

Package leaflet: Information for the user

RXULTI 0.25 mg film-coated tablets

RXULTI 0.5 mg film-coated tablets

RXULTI 1 mg film-coated tablets

RXULTI 2 mg film-coated tablets

RXULTI 3 mg film-coated tablets

RXULTI 4 mg film-coated tablets

brexpiprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What RXULTI is and what it is used for
2. What you need to know before you take RXULTI
3. How to take RXULTI
4. Possible side effects
5. How to store RXULTI
6. Contents of the pack and other information

1. What RXULTI is and what it is used for

RXULTI contains the active substance brexpiprazole, which belongs to a group of medicines called antipsychotics.

It is used to treat schizophrenia in adult and adolescent patients aged 13 years and older - a disease with symptoms such as hearing, seeing or sensing things - which are not there, suspiciousness, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

RXULTI can help to keep the symptoms under control and to prevent relapse as you continue treatment.

2. What you need to know before you take RXULTI

Do not take RXULTI

- if you are allergic to brexpiprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor immediately if you

- experience a combination of fever, sweating, faster breathing, muscle stiffness and drowsiness or sleepiness (may be signs of neuroleptic malignant syndrome).
- are having any thoughts or feelings about hurting yourself or to commit suicide. Suicidal thoughts and behaviours are more likely at the beginning of the treatment.

- or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse-control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
- have any difficulty in swallowing.
- have or had a low number of white blood cells in your blood and get a fever or any other sign of infection. This may for example be the case if other medicines lowered your white blood cells in the past. Your doctor will regularly measure the white blood cells in your blood to minimise the risk for diseases called leukopenia, neutropenia and agranulocytosis. It is important that you get your blood checked regularly, as this may be fatal. Your doctor will stop the treatment immediately if the white blood cells in your blood are too low.

Talk to your doctor or pharmacist before taking RXULTI, or during treatment if you have

- or had heart problems or a history of stroke, especially if you know that you have other risks factors for stroke.
- dementia (loss of memory and other mental abilities) especially if you are elderly.
- irregular heart beat or if someone else in your family has a history of irregular heart beat (including so called QT prolongation seen with ECG monitoring). Please inform your doctor if you take any other medicines that are known to prolong the QT interval.
- an electrolyte imbalance (problems with the amount of salts in your blood).
- or had low or high blood pressure.
- a history of blood clots, or if someone else in your family has a history of blood clots, as medicines for schizophrenia have been associated with formation of blood clots.
- or had dizziness on standing up due to a drop in your blood pressure, which may cause fainting.
- or had problems with your movements called extrapyramidal symptoms (EPS) in the past. These may include jerky movements, spasms, restlessness or slow movements.
- ever experienced or start to experience restlessness and inability to sit still. These symptoms may occur early during treatment. Tell your doctor if this happens.
- diabetes or risk factors for diabetes (e.g., obesity, or someone else in your family has diabetes). Your doctor will need to check your blood sugar regularly since it may be increased by this medicine. Signs of high blood sugar level are excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak.
- a history of seizures (fits) or epilepsy.
- ever inhaled food, stomach acid, or saliva into your lungs causing a disease called aspiration pneumonia.
- increased levels of the hormone prolactin or have a tumour in your pituitary gland.

Weight gain

This medicine may cause significant weight gain, which may affect your health. Your doctor will therefore check your weight and your fats in the blood regularly.

Body temperature

While taking RXULTI you should avoid getting over-heated or dehydrated. Do not over-exercise and drink plenty of water.

Children and adolescents

This medicine must not be taken by children under 13 years of age. The safety and effectiveness in these patients were not evaluated.

Other medicines and RXULTI

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

RXULTI may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine to keep your blood pressure under control.

