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Rxulti (*brexpiprazole*)

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

What is Rxulti and what is it used for?

Rxulti is an antipsychotic medicine used to treat schizophrenia in adults. Schizophrenia is a mental illness with symptoms such as delusions, disorganised thinking and speech, suspiciousness and hallucinations (seeing, hearing or feeling things that are not there).

Rxulti contains the active substance brexpiprazole.

How is Rxulti used?

Rxulti is available as tablets (0.25, 0.5, 1, 2, 3 and 4 mg) to be taken by mouth. The recommended starting dose is 1 mg once daily for the first 4 days. The dose is then increased to 2 mg once daily taken on days 5, 6 and 7 and increased again if necessary to 4 mg once daily on day 8. The recommended dose is between 2 and 4 mg daily and 4 mg is the maximum recommended daily dose.

In patients with moderately or severely reduced kidney or liver function the dose should be limited to 3 mg once a day. In patients taking certain other medicines the doctor may need to adjust the dose of Rxulti.

Rxulti can only be obtained with a prescription.

For more information about using Rxulti, see the package leaflet or contact your doctor or pharmacist.

How does Rxulti work?

The active substance in Rxulti, brexpiprazole, is thought to attach to receptors (targets) in the brain for several neurotransmitters (substances nerve cells use to communicate with neighbouring cells) including dopamine, serotonin and noradrenaline. These neurotransmitters play a role in schizophrenia, and by acting at their receptors, brexpiprazole helps normalise the activity of the brain and reduce symptoms of schizophrenia.

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What benefits of Rxulti have been shown in studies?

Rxulti has been shown to be effective at reducing symptoms of schizophrenia in 5 main studies involving 2,404 adults with schizophrenia, although there were some inconsistent results.

In 4 of the studies, Rxulti was compared with placebo (a dummy treatment) and the main measure of effectiveness was reduction of symptoms on a standard rating scale called PANSS (positive and negative syndrome scale) which ranges from a minimum of 30 (no symptoms) to a maximum of 210 (severest symptoms) after 6 weeks of treatment.

In the first study, the PANSS score fell by around 21 and 20 points with 2 mg and 4 mg Rxulti respectively compared with 12 points with placebo.

In the second study, the PANSS score fell by around 20 points with 4 mg Rxulti compared with 14 points with placebo. However, there was not considered to be a difference between 2 mg Rxulti and placebo.

In the third study, the PANSS score fell by around 15 points with 2 mg Rxulti compared with 8 points with placebo and there was not considered to be a difference between 4 mg Rxulti and placebo.

In the fourth study, doses of Rxulti ranging from 2 to 4 mg were compared with placebo and with another antipsychotic medicine, quetiapine. After 6 weeks, there was not considered to be a difference between Rxulti and placebo. Results at 2, 3 and 4 weeks showed improvement in symptoms with Rxulti compared with placebo. Quetiapine showed improvement in symptoms at 6 weeks compared with placebo.

The fifth study compared Rxulti with placebo over one year, and the main measure of effectiveness was the risk of relapse (worsening of symptoms). Rxulti was more effective than placebo in preventing relapse: after a year, 14% of patients taking Rxulti had relapsed compared with 38% of patients taking placebo.

What are the risks associated with Rxulti?

The most common side effects with Rxulti are akathisia (a constant urge to move, which may affect around 6 in 100 people) and weight gain (which may affect around 4 in 100 people).

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

Why is Rxulti authorised in the EU?

Rxulti was effective at reducing symptoms of schizophrenia. Although the reductions in symptoms were not consistent across the studies, this often occurs in studies with antipsychotic medicines and the European Medicines Agency considered that the effects were sufficient to conclude that Rxulti is beneficial to patients with schizophrenia. Based on available data, it is not possible to say how Rxulti compares with other medicines of the same type. The safety profile of Rxulti is similar to other antipsychotic medicines. The Agency decided that Rxulti'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 Rxulti?

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

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

Other information about Rxulti

Rxulti received a marketing authorisation valid throughout the EU on 26 July 2018.

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

This overview was last updated in 07-2018.