EMA/120302/2025
EMEA/H/C/003841

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 and adolescents from 13 years of age. 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 to be taken by mouth once a day. The recommended starting dose depends on the age of the patient; the dose is then progressively increased based on the patient's response and how well treatment is tolerated. In patients with kidney or liver problems and in those 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.

What benefits of Rxulti have been shown in studies?

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

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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.

In adolescents, Rxulti was found to be effective at reducing symptoms of schizophrenia in two studies. One short-term study involved 315 adolescents and compared the effect of Rxulti, aripiprazole (another medicine for schizophrenia) and placebo on symptoms of schizophrenia. After 6 weeks of treatment, the PANSS score fell by an average of around 23 points in patients taking Rxulti at doses ranging from 2 to 4 mg, around 24 points in patients taking aripiprazole, and around 17 points in patients taking placebo.

Another ongoing long-term study showed an overall decrease of PANSS score in patients taking Rxulti, with the effect maintained for up to 24 months of treatment. Rxulti was not compared with placebo or another treatment in this study.

What are the risks associated with Rxulti?

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

The most common side effects with Rxulti in adults (which may affect up to 1 in 10 people) include akathisia (a constant urge to move) and weight gain; in adolescents, these include nausea (feeling sick), sleepiness and akathisia.

Why is Rxulti authorised in the EU?

Rxulti was shown to be effective at reducing symptoms of schizophrenia in adults and adolescents. Although the reductions in symptoms in adults were not consistent across the studies, this often occurs in studies with antipsychotic medicines and the European Medicines Agency considered that the effects observed were sufficient to conclude that Rxulti is beneficial to patients with schizophrenia. Although there was some uncertainty on the benefits of Rxulti in the short term in younger patients (below 15 years of age), its beneficial effect in this age group is supported by the long-term data and by the fact that the medicine was shown to behave in the body in the same way across age groups. The safety

profile of Rxulti is manageable and similar among adults and adolescents, and in line with that of other antipsychotic medicines. The Agency therefore 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 03-2025.