NOVARTIS

JALRAMET 50 mg/850 mg tablet

JALRAMET 50 mg/1 000 mg tablet

Vildagliptin 50 mg per tablet

Metformin hydrochloride 850 mg or 1000 mg per tablet

Patient Information Leaflet

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JALRAMET 50 / 850 mg

JALRAMET 50 / 1000 mg

Vildagliptin 50 mg / Metformin 850 mg or Vildagliptin 50 mg / Metformin 1000 mg

Read all of this leaflet carefully before you start taking JALRAMET

- 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.
- JALRAMET 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 JALRAMET is and what it is used for

JALRAMET is available as tablets. Each tablet of JALRAMET contains two active substances: vildagliptin and metformin hydrochloride.

Two dosage strengths are available:

- One tablet containing 50 mg vildagliptin and 850 mg metformin hydrochloride.
- One tablet containing 50 mg vildagliptin and 1 000 mg metformin hydrochloride.

JALRAMET is a medicine used to treat type 2 diabetes.

JALRAMET helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.

Your doctor has prescribed JALRAMET for you if your blood sugar level has been controlled when you take vildagliptin and metformin hydrochloride as separate tablets and at the same dosages.

JALRAMET can also be prescribed for you in combination with a sulphonylurea if your blood sugar level has been controlled on vildagliptin, metformin hydrochloride and a sulphonylurea as separate tablets and the same dosages.

JALRAMET can also be prescribed for you as add-on to insulin if your blood sugar levels has been controlled on a stable dose of insulin plus vildagliptin and metformin hydrochloride as separate tablets and the same dosages.

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

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

2. What you need to know before you take JALRAMET

Do not take JALRAMET:

- if you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or any of the other ingredients of JALRAMET,
- if you have severely reduced kidney function (this will be decided by your doctor),
- if you have recently had a heart attack, have a heart failure, or if you have serious problems with your blood circulation, including shock or breathing difficulties,
- if you have or have had serious complications of your diabetes, such as diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea or vomiting) or diabetic coma,
- if you have a problem with your liver,
- if you drink alcohol excessively (whether every day or only from time to time).

Warnings and precautions

Take special care with JALRAMET:

- JALRAMET is not a substitute for insulin. You should therefore neither receive JALRAMET for the treatment of type 1 diabetes (i.e. your body does not produce insulin at all) nor for the treatment of a condition called diabetic ketoacidosis.
- If you experience one or more of the following symptoms: feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, dizziness, irregular heartbeat, or rapid breathing. Patients taking metformin (one of the active substances of JALRAMET) have experienced a condition called lactic acidosis (too much lactic acid in the blood). This is more likely to occur in patients whose kidneys are not working properly.
- If you experience nausea, sweating, weakness, dizziness, trembling, headache (signs of low level of sugar (glucose) in the blood) which could be due to lack of food, too strenuous exercise without sufficient food intake, excessive alcohol intake (usually not with JALRAMET alone).
- If you are going to have a contrast X-ray (a specific type of X-ray involving an injectable dye). You will need to temporarily stop taking JALRAMET before or at the time of and for a few days after the procedure.

If you experience some of these symptoms, stop taking JALRAMET and consult a doctor immediately:

- If you are going to have an operation under general anaesthetic, you may need to stop taking JALRAMET for a couple of days before and after the procedure. Your doctor will decide when you must stop and when to restart your treatment with JALRAMET.
- If you drink alcohol excessively, either every day or only from time to time.
- If you have a liver disease.

- If your diabetes control worsens suddenly or if you have abnormal blood sugar tests or feel ill, contact your doctor.
- If you experience joint pain, sometimes severe.

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

Monitoring your JALRAMET treatment:

Your doctor should ensure the following:

- your blood and urine should be tested for sugar regularly
- your kidney function should be checked:
    - at start of treatment
    - at least once a year whilst you are on treatment
    - more often if you are elderly or if your kidney function starts to decrease
- 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 JALRAMET because of liver problems, you should never start taking JALRAMET again.
- a general blood test at least once a year
- a check of vitamin B_{12} levels at least every two to three years

JALRAMET and older people:

Your doctor will check how well your kidneys work. You may need more frequent checks if you have kidney problems.

