of risk to the child.
Men with a partner of childbearing potential should not father a child while receiving treatment with Eribulin. Men must use an effective method of contraception while taking Eribulin and for 4 months after treatment.

Driving and using machines
Eribulin 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 contains ethanol (alcohol)
This medicine contains 80 mg of ethanol (alcohol) in each vial. The amount in a 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 Eribulin is given

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

How often will you be given Eribulin?
Eribulin 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 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 (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 (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 (may affect up to 1 in 100 people):
- 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 (may affect up to 1 in 1000 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play and Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eribulin

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.

In-use shelf life

Chemical and physical in-use stability of the undiluted solution in a syringe has been demonstrated for 24 hours at 20 to 25 °C and 96 hours at 2 to 8 °C.

Chemical and physical in-use stability of the diluted solution (0.018 mg/ml to 0.18 mg/ml eribulin in sodium chloride (0.9%)) has been demonstrated for 48 hours at 2 to 8 °C.

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, unless dilution has taken place in controlled and validated aseptic conditions.

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.

Your doctor or nurse is responsible for storage, preparation and disposal of this medicine.

6. Contents of the pack and other information

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

What Eribulin looks like and contents of the pack
Eribulin is a clear, colourless aqueous solution for injection with pH 6.0-9.0 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
Zentiva Pharma UK Limited,
12 New Fetter Lane,
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Manufacturer
AqVida GmbH,
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This leaflet was last revised in November 2024

ZENTIVA 1065047190

ZENTIVA

GENERAL INFO:

PM CODE:	1065047190
PRODUCT NAME:	PIL ERIBULIN 0.88MG/2ML SLIJF VL1 GB
SAP ID / GMID:	937569
AW VERSION:	V3
CREATION DATE:	16.12.2025
AW BY:	ZT012022
SUPPLIER:	AQVIDA

REASON OF REVISION:

New Keyline 132x750mm. (As per CMO request)

TECHNICAL INFO:

FORMAT (size):	132 × 750 mm
LAETUS (pharma code):	N/A
FONT + MIN. SIZE:	Helvetica Neue LT W1G 8.5 pt
MATERIAL TYPE (TS):	N/A

COLOURS: [1]

■ Black

TECH. COLOURS: [1]

■ DieCut

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ZENTIVA **artwork check list**

Infobox check		
PM code	(acc. Vista)	OK
Product name	(acc. Vista)	OK
SAP ID / GMID	(acc. Vista)	OK
Colors	(add only used colors)	OK

Technical check		
Keyline	(acc. pack size/strength/dosage form)	OK
Inner safezones	(acc. keyline)	OK
Leatus code:	position and orientation	N/A
	value of code	N/A

Design check		
Corresponds to:	leaflet design manual	OK
	registered mockup	OK
PM code placed on artwork	(acc. Vista)	OK
Color separations	(are colors used properly?)	OK
Logo placement	(check if proper logo is used)	OK

Legislation check		
Font size	(minimum font size is 8.5 pt - Helvetica)	OK
Line spacing	(minimum line spacing is 8.5 pt)	OK
Text according to:	QRD (text used acc. Vista)	OK
	Annotated PDF (acc. Vista)	OK

New version check		V3
Update infobox	(version and other data if needed)	OK
Applied corrections	(check if only requested corrections have been applied)	OK