LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Jivolar
(sitagliptin phosphate monohydrate, metformin hydrochloride)

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Summary Public Assessment Report

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sitagliptin phosphate monohydrate, metformin hydrochloride

film-coated tablet, 50 mg/850 mg and 50 mg/1000 mg, respectively

This is a summary of the public assessment report (PAR) for Jivolar. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jivolar and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Janumet.

Jivolar contains two different medicines called sitagliptin and metformin.
- sitagliptin belongs to a class of medicines called DPP-4 blocking agents (dipeptidyl peptidase-4 blocking agents)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by the body.

Along with diet and exercise, this medicine helps lower the blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

'Type 2 diabetes mellitus' is a condition in which the body does not make enough insulin, and the insulin that the body produces does not work as well as it should. The body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

How does Jivolar work?

Sitagliptin
By selectively blocking the DPP-4 enzyme, sitagliptin increases the levels of two known active incretin hormones, *glucagon-like peptide-1 (GLP-1)* and *glucose-dependent insulinotropic polypeptide (GIP)*. The incretin hormones *GLP-1* and *GIP* are involved in the regulation of blood sugar. When blood sugar (glucose) levels are low, insulin release is not elevated and glucagon release is not blocked. When blood glucose levels are normal or elevated, *GLP-1* and *GIP* increase insulin production and its release from pancreas. *GLP-1* also lowers the release of glucagon hormone from pancreas, leading to reduced glucose production in the liver.

Metformin
Metformin is a biguanide which lowers both basal blood glucose (no food intake) and blood glucose after having a meal. It does not stimulate insulin secretion and therefore does not produce low blood sugar (hypoglycaemia).
Metformin acts by reducing glucose production in liver, by increasing insulin sensitivity in muscle (for improved glucose use and uptake of cells) and by delaying glucose uptake in the intestine.

Metformin stimulates glycogen synthesis in cells by acting on glycogen synthase. Metformin increases the transport capacity of specific types of glucose transporters on the cell surface (*GLUT-1* and *GLUT-4*).

How is Jivolar used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Jivolar have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Janumet. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Jivolar?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Jivolar approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Janumet, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Jivolar?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Jivolar

The full PAR for Jivolar can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Jivolar, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-02.