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## Zynquista (*sotagliflozin*)

An overview of Zynquista and why it is authorised in the EU

### What is Zynquista and what is it used for?

Zynquista is a diabetes medicine used with insulin to treat adults with type 1 diabetes. It is used in overweight patients (body mass index of at least 27 kg/m<sup>2</sup>) when insulin on its own does not control blood sugar well enough.

Zynquista contains the active substance sotagliflozin.

### How is Zynquista used?

Zynquista is available as 200 mg tablets. The recommended dose is 1 tablet once a day before the first meal of the day. After 3 months, the doctor may increase the dose to 2 tablets once a day if additional blood sugar control is needed.

The medicine should be used with precautions to reduce the risk of diabetic ketoacidosis (a serious complication of diabetes with high levels of ketones in the blood).

Zynquista can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in managing type 1 diabetes. For more information about using Zynquista, see the package leaflet or contact your doctor or pharmacist.

### How does Zynquista work?

In type 1 diabetes, the body does not make enough insulin to control the amount of glucose (sugar) in the blood, resulting in high levels of glucose in the blood.

The active substance in Zynquista, sotagliflozin, blocks the action of two proteins known as glucose transporters (SGLT1 and SGLT2) which are found in the intestine and the kidneys. By blocking SGLT1 in the intestine, sotagliflozin delays the absorption of glucose into the blood after a meal.

In the kidneys, sotagliflozin blocks SGLT2 involved in stopping glucose in the bloodstream from being passed out into the urine. As result, sotagliflozin causes the kidney to pass out more glucose in the urine, thereby reducing the levels of glucose in the blood.



## What benefits of Zynquista have been shown in studies?

Zynquista was found effective at controlling blood glucose levels in 3 main studies in patients with type 1 diabetes.

In two of these studies, involving a total of 1,575 patients, two doses of Zynquista (200 and 400 mg) were compared with placebo when given in addition to insulin. The main measure of effectiveness was the level of glycosylated haemoglobin (HbA1c), which indicates how well blood glucose is controlled. Adding Zynquista 200 or 400 mg to insulin led to a reduction in HbA1c levels of about 0.4 percentage points after 24 weeks of treatment, compared with almost no reduction in HbA1c levels after adding placebo to insulin.

In the third study involving 1,405 patients, only the higher dose of Zynquista (400 mg) was studied. The main measure of effectiveness was the proportion of patients who had HbA1c levels less than 7.0% and no episodes of severe hypoglycaemia (low blood glucose levels) or diabetic ketoacidosis. On this basis, Zynquista 400 mg added to insulin was effective in around 29% of patients, compared with 15% of patients receiving placebo plus insulin.

## What are the risks associated with Zynquista?

The most common side effect with Zynquista (which may affect more than 1 in 10 people) is genital infection in women. Other common side effects (which may affect up to 1 in 10 people) include diabetic ketoacidosis, diarrhoea and genital infection in men.

For the full list of side effects and restrictions with Zynquista, see the package leaflet.

## Why is Zynquista authorised in the EU?

Zynquista, taken together with insulin, is effective in lowering blood glucose levels in patients with type 1 diabetes whose blood sugar is not controlled well enough with insulin alone. In addition, patients treated with the medicine have beneficial reductions in weight and blood pressure.

Zynquista's common side effects, which are related to the way the medicine works, such as increased genital infections, are considered manageable and similar to those of other medicines of a similar class. However, since Zynquista increases the risk of diabetic ketoacidosis considerably in patients with type 1 diabetes, it is recommended only in overweight and obese patients who are expected to benefit most from treatment. In addition, precautions have been recommended to reduce the risk of diabetic ketoacidosis.

The European Medicines Agency decided that Zynquista's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Zynquista will provide information on measures to reduce the risk of diabetic ketoacidosis, including a patient alert card and guide for patients and their carers, as well as a guide for healthcare professionals, including a prescriber's checklist. The company will also conduct a study to estimate the frequency of diabetic ketoacidosis in patients with type 1 diabetes treated with the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zynquista have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zynquista are continuously monitored. Side effects reported with Zynquista are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Zynquista**

Zynquista received a marketing authorisation valid throughout the EU on 26 April 2019.

Further information on Zynquista can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/zynquista](http://ema.europa.eu/medicines/human/EPAR/zynquista).

This overview was last updated in 04-2019.

Medicinal Product no longer authorised