PACKAGE LEAFLET

Package leaflet: Information for the user

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

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

Eribulin Accord 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 AccordEribulin

Accord

Do not use Eribulin Accord
- 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 Accord:
- 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 Accord

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

Pregnancy, breast-feeding and fertility
Eribulin Accord 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 Accord and for 7 months after treatment.

Eribulin Accord 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 Accord. Men must use an effective method of contraception while taking Eribulin Accord and for 4 months after treatment. **Driving and using machines**
Eribulin Accord 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 Accord contains alcohol (ethanol)
This medicine contains 39.45 mg of alcohol (ethanol) in each ml. The amount in each ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

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

3. How to use Eribulin Accord

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

How often will you be given Eribulin Accord?
Eribulin Accord 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 Accord 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
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 Accord

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 Accord is diluted for infusion, the diluted solution should be used immediately. If not used immediately the diluted solution should be stored at 2- 8°C for no longer than 72 hours.

If Eribulin Accord as an undiluted solution has been transferred into a syringe, it should be stored at 15-25°C and ambient lighting for no longer than 4 hours, or at 2- 8°C for no longer than 24 hours.

Do not use this medicine if you notice any visible signs of discolouration or contamination.

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 Accord contains

- The active substance is eribulin.
- Each ml contains eribulin mesilate equivalent to 0.44 mg eribulin.
  Each vial of 2 ml contains eribulin mesilate equivalent to 0.88 mg eribulin.
- The other ingredients are ethanol and water for injections, with hydrochloric acid (for pH-adjustment) and sodium hydroxide (for pH-adjustment) possibly present in very small amounts.

What Eribulin Accord looks like and contents of the pack

Eribulin Accord is a clear, colourless solution for injection, practically free from particles provided in a glass vial.

Each pack contains 1 or 6 vials of 2 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited,

Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer
Accord Healthcare Polska Sp.z o.o.
ul. Lutomierska 50,
95-200 Pabianice
Poland

Or

Accord Healthcare Single Member S.A.
64th Km National Road Athens, Lamia, 32009, Greece

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

Name of the Member State	**Name of the medicine**
Austria	Eribulin Accord 0,44 mg/ml Injektionslösung
Germany	Eribulin Accord 0,44 mg/ml Injektionslösung
Denmark	Eribulin Accord 0.44 mg/ml
Finland	Eribulin Accord 0.44 mg/ml Injektioneste, liuos
Norway	Eribulin Accord
Sweden	Eribulin Accord
Estonia	Eribulin Accord
Lithuania	Eribulin Accord 0,44 mg/ml injekcinis tirpalas
Ireland	Eribulin Accord 0.44 mg/ml solution for injection
Cyprus	Eribulin Accord 0.44 mg/ml Ενέσιμο διάλυμα
Italy	Eribulina Accord
Greece	Eribulin /Accord
Croatia	Eribulin Accord 0,44 mg/ml otopina za injekciju
Bulgaria	Ерибулин Accord 0,44 mg/ml Инжекционен разтвор
	Eribulin Accord 0.44 mg/ml solution for injection
Romania	Eribulin Accord 0.44 mg/ml Soluţie injectabilă
Slovakia	Eribulin Accord 0.44 mg/ml Injekčný roztok
Czechia	Eribulin Accord
Slovenia	Eribulin Accord 0,44 mg/ml raztopina za injiciranje
Poland	Eribulin Accord
France	Eribuline Accord 0.44 mg/ml Solution injectable

This leaflet was last revised in {**05/2026**}.

Please refer to SmPC for full information.
The following information is intended for healthcare professionals only:

Eribulin Accord should only be prescribed by a qualified physician experienced in the appropriate use of anti-cancer therapy. It should be administered by an appropriately qualified healthcare professional only.

Posology

The recommended dose of eribulin as the ready to use solution is 1.23 mg/m^2 which should be administered intravenously over 2 to 5 minutes on Days 1 and 8 of every 21-day cycle.

Please note:
In the EU the recommended dose refers to the base of the active substance (eribulin). Calculation of the individual dose to be administered to a patient must be based on the strength of the ready to use solution that contains 0.44 mg/ml eribulin and the dose recommendation of 1.23 mg/m^2. The dose reduction recommendations shown below are also shown as the dose of eribulin to be administered based on the strength of the ready to use solution.

In the pivotal trials, the corresponding publications and in some other regions e.g. the United States and Switzerland, the recommended dose is based on the salt form (eribulin mesilate).

Patients may experience nausea or vomiting. Antiemetic prophylaxis including corticosteroids should be considered.

