NOVARTIS

JALRA 50 mg, tablet

Vildagliptin 50 mg per tablet

PATIENT INFORMATION LEAFLET

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JALRA 50 mg

Vildagliptin 50 mg

Contains Sugar (Lactose)

Read all of this leaflet carefully before you start taking JALRA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- JALRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this Leaflet

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

1. What JALRA is and what it is used for

Each JALRA tablet contains 50 mg of the active substance vildagliptin.

JALRA is a medicine used to treat patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

JALRA works by making the pancreas produce insulin and less glucagon. JALRA helps to control your blood sugar level.

Your doctor has prescribed JALRA in combination with other antidiabetics depending on your condition.

It is important that you continue to follow the diet and/or exercise advised for you, whilst you are on treatment with JALRA.

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

2. What you need to know before you take JALRA

Follow all instructions given to you by your doctor or pharmacist carefully.

Do not take JALRA:

- If you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of JALRA.
- If you have liver problems.

Warnings and special precautions

Take special care with JALRA:

- If you are suffering from heart failure, your doctor will decide whether or not to prescribe JALRA depending on the degree of your condition.
- JALRA is not a substitute for insulin. You should therefore not receive JALRA for the treatment of type I diabetes.
- If you experience joint pain, sometimes severe.
- If you experience rash or areas of peeling skin or blisters

If any of these apply to you, tell your doctor before you take JALRA.

Your doctor should ensure the following:

- your blood and urine should be tested for sugar regularly
- your liver function should be checked:

  - at start of treatment
  - every 3 months during the first year of treatment and regularly thereafter

If your doctor told you to stop your treatment with JALRA because of liver problems, you should never start taking JALRA again.

Children:

There is no information available on the use of JALRA in children (less than 18 years). The use of JALRA in these patients is therefore not recommended.

Other medicines and JALRA:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of JALRA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice

JALRA with food and drink:

JALRA can be taken with or without a meal.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of JALRA in pregnancy and breastfeeding has not been established.

Tell your doctor if you are, you think you might be or are planning to become pregnant. Your doctor will discuss with you the potential risk of taking JALRA during pregnancy.

Driving and using machines:

JALRA may cause dizziness.

If you experience dizziness while taking JALRA, you should avoid driving vehicles or using machines.

JALRA contains lactose:

JALRA contains an ingredient called lactose (milk sugar). If you have severe lactose intolerance eg, galactosaemia, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking JALRA.

HOW TO TAKE JALRA

Follow all instructions given to you by your doctor and pharmacist carefully. Do not take more JALRA than your doctor has prescribed. Do not share medicines prescribed for you with others.

How much JALRA to take:

Your doctor has prescribed JALRA in combination with other antidiabetics if one medicine alone is not sufficient to control your blood sugar level.

Do not share medicines prescribed for you with any other person.

Always take JALRA exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose of JALRA is 50 mg once a day (taken in the morning) or 50 mg twice a day (one tablet in the morning and in the evening).

The tablets should be swallowed whole with a glass of water.

Continue taking JALRA every day for as long as your doctor tells you. You may have to stay on the treatment for a long period of time. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If your doctor has told you to stop your treatment with JALRA because of liver problems you should never start taking JALRA again.

If you have questions about how long to take JALRA, talk to your doctor.

If you take more JALRA than you should:

If you have accidentally taken too many JALRA tablets, or if someone else has used your medicine tell your doctor or pharmacist straight away. You may need medical attention. Show them the pack, if possible. If neither is available, go to the nearest hospital or poison centre.

If you forget to take JALRA:

If you forget to take JALRA, take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the dose you missed.
Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

JALRA can have side effects. Not all side effects reported for JALRA are included in this leaflet. Should your general health worsen while taking JALRA, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may occur whilst taking JALRA:

Some symptoms need immediate medical attention:
You should stop taking JALRA and see your doctor immediately if you experience the following symptoms:

- Swollen face, tongue, lips or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called ‘angioedema’).
- Yellow skin and eyes, nausea, loss of appetite, light-coloured urine (possible symptoms of liver problems).

- Severe upper stomach pain (possible sign of inflamed pancreas).

Other side effects:

Frequent: Trembling, headache, dizziness, weakness, nausea, decreased blood glucose, heartburn, constipation, swollen legs, chills , low level of glucose (sugar) in the blood, excessive sweating

Less frequent: Diarrhoea, flatulence, itchy rash, (localised) areas of peeling of skin or blisters, joint pains.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of JALRA.

5. How to store JALRA

- Store at or below 30 °C in the original package. Protect from moisture.
- Do not remove blister from carton until required for use.
- Do not use after the expiry date shown on the box.
- Do not use any JALRA pack that is damaged or shows signs of tampering.
- Keep all medicines out of the reach and sight of children.

6. Content of the pack and other information

What JALRA contains:

What JALRA looks like and contents of the pack

JALRA is a white to light yellowish, round, flat, bevelled edged tablet. One side is debossed with "NVR", and the other side with "FB".

JALRA is packed in 28 or 56 tablets in PA/Al/PVC (polyamide / aluminium / polyvinylchloride) blisters with an aluminium foil backing.

Holder of certificate of registration:

Novartis South Africa (Pty) Ltd.

Magwa crescent west,

Waterfall City

Jukskei view

Johannesburg

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