

# RILTARED 25 (Erlotinib Film-Coated Tablets 25mg)

# RILTARED 100 (Erlotinib Film-Coated Tablets 100mg)

# RILTARED 150 (Erlotinib Film-Coated Tablets 150mg)

Contains active ingredient Erlotinib Hydrochloride (25mg, 100mg, 150mg as Erlotinib)

## What is in this leaflet

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### 1. What Riltared is used for

Riltared contains the active ingredient erlotinib hydrochloride

Riltared is indicated for adults. This medicine can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations. It can also be prescribed if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

Riltared is also used in combination with gemcitabine for the treatment of pancreatic cancer.

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

### 2. How Riltared works

As a targeted cancer treatment, Riltared targets a specific protein on the surface of the cancer cells called EGFR/ HER1 (epidermal growth factor receptor 1). It slows or blocks the activity of EGFR and may cause the cancer cells to die, with potentially less damage to normal cells. However, the way Riltared works to treat cancer is not fully known.

### 3. Before you use Riltared

#### - When you must not use it

#### Do not take Riltared if:

1. you have had an allergic reaction to Riltared or any ingredients listed at the end of this leaflet

2. the package is torn or shows signs of tampering.
3. the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Riltared, talk to your doctor.

#### *Use in children*

Do not give Riltared to children. Safety and effectiveness in patients less than 18 years of age have not been established.

#### - Before you start to use it

Your doctor must know about all the following before you start to take Riltared.

Tell your doctor if:

#### 1. you are pregnant or plan to become pregnant.

Riltared may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Riltared while you are pregnant.

If you are a woman who could become pregnant, use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet.

If you become pregnant while you are being treated with Riltared, tell your doctor immediately.

#### 2. you are breast-feeding or plan to breast-feed.

It is not known whether erlotinib passes into breast milk. It is not recommended that you breast-feed while taking Riltared and for at least 2 weeks after the final dose.

#### 3. you have liver problems.

It is not known whether Riltared has a different effect if your liver is not functioning normally.

#### 4. you have kidney problems

#### 5. you have a history of stomach ulcers or inflammation of the bowel wall

#### 6. you are allergic to any other

#### medicines, foods, dyes or preservatives

#### 7. you cannot tolerate lactose

If you have not told your doctor about any of the above, tell them before you start taking Riltared.

#### - Taking other medicines

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

Some medicines may interfere with Riltared. These medicines include:

- antacids, medicines used to treat heartburn and indigestion
- ciprofloxacin, a medicine used to treat bacterial infection
- corticosteroids, a group of medicines used to treat inflammation
- erythromycin, a medicine used to treat bacterial infection
- H2 antagonists, a group of medicines used to treat stomach ulcers or reflux
- ketoconazole, a medicine used to treat fungal infection
- midazolam, a medicine used to induce drowsiness before an operation
- non-steroidal anti-inflammatory medicines (NSAIDs), a group of medicines commonly used as pain killers
- statins, a group of medicines used to lower cholesterol
- omeprazole, a medicine used for indigestion or stomach ulcers
- rifampicin and rifabutin, medicines used to treat bacterial infection
- other medicines used to treat cancer

There are some medicines that may still be taken with Riltared but may require close supervision by your doctor. These medicines include:

- warfarin, a medicine used to thin the blood

Your doctor will need to regularly monitor you with blood tests. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Riltared.

In addition, grapefruit and grapefruit juice have an effect on how Riltared

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works. Do not eat grapefruit or drink grapefruit juice while on treatment with Riltared, except under the care of your doctor.

#### 4. How to use Riltared

##### - How much to use

Take Riltared exactly as your doctor has prescribed.

Your doctor will tell you how many Riltared tablets to take each day.

For non-small-cell lung cancer, the usual dose is one 150 mg tablet each day.

For pancreatic cancer, given in combination with gemcitabine, the usual dose is one 100 mg tablet each day.

##### - When to use it

Swallow the tablets whole with a glass of water. Do not chew the tablets.

Take Riltared tablet at least 1 hour before you eat or at least 2 hours after you have eaten.

Do not take Riltared with food.

##### - How long to use it

The duration of treatment with Riltared varies, depending on the nature of your illness and your individual response to the treatment.

Continue taking Riltared until your doctor tells you to stop.

