

PACKAGE LEAFLET

Package leaflet: Information for the user
Eribulin Tillomed 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 Tillomed is and what it is used for
2. What you need to know before you use Eribulin Tillomed
3. How to use Eribulin Tillomed
4. Possible side effects
5. How to store Eribulin Tillomed
6. Contents of the pack and other information

1. What Eribulin Tillomed is and what it is used for

Eribulin Tillomed 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 Tillomed

Do not use Eribulin Tillomed:

- 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 Tillomed.

- 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.

Other medicines and Eribulin Tillomed

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 Tillomed and for 7 months after treatment.

Eribulin Tillomed 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 Tillomed. Men must use an effective method of contraception while taking Eribulin Tillomed 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 Tillomed contains ethanol and sodium

Eribulin Tillomed contains 39.575 mg ethanol per ml.

Vial 2 ml

This medicine contains 79.15 mg of alcohol (ethanol) in each vial. The amount in 2 ml of this medicine is equivalent to less than 2 ml beer or 0.8 ml wine.

Vial 3 ml

This medicine contains 118.725 mg of alcohol (ethanol) in each vial. The amount in 3 ml of this medicine is equivalent to less than 3 ml beer or 1.2 ml wine.

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

Eribulin Tillomed contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How to use Eribulin Tillomed

Eribulin Tillomed 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 m²) which is calculated from your weight and height. The usual dose of Eribulin Tillomed 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 Eribulin Tillomed is given it is recommended that a saline solution is flushed into the vein after Eribulin Tillomed is given.

How often will you be given Eribulin Tillomed?

Eribulin Tillomed 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 Tillomed and seek medical attention straightaway:**

- 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) 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 (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 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 pharmacist. 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 HPRA pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Eribulin Tillomed

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

Chemical and physical in-use stability for the undiluted solution in a syringe has been demonstrated for up to 4 hours when stored at 15⁰C-25 °C and ambient lighting or up to 24 hours at 2⁰C - 8°C.

Chemical and physical in-use stability for the diluted solution (0.018 mg/ml to 0.18 mg/ml Eribulin Tillomed in sodium chloride 9 mg/ml (0.9%) solution for injection) has been demonstrated for up to 72 hours at 2⁰C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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 2⁰C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

This medicine does not require any special storage precautions.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Eribulin Tillomed contains

The active substance is eribulin. Each 2 ml vial contains eribulin mesilate equivalent to 0.88 mg eribulin. Each 3 ml vial contains eribulin mesilate equivalent to 1.32 mg eribulin.

The other ingredients are ethanol anhydrous and water for injections, with sodium hydroxide and hydrochloric acid (for pH adjustment).

What Eribulin Tillomed looks like and contents of the pack

Eribulin Tillomed contains a clear colourless solution, free from visible particles in a glass vial containing 2 ml or 3 ml solution for injection.

Each carton contains either 1 vial or 6 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Tillomed Malta Ltd.
Tower Business Centre,
2nd floor Tower Street, Swatar,
Birkirkara BKR4013,
Malta

Manufacturer

Tillomed Malta Ltd.
Malta Life Sciences Park,
LS2.01.06 Industrial Estate,
San Gwann, SGN 3000, Malta

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

Austria	Eribulin Tillomed 0,44 mg/ml Injektionslösung
Belgium	Eribulin Tillomed 0,44 mg/ml oplossing voor injectie Eribulin Tillomed 0,44 mg/ml solution pour injection Eribulin Tillomed 0,44 mg/ml Injektionslösung
Bulgaria	Eribulin Tillomed 0.44 mg/ml Инжекционен разтвор Eribulin Tillomed 0.44 mg/ml Solution for Injection
Cyprus	Eribulin Tillomed 0.44 mg/ml ενέσιμο διάλυμα
Czech Republic	ERIBULIN TILLOMED
Denmark	Eribulin Tillomed
Finland	Eribulin Tillomed
Sweden	Eribulin Tillomed
Norway	Eribulin Tillomed
France	ERIBULINE TILLOMED 0.44 mg/ml, Solution injectable
Germany	Eribulin Tillomed 0,44 mg/ml Injektionslösung

Greece	Eribulin/ Tillomed
Hungary	Eribulin Tillomed 0.44 mg/ml oldatos injekció
Ireland	Eribulin Tillomed 0.44 mg/ml Solution for Injection
Italy	ERIBULINA TILLOMED
Lithuania	Eribulin Tillomed 0.44 mg/ml injekcinis tirpalas
Malta	Eribulin Tillomed 0.44 mg/ml Solution for Injection
Netherland	Eribulin Tillomed 0,44 mg/mL oplossing voor injectie
Poland	Eribulin Tillomed
Portugal	Eribulin Tillomed 0.44 mg/ml solução injetável
Slovakia	Eribulin Tillomed 0.44 mg/ml injekčný roztok
Spain	Eribulin Tillomed 0,44 mg/ml Solución para inyección

This leaflet was last revised in March 2026.