27 April 2018
EMA/251728/2018
EMEA/H/C/004057/II/0013

Withdrawal of application for a change to the marketing authorisation for Qtern (saxagliptin / dapagliflozin)

On 3 April 2018, AstraZeneca AB officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wished to withdraw its application to extend the approved use of Qtern in the treatment of type 2 diabetes.

What is Qtern?

Qtern is a diabetes medicine that is already used in adults with type 2 diabetes to improve control of their blood glucose (sugar) levels. It contains the active substances saxagliptin and dapagliflozin.

Qtern is used in patients in whom treatment with a combination of several other diabetes medicines (metformin and/or a sulfonylurea plus either saxagliptin or dapagliflozin) is not working well enough. It is also used to replace saxagliptin and dapagliflozin given as separate tablets.

Qtern has been authorised in the EU since July 2016.

Further information on Qtern's current uses can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

What was Qtern expected to be used for?

Qtern was also expected to be used earlier in treatment when metformin with or without a sulfonylurea is not working well enough and adding another oral medicine (like one of the ingredients of Qtern) is unlikely to help.

How does Qtern work?

One of its active substances, dapagliflozin, blocks the effect of a protein in the kidney called SGLT2 that retains glucose in the body. Blocking this causes more glucose to be removed in the urine, thereby reducing the levels of glucose in the blood. The other active substance, saxagliptin, blocks the breakdown of hormones called incretins. By increasing levels of incretin hormones in the blood, saxagliptin stimulates the pancreas to produce more insulin when blood glucose levels are high. It also indirectly reduces the amount of glucose made by the liver.

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As a result of the action of both active substances, the blood glucose is reduced and this helps to control type 2 diabetes.

What did the company present to support its application?

The applicant presented data from two main studies involving over 2,500 patients with type 2 diabetes that was not adequately controlled with metformin-based treatment.

In one study in patients whose blood sugar was not controlled by metformin alone, adding treatment with dapagliflozin or with saxagliptin plus dapagliflozin (the ingredients of Qtern) was compared with adding treatment with a sulfonylurea. In the other study, the effects of adding treatment with Qtern were compared with those of adding insulin in patients whose blood sugar was not adequately controlled with metformin with our without a sulfonylurea.

In both studies, the main measure of effectiveness was the change in the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it was withdrawing the application because of objections expressed during the initial evaluation.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Qtern.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Qtern for its authorised use in the treatment of type 2 diabetes?

There are no consequences for the use of Qtern in its authorised indication.