

What is it and how is it used?

Jalra belongs to a group of medicines called “oral antidiabetics”.

Jalra is used to treat 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.

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.

Jalra works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level.

Your doctor will prescribe Jalra together with certain other antidiabetic medicines which you will already be taking to control diabetes, if one medicine alone is not enough to control your blood sugar level.

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.

What do you have to consider before using it?

Do not take Jalra:

- if you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of Jalra (see section 6: Further information). 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.

Take special care with Jalra:

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

- if you have type 1 diabetes (i.e. your body does not produce insulin).
- if you have moderate or severe kidney disease.
- if you are on dialysis.
- if you have liver disease.
- if you suffer from heart failure.

If you have previously taken vildagliptin but had to stop taking it because of side effects (liver disease), you should not take this product.

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.

The use of Jalra in children and adolescents is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your doctor may wish to alter your dose of Jalra if you are taking other medicines (such as medicines so called thiazides, corticosteroids, thyroid products and certain products affecting the nervous system).

Taking Jalra with food and drink

You can take Jalra with or without food.

Pregnancy and breast-feeding

Women who are pregnant or plan to become pregnant should consult their doctor before taking Jalra.

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.

Important information about some of the ingredients of Jalra

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.

How is it used?

Always take Jalra exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take

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 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, or

100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Jalra with another medicine called metformin or a glitazone.

Your doctor will prescribe Jalra together with another medicine to control your blood sugar level.

When and how to take Jalra

Take this medicine in the morning or in the morning and evening.

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.

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.

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.

What are possible side effects?

Like all medicines, Jalra can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

very common: affects more than 1 patient in 10

common: affects 1 to 10 patients in 100

uncommon: affects 1 to 10 patients in 1,000

rare: affects 1 to 10 patients in 10,000

very rare: affects less than 1 patient in 10,000

not known: frequency cannot be estimated from the available data.

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): 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) (rare): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).

Other side effects

Some patients have had the following side effects while taking Jalra and metformin:

Common: Trembling, headache, dizziness, nausea, low blood glucose

Uncommon: Tiredness

Some patients have had the following side effects while taking Jalra and a sulphonylurea:

Common: Trembling, headache, dizziness, weakness, low blood glucose

Uncommon: Constipation

Very rare: Sore throat, runny nose

Some patients have had the following side effects while taking Jalra and a glitazone:

Common: Weight increase, swollen hands, ankle or feet (oedema)

Uncommon: Headache, weakness, low blood glucose

Some patients have had the following side effects while taking Jalra alone:

Common: Dizziness

Uncommon: Headache, constipation, swollen hands, ankle or feet (oedema), joint pain, low blood glucose

Very rare: Sore throat, runny nose, fever

Since this product has been marketed, the following side effects have also been reported (frequency not known):

Itchy rash

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

How should it be stored?

Keep out of the reach and sight of children.

Do not use Jalra after the expiry date which is stated on the blister and the carton. 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.