Dose delays during therapy

The administration of Eribulin Accord should be delayed on Day 1 or Day 8 for any of the following:
- absolute neutrophil count (ANC) < 1 x 10^9/l
- platelets < 75 x 10^9/l
- grade 3 or 4 non-hematological toxicities.

Dose reduction during therapy

Dose reduction recommendations for retreatment are shown in the following table.

Dose reduction recommendations

Adverse reaction after previous Eribulin Accord administration	**Recommended dose of eribulin**
Haematological:	
ANC < 0.5 x 10^9/l lasting more than 7 days	0.97 mg/m^2
ANC < 1 x 10^9/l neutropenia complicated by fever or infection	
Platelets < 25 x 10^9/l thrombocytopenia	
Platelets < 50 x 10^9/l thrombocytopenia complicated by haemorrhage or requiring blood or platelet transfusion	
Non-haematological:	
Any Grade 3 or 4 in the previous cycle	
Reoccurrence of any haematological or non-haematological adverse reactions as specified above	
Despite reduction to 0.97 mg/m^2	0.62 mg/m^2
Despite reduction to 0.62 mg/m^2	Consider discontinuation

The dose of eribulin should not be re-escalated after it has been reduced.

Patients with hepatic impairment

Impaired liver function due to metastases
The recommended dose of eribulin in patients with mild hepatic impairment (Child-Pugh A) is 0.97 mg/m^2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle. The recommended dose of eribulin in patients with moderate hepatic impairment (Child-Pugh B) is 0.62 mg/m^2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.
Severe hepatic impairment (Child-Pugh C) has not been studied but it is expected that a more marked dose reduction is needed if eribulin is used in these patients.

Impaired liver function due to cirrhosis
This patient group has not been studied. The doses above may be used in mild and moderate impairment but close monitoring is advised as the doses may need readjustment.

Patients with renal impairment
Some patients with moderately or severely impaired renal function (creatinine clearance <50 ml/min) may have increased eribulin exposure and may need a reduction of the dose. For all patients with renal impairment, caution and close safety monitoring is advised.

Elderly patients

No specific dose adjustments are recommended based on the age of the patient .

Paediatric population

There is no relevant use of Eribulin Accord in children and adolescents for the indication of breast cancer.

There is no relevant use of Eribulin Accord in the paediatric population for the indication of soft tissue sarcoma .

Method of administration

Eribulin Accord is for intravenous use. The dose may be diluted in up to 100 ml of sodium chloride 9 mg/ml (0.9%) solution for injection. It should not be diluted in glucose 5% infusion solution. For instructions on the dilution of the medicinal product before administration, see Special precautions for disposal <and other handling. Good peripheral venous access, or a patent central line, should be ensured prior to administration. There is no evidence that eribulin mesilate is a vesicant or an irritant. In the event of extravasation, treatment should be symptomatic. For information relevant to the handling of cytotoxic medicinal products see section Special precautions for disposal and other handling.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products except those mentioned in section Special precautions for disposal and other handling.

Storage and shelf life of the diluted solution
In-use shelf life
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°C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Chemical and physical in-use stability of Eribulin Accord as an undiluted solution in a syringe has been demonstrated for up to 4 hours at 15-25°C and ambient lighting or up to 24 hours at 2°C - 8°C.

Chemical and physical in-use stability of Eribulin Accord as a diluted solution (0.018 mg/mL to 0.18 mg/mL eribulin in sodium chloride 9 mg/mL (0.9%)) has been demonstrated for up to 72 hours at 2°C - 8°C.

Special precautions for disposal and other handling

Eribulin is a cytotoxic anticancer medicinal product and, as with other toxic compounds, caution should be exercised in its handling. The use of gloves, goggles, and protective clothing is recommended. If the skin comes into contact with the solution it should be washed immediately and thoroughly with soap and water. If it contacts mucous membranes, the membranes should be flushed thoroughly with water. Eribulin should only be prepared and administered by personnel appropriately trained in handling of cytotoxic agents. Pregnant staff should not handle Eribulin Accord.

Using aseptic technique Eribulin can be diluted up to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection. Following administration, it is recommended that the intravenous line be flushed with sodium chloride 9 mg/ml (0.9%) solution for injection to ensure administration of the complete dose. It must not be mixed with other medicinal products and should not be diluted in glucose 5% infusion solution.

If using a spike to administer the product refer to the instructions provided from the device manufacturer. Eribulin Accord vials have a 13mm stopper. The device selected should be compatible with small vial stoppers.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.