

Redlyna film-coated Tablets

Linagliptin 5mg

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What REDLYNA is used for

Redlyna is used for 'type 2 diabetes' in adults, if the disease cannot be adequately controlled with diet and exercise alone.

It is important to keep following the advice about diet and exercise that you have been given by your doctor or nurse.

How REDLYNA works

Redlyna contains the active substance linagliptin which belongs to a group of medicines called "oral anti-diabetics". Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

Before you take REDLYNA

-When you must not take it

- if you are allergic to linagliptin or any of the other ingredients of this medicine

-Before you start to take it

Talk to your doctor, pharmacist or nurse before taking Redlyna if you:

- have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). Redlyna should not be used to treat these conditions.
- have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood.
- have or have had a disease of the pancreas.

If you have symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain), you should consult your doctor.

If you encounter blistering of the skin it

may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Redlyna.

Children and adolescents

REDLYNA is not recommended for use in children or adolescents under 18 years.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is unknown if Redlyna is harmful to the unborn child. Therefore, it is preferable to avoid using Redlyna if you are pregnant.

It is not known if Redlyna passes into human breast milk. A decision must be made by your doctor whether to discontinue breast-feeding or to discontinue/abstain from Redlyna therapy.

Driving and using machines

There is no data available on the effects of Redlyna on ability to drive and use machines.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor if you are using medicines containing any of the following active substances:

- Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.

How to take REDLYNA

-How much to take

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Redlyna is one 5 mg tablet once a day.

-When to take it

Try to take the tablet at the same time each day.

You can take Redlyna with or without food.

-How long to take it

Do not stop taking Redlyna without first consulting your doctor. Your blood sugar levels may increase when you stop taking Redlyna.

-If you forget to take it

- If you forget to take a dose of Redlyna, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

-If you have taken too much (overdose)

If you take more Redlyna than you should, talk to a doctor immediately.

While you are taking REDLYNA

-Things you must do

Always follow your doctor's instructions carefully.

-Things you must not do

- Do not give REDLYNA to anyone else, even if they have the same condition as you.
- Do not use REDLYNA to treat any other medical complaints unless your doctor tells you to.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some symptoms need immediate medical attention. You should stop taking Redlyna and see your doctor immediately if you experience the following symptoms of low blood sugar: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion (hypoglycaemia).

Some patients have experienced allergic reactions (hypersensitivity; frequency uncommon, may affect up to 1 in 100 people) while taking Redlyna alone for the treatment of diabetes, which may be serious. Some patients experienced rash (frequency uncommon), hives (urticaria; frequency rare, may affect up to 1 in 1000 people), and swelling of the face, lips, tongue, and throat that may cause

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difficulty in breathing or swallowing (angioedema; frequency rare). If you experience any of the signs of illness mentioned above, stop taking Redlyna and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency uncommon, may affect up to 1 in 100 people) while taking Redlyna alone for the treatment of diabetes.

STOP taking Redlyna and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

Some patients have had the following side effects while taking Redlyna alone for the treatment of diabetes:

- Common: level of lipase in the blood increased.
- Uncommon: inflamed nose or throat (nasopharyngitis), cough, level of amylase in the blood increased.
- Rare: blistering of skin (bullous pemphigoid).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of REDLYNA

-Storage

- 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 blister after EXP. The expiry date refers to the last day of that month.
- Store below 30°C

-Disposal

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.

Product description

What it looks like

Light red, round, biconvex, bevel-edged, film coated tablets debossed 'Y' (logo) on one side and '5' on the other side. Pack Size: Two blisters containing 15 tablets each are packed into an outer carton with a pack insert.

Ingredients

Each film-coated tablet contains 50 mg of Linagliptin

Inactive ingredients: Mannitol USP (Pearlitol SD 200), Copovidone NF (Kollidon VA 64), Corn Starch NF (B700), Magnesium Stearate NF (From Vegetable source), Opadry Brown 03F565091

MAL number:

xxxxx

Manufacturer

Dr. Reddy's Laboratories Limited
FTO - SEZ Process Unit – 01,
Survey No: 57 to 59, 60, 62 & 72,
Sector No: 9 - 14 and 17 - 20
Devunipalavalasa (Village),
Ranasthalam (Mandal),
Srikakulam (District),
Andhra Pradesh - 532409, India.

Product Registration Holder

Dr. Reddy's Laboratories Malaysia Sdn. Bhd.
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Malaysia

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