Children and Adolescents

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

Other medicines and JALRAMET

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor. This is particularly important with the following medicines:

• certain medicines used to treat infections (e.g. vancomycin, trimethoprim)

• certain medicines used to treat inflammation (e.g. corticosteroids)

• certain medicines used to treat high blood pressure (e.g. amiloride, triamterene, nifedipine, enalapril, losartan, diuretics)

• certain medicines used to treat irregular heartbeat (e.g. digoxin, quinidine)

• certain medicines used to reduce pain (e.g. morphine, diclofenac)

• certain medicines used to treat stomach disorders (e.g. cimetidine, ranitidine)

• certain medicines used to treat some psychiatric disorders (e.g. phenothiazine)

• certain medicines used to treat thyroid disorders

• oral contraceptives, certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g. oestrogen)

Do not drink alcohol excessively or take medicines that contain alcohol whilst taking JALRAMET tablets.

Taking JALRAMET with food and drink

It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established.

You should not use JALRAMET if you are pregnant or breastfeeding your infant.

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.

Your doctor will discuss with you the potential risk of taking JALRAMET during pregnancy.

Driving and using machines

If you feel dizzy while taking JALRAMET, do not drive vehicles or use any tools or machines until you are well enough to do so again.

3. How to take JALRAMET

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

You should check with your doctor or pharmacist if you are unsure.

If you get the impression that the effect of JALRAMET is too strong or too weak, tell your doctor or pharmacist.

How much JALRAMET to take

Your doctor will tell you exactly how many tablets of JALRAMET to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

If you have reduced kidney function, your doctor may prescribe a lower dose. Also, if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Do not take more JALRAMET than your doctor has prescribed.

When and how to take JALRAMET

JALRAMET should be taken in the morning and/or in the evening. It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.

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

How long to take JALRAMET

Continue taking JALRAMET every day for as long as your doctor tells you. You may have to stay on this 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 tells you to stop your treatment with JALRAMET because of liver problems, you should never start taking JALRAMET again.

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

If you take more JALRAMET than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take JALRAMET

It is advisable to take your medicine at the same time each day. If you forget to take JALRAMET, take it as soon as you remember and take your next dose at its 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 the forgotten tablet.

4. Possible side effects

JALRAMET can have side effects.

Not all side effects reported for JALRAMET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking JALRAMET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called 'angioedema').

These are all very serious side effects. If you have them, you have had a serious allergic reaction to JALRAMET. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, unexplained weight loss, dizziness, irregular heartbeat, or rapid breathing (symptoms of lactic acidosis). If this happens you must stop taking JALRAMET and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.
- Yellow skin and eyes, nausea, loss of appetite, dark urine (symptoms of liver problems).
- Severe upper stomach pain (possible sign of inflamed pancreas).
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as ‘hypoglycaemia’).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Nausea, vomiting, diarrhoea, abdominal pain, loss of appetite.
- Dizziness, headache, involuntary trembling, metallic taste in the mouth.
- Chills, heartburn, decreased blood glucose, weakness, excessive sweating.
- Constipation, swollen hands, ankle or feet (oedema), flatulence.
- Skin reddening, itching, areas of peeling skin or blisters, and joint pains.
- Decrease in the level of vitamin B_{12} in the blood (anaemia).
- Abnormal liver function test results.

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 JALRAMET.

5. How to store JALRAMET

- 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 JALRAMET pack that is damaged or shows signs of tampering.
- Keep out of the reach of children.

6. Content of the pack and other information

What JALRAMET contains

Each JALRAMET 50 / 850 mg tablet contains 50 mg vildagliptin and 850 mg metformin hydrochloride.
Each JALRAMET 50 / 1000 mg tablet contains 50 mg vildagliptin and 1 000 mg metformin hydrochloride.

The other ingredients are:

Hydroxypropyl cellulose, hypromellose, iron oxide yellow, magnesium stearate, polyethylene glycol, talc, titanium dioxide.

What JALRAMET looks like and contents of the pack

JALRAMET 50 mg/850 mg: yellow, ovaloid bevelled edge, film-coated tablet imprinted with "NVR" on one side and "SEH" on the other side.

JALRAMET 50 mg/1 000 mg: dark yellow, ovaloid bevelled edge, film-coated tablet imprinted with "NVR" on one side and "FLO" on the other side.

JALRAMET is supplied in packs of 10, 30, 60, 120, 180 or 360's tablets in PA/AI/PVC (polyamide/aluminium/polyvinylchloride) blisters with an aluminium foil backing. Not all pack sizes may be marketed.

The blister foil is imprinted with the proprietary name, company name, batch number and expiry date.

Holder of certificate of registration

Novartis South Africa (Pty) Ltd.

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Waterfall City

Jukskei view

Johannesburg

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Access to the corresponding Professional Information

The corresponding PI can be obtained from the SAHPRA website.