B. PACKAGE LEAFLET

Package leaflet: Information for the user

Jalra 50 mg tablets
vildagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Jalra is and what it is used for

The active substance of Jalra, vildagliptin, belongs to a group of medicines called "oral antidiabetics".

Jalra is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Jalra either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How Jalra works
Jalra works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. What you need to know before you take Jalra

Do not take Jalra:
- if you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to vildagliptin or any of the other ingredients of Jalra, do not take this medicine and talk to your doctor.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Jalra.
- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition

called diabetic ketoacidosis.
- if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with Jalra in order to avoid low blood glucose [hypoglycaemia]).
- if you have moderate or severe kidney disease (you will need to take a lower dose of Jalra).
- if you are on dialysis.
- if you have liver disease.
- if you suffer from heart failure.
- if you have or have had a disease of the pancreas.

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Jalra. Should these occur, you should promptly consult your doctor.

A test to determine your liver function will be performed before the start of Jalra treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

Children and adolescents
The use of Jalra in children and adolescents up to 18 years of age is not recommended.

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

Your doctor may wish to alter your dose of Jalra if you are taking other medicines such as:
- thiazides or other diuretics (also called water tablets)
- corticosteroids(generally used to treat inflammation)
- thyroid medicines
- certain medicines affecting the nervous system.

Pregnancy and breast-feeding
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.

You should not use Jalra during pregnancy. It is not known if Jalra passes into breast milk. You should not use Jalra if you are breast-feeding or plan to breast-feed.

Driving and using machines
If you feel dizzy while taking Jalra, do not drive or use machines.

Jalra contains lactose
Jalra contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Jalra contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Jalra

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist

if you are not sure.

How much to take and when
The amount of Jalra people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Jalra to take. The maximum daily dose is 100 mg.

The usual dose of Jalra is either:
- 50 mg daily taken as one dose in the morning if you are taking Jalra with another medicine called a sulphonylurea.

- 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Jalra alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin.

- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Jalra
- Swallow the tablets whole with some water.

How long to take Jalra
- Take Jalra every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Jalra than you should
If you take too many Jalra tablets, or if someone else has taken your medicine, **talk to your doctor straight away.** Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Jalra
If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Jalra
Do not stop taking Jalra unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

4. Possible 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 Jalra and see your doctor immediately if you experience the following side effects:
- Angioedema (rare: may affect up to 1 in 1 000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulties breathing, sudden onset rash or hives, which may indicate a reaction called “angioedema”.
- Liver disease (hepatitis) (frequency not known): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
- Inflammation of the pancreas (pancreatitis) (rare: may affect up to 1 in 1 000 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects

Some patients have had the following side effects while taking Jalra:
- Very common (may affect more than 1 in 10 people): sore throat, runny nose, fever.
- Common (may affect up to 1 in 10 people): itchy rash, trembling, headache, dizziness, muscle pain, joint pain, constipation, swollen hands, ankles or feet (oedema), excessive sweating, vomiting, pain in and around the stomach (abdominal pain), diarrhoea, heartburn, nausea (feeling sick), blurred vision.
- Uncommon (may affect up to 1 in 100 people): weight increase, chills, weakness, sexual dysfunction, joint pain, low blood glucose, flatulence.
- Rare (may affect up to 1 in 1 000 people): inflammation of the pancreas.

Since this product has been marketed, the following side effects have also been reported:
- Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jalra

- 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 blister and the carton after "EXP". The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- Do not use any Jalra pack that is damaged or shows signs of tampering.
- 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.

6. Contents of the pack and other information

What Jalra contains
- The active substance is vildagliptin.
  Each tablet contains 50 mg vildagliptin.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, sodium starch glycolate (type A) and magnesium stearate.

What Jalra looks like and contents of the pack
Jalra 50 mg tablets are round, white to light yellowish and flat, with "NVR" on one side and "FB" on the other.

Jalra 50 mg tablets are available in packs containing 7, 14, 28, 30, 56, 60, 90, 112, 180 or 336 tablets and in multipacks comprising 3 cartons, each containing 112 tablets.

Not all pack sizes may be marketed in your country.

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu