

ERIBULIN DR. REDDY'S

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ERIBULIN DR. REDDY'S?

ERIBULIN DR. REDDY'S contains the active ingredient eribulin mesilate. ERIBULIN DR. REDDY'S is used to treatment of breast cancer and it is also used in adults for advanced or metastatic liposarcoma (a type of cancer that arises from fat tissue). For more information, see Section [1. Why am I using ERIBULIN DR. REDDY'S?](#) in the full CMI.

2. What should I know before I use ERIBULIN DR. REDDY'S?

Do not use if you have ever had an allergic reaction to eribulin mesilate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ERIBULIN DR. REDDY'S?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with eribulin mesilate and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given ERIBULIN DR. REDDY'S?

- ERIBULIN DR. REDDY'S will be given to you by a doctor or nurse as an injection into a vein, usually over a period of 2-5 minutes, but this may take longer.
- Your doctor will decide how much ERIBULIN DR. REDDY'S you will be given."

More instructions can be found in Section [4. How am I given ERIBULIN DR. REDDY'S?](#) in the full CMI.

5. What should I know while using ERIBULIN DR. REDDY'S?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist when you visit that you are using eribulin mesilate.• If you become pregnant while taking ERIBULIN DR. REDDY'S, tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">• Do not take any other medicines, without telling your doctor
Driving or using machines	<ul style="list-style-type: none">• Be careful while driving or operating machinery until you know how ERIBULIN DR. REDDY'S affects you• Do not drive or use machinery if you feel tired or dizzy

For more information, see Section [5. What should I know while using eribulin mesilate?](#) in the full CMI.

6. Are there any side effects?

Decrease in the number of white blood cells, red blood cells and platelets in your blood are most common. This may mean you are at increased risk of infection, feel more tired or weak, bruise more easily or take longer to stop bleeding."

Nausea, vomiting, constipation, diarrhoea, tiredness or weakness, fever, loss of appetite, weight loss, hair loss and head ache are most common side effects.

Infection with fever, chills, pneumonia, fast heart rate, flushing, vertigo, dizziness are common side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ERIBULIN DR. REDDY'S

Active ingredient(s): *Eribulin mesilate (erib-u-lin)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ERIBULIN DR. REDDY'S. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ERIBULIN DR. REDDY'S.**

Where to find information in this leaflet:

- [1. Why am I using ERIBULIN DR. REDDY'S?](#)
- [2. What should I know before I use ERIBULIN DR. REDDY'S?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given the ERIBULIN DR. REDDY'S?](#)
- [5. What should I know while using ERIBULIN DR. REDDY'S?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ERIBULIN DR. REDDY'S?

ERIBULIN DR. REDDY'S contains the active ingredient eribulin mesilate.

ERIBULIN DR. REDDY'S belongs to a group of medicines called Anti-cancer agents. It works by stopping the growth and spread of cancer cells.

ERIBULIN DR. REDDY'S is used for the treatment of breast cancer. It is used when at least one other therapy for locally advanced or metastatic breast cancer (i.e.; breast cancer that has spread beyond the original tumour) 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use ERIBULIN DR. REDDY'S?

Warnings

Do not use ERIBULIN DR. REDDY'S if:

- you are allergic (hypersensitive) to eribulin mesilate or any of the other ingredients of ERIBULIN DR. REDDY'S. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body.
- rash, itching or hives on the skin.
- you are breast feeding.

Check with your doctor if you:

- have liver or kidney problems
- have a fever or an infection
- experience numbness, tingling, prickling sensations, sensitivity to touch or muscle weakness
- have heart problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

ERIBULIN DR. REDDY'S 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. It may also cause future 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 DR. REDDY'S.

ERIBULIN DR. REDDY'S should not be used during breastfeeding because of the possibility of risk to the child.

Important information about some of the ingredients of ERIBULIN DR. REDDY'S

This medicinal product contains small amounts of ethanol (alcohol), less than 0.1 mL in a vial.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ERIBULIN DR. REDDY'S.