##### - If you forget to use it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time. If you are not sure what to do, ask your doctor or pharmacist.

##### - If you use too much (overdose)

Contact your doctor or pharmacist immediately.

You may have increased side effects and your doctor may interrupt your treatment.

#### 5. While you are using it

##### - Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Riltared.

Tell your doctor if you become pregnant while taking Riltared.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

##### - Things you must not do

**Do not stop taking Riltared or change the dose without first checking with your doctor.**

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Riltared to anyone else even if they have the same condition as you.

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

Smoking may affect how well Riltared works for you. If you smoke, you should stop smoking before starting treatment with Riltared. Talk with your doctor about how to quit smoking. If you continue to smoke, you should talk to your doctor before taking Riltared.

##### - Things to be careful of

It is very unlikely that Riltared will affect your ability to drive or use machines.

Be careful driving or operating machinery until you know how Riltared affects you.

#### 6. Side effects

Riltared helps people with non-small cell lung cancer and pancreatic cancer but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**The most common side effects in patients who took Riltared were generally mild to moderate rash and diarrhea. You may also have other changes in your skin.**

The rash from Riltared therapy may appear on your upper body or face. Typically rash occurs within 8 days of starting treatment, but it may occur any time during treatment with Riltared. The rash is not an allergic reaction. It may look like acne or dry skin. It is not acne.

Some suggestions to prevent rash are early use of alcohol-free moisturizer, avoidance of direct sunlight exposure and use a high-factor sunscreen whenever you are outdoors. However, talk to your doctor if a rash occurs.

Hair and nail changes have also been seen with Riltared, but mostly are non-serious.

Typically, diarrhea may develop within 12 days of starting Riltared. Diarrhoea is manageable with rehydration, Riltared dose adjustment and medication as per your doctor's recommendation. Therefore, talk to your doctor if diarrhoea occurs.

Please see the Riltared full prescribing information for complete safety information. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor immediately if you have these signs or symptoms:**

- New or worsening skin rash
- Serious or ongoing diarrhoea, nausea, loss of appetite, or vomiting
- New or worsening shortness of breath or cough
- Eye irritation

Tell your doctor if you notice anything

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else that is making you feel unwell.

**You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).**

## 7. Storage and Disposal of Riltared

### Storage

Keep your tablets in their container until it is time to take them.

If you take the tablets out of their container they may not keep well.

Keep Riltared in a place where the temperature stays below 30°C.

Keep Riltared where young children cannot reach it.

### - Disposal

If your doctor tells you to stop taking Riltared, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

## 8. Product Description

RILTARED is available in three strengths: 25 mg, 100 mg and 150 mg. Each tablet strengths comes in packs of 30 tablets.

### - What it looks like

- Riltared 25 mg tablets are White to off white film coated round tablets with 'E' de-bossed on one side and plain on other side
- Riltared 100 mg tablets are White to off white film coated round tablets with 'E' de-bossed on one side and '100' on other side
- Riltared 150 mg tablets are White to ff white film coated round tablets with 'E' de-bossed on one side and '150' on other side.

### - Ingredients

#### - **Active ingredient**

- Erlotinib hydrochloride

#### - **Inactive ingredients**

- lactose monohydrate
- cellulose microcrystalline
- sodium starch glycolate type A

- sodium lauryl sulfate

- magnesium stearate

The tablets have a film-coating which contains:

- hypromellose
- hydroxypropylcellulose
- macrogol
- titanium dioxide

### - MAL number

Riltared (Erlotinib tablets 25 mg) –

XXXX

Riltared (Erlotinib tablets 100 mg) -

XXXX

Riltared (Erlotinib tablets 150 mg) –

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## 9. Manufacturer

Dr. Reddy's Laboratories Ltd,  
Formulation Unit -VII,  
Plot No, P1 to P9, Phase III,  
VSEZ, Duvvada,  
Visakhapatnam District -530046,  
Andhra Pradesh, India.

## 10. Product Registration Holder

Dr. Reddy's Laboratories Malaysia  
Sdn. Bhd.  
Unit 10-06, Level 10, Menara MBMR  
No. 1, Jalan Syed Putra,  
58000 Kuala Lumpur Malaysia

## 11. Date of revision

11/04/22

## Serial Number

NPRA (R2) 21/118