4. How am I given ERIBULIN DR. REDDY'S?

How much will be given

- ERIBULIN DR. REDDY'S will be given to you by a doctor or nurse as an injection into a vein, usually over a period of

2- 5 minutes, but this may take longer. 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 DR. REDDY'S is 1.4mg/m², but this may be adjusted by your doctor based on your blood test results or other factors.

How often will you be given ERIBULIN DR. REDDY'S?

- ERIBULIN DR. REDDY'S is usually given on Days 1 and 8 of every 21-day cycle. 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. Your doctor will determine how many cycles of treatment you should receive.
- If you have any further questions about the use of this product, ask your doctor.

5. What should I know while using ERIBULIN DR. REDDY'S

Things you must do

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking ERIBULIN DR. REDDY'S, tell your doctor immediately.

Things you must not do

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ERIBULIN DR. REDDY'S affects you.

ERIBULIN DR. REDDY'S may cause side effects such as tiredness (very common) and dizziness (common).

Do not drive or use machinery if you feel tired or dizzy.

Looking after your medicine

Storage

Keep out of reach and sight of children.

Do not use ERIBULIN DR. REDDY'S after the expiry date which is stated on the carton and the vial. The expiry date refers to the last day of the month.

ERIBULIN DR. REDDY'S will be stored in a pharmacy or in the ward of a hospital.

and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Decrease in the number of white blood cells or red blood cells • Nausea, vomiting, constipation, diarrhoea • Tiredness or weakness • Fever • Loss of appetite, weight loss • Pain in the joints, muscles, back or limb extremities • Numbness, tingling or prickling sensations in the ends of your limbs • Headache • Hair loss • Difficulty breathing, cough • Decrease in the number of platelets (which may result in bruising or taking longer to stop bleeding) or lymphocytes (based on blood tests) • Infection with fever, chills, pneumonia • Fast heart rate, flushing • Vertigo, dizziness • Increased production of tears, conjunctivitis (redness and soreness of the surface of the eye), nose bleeds • Dehydration, dry mouth, oral thrush, cold sores, indigestion, heartburn, abdominal pain or swelling • Swelling of soft tissues or mucosal tissues, pains, (in particular chest, back and bone pain), muscle spasm or weakness • Mouth, respiratory and urinary tract infections, painful urination. • Sore throat, red, sore or runny nose, flu-like symptoms, throat pain • Liver function test abnormalities, altered level of sugar, bilirubin, phosphates, potassium, calcium or magnesium in the blood • Abnormal sensations of touch • Inability to sleep, depression, changed sense of taste 	<p>Speak to your doctor, if you have any of these less serious side effects and they worry you.</p>

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor

<ul style="list-style-type: none"> • Rash, itching, swelling and numbness of the hand and feet, nail problems, dry or red skin. • Excessive sweating (including night sweats) • Ringing in the ears • Blood clots in the lungs • Shingles. • Mouth ulcers. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 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 allergic reaction. • Blood clots, including in the lungs. • Kidney failure, blood or protein in the urine • Widespread inflammation of the lungs which may lead to scarring • Inflammation of the pancreas • Mouth ulcers • Rapid swelling of an area of the skin. • A serious disorder of blood clotting resulting in the widespread formation of blood clots and internal bleeding 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed above may also occur in some people.

Reporting side effects

After you have received ERIBULIN DR. REDDY'S for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ERIBULIN DR. REDDY'S contains

Active ingredient	Eribulin mesilate
Other ingredients	Ethanol Sodium Hydroxide Water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What ERIBULIN DR. REDDY'S looks like

ERIBULIN DR. REDDY'S is 1mg/ 2ml is clear colourless solution free from visible particulate matter presented in 5 mL,

(AUST R 390346).

Who distributes ERIBULIN DR. REDDY'S

Dr Reddy's Laboratories (Australia) Pty Ltd

Level 3, 390 St Kilda Road

Melbourne, VIC, 3004

Toll Free Number: 1800 733 39703

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