Receiving RXULTI with some medicines may mean the doctor will need to change your dose of RXULTI or the other medicines. It is especially important to mention the following medicines to your doctor:

- medicines to correct heart rhythm (such as quinidine),
- antidepressants or herbal remedies used to treat depression and anxiety (such as fluoxetine, paroxetine, St. John's Wort),
- antifungal medicines (such as ketoconazole, itraconazole),
- certain medicines to treat HIV infection (such as ritonavir),
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenobarbital),
- antibiotics to treat bacterial infections (such as clarithromycin),
- certain antibiotics used to treat tuberculosis (such as rifampicin),
- medicines like moxifloxacin (an antibiotic) known to prolong your QT interval (an important measurement of your heart function in an electrocardiogram [ECG]),
- medicines changing the salt concentrations in your body (causing a so-called electrolyte imbalance), for example water tablets such as furosemide, bendroflumethiazide.
- medicines increasing an enzyme called creatine phosphokinase (CPK), for example medicines known as statins like simvastatin to reduce cholesterol levels in your blood,
- medicines having an effect on the central nervous system like codeine (a cough suppressant) or morphine (used to treat severe pain).

RXULTI with food and alcohol

RXULTI can be taken with or without food. Alcohol should be avoided as it can influence how this medicine works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take RXULTI during your pregnancy. If you are of childbearing age, you should use effective contraception while taking RXULTI. Babies of mothers who take this medicine during the last three months of their pregnancy may show the following symptoms: shaking, muscle stiffness and/or muscle weakness, sleepiness, restlessness, breathing problems and difficulty in feeding. If your baby has any of these symptoms, you should contact your doctor.

Talk to your doctor about the best way to feed your baby if you are taking RXULTI. Your doctor will consider the benefit of the therapy for you and the benefit of breast-feeding for your baby.

Driving and using machines

There is a chance that the medicine could affect your ability to drive and use machines. Please check that you are not feeling dizzy or sleepy before you start driving or handling machines. Do not drive or use any tools or machines until you know that this medicine does not affect you in a negative way.

RXULTI contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take RXULTI

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your medicine will usually be given to you in increasing doses as follows:

For adults:

- for the first 4 days take one 1 mg film-coated tablet per day,
- from day 5 to day 7 take two 1 mg film-coated tablets per day,
- from day 8 onwards take one film-coated tablet of the strength prescribed by your doctor each day.

Paediatric patients:

- for the first 4 days take one 0.5 mg film-coated tablet per day,
- from day 5 to day 7 take one 1 mg film-coated tablet per day,
- from day 8 onwards take one film-coated tablet of the strength prescribed by your doctor each day.

However, your doctor may prescribe a lower or higher dose to a maximum of 4 mg once a day.

It does not matter whether you take your medicine with or without food.

If you were taking other medicine to treat schizophrenia before starting RXULTI, your doctor will decide whether to stop the other medicine gradually or immediately and how to adjust the dose of RXULTI. Your doctor will also inform you how to act if you switch from RXULTI to other medicine.

Patients with kidney problems

If you have kidney problems, your doctor may adjust your dose of this medicine.

Patients with liver problems

If you have liver problems, your doctor may adjust your dose of this medicine.

If you take more RXULTI than you should

If you have taken more RXULTI than your prescribed dose, contact your doctor or your local hospital immediately. Remember to take the medicine pack with you so that it is clear what you have taken.

If you forget to take RXULTI

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose. If you miss two or more doses, contact your doctor.

If you stop taking RXULTI

If you stop taking this medicine, you will lose the effects of the medicine. Even if you feel better, do not alter or stop your daily dose of RXULTI unless told to do so by your doctor as your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During treatment you may experience these serious side effects that require urgent medical attention. Tell your doctor **immediately** if you have:

- thoughts or feelings about hurting yourself or to commit suicide or a suicide attempt (*uncommon side effect* - may affect up to 1 in 100 people).
- combination of fever, sweating, muscle stiffness, and drowsiness or sleepiness. These can be the signs of the so-called neuroleptic malignant syndrome (it is not known how many people are affected).
- irregularities in heart rhythm that may be due to abnormal nerve impulses in the heart, abnormal readings during heart examination (ECG), QT prolongation - it is not known how many people are affected.

- symptoms related to blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing (*uncommon side effect* - may affect up to 1 in 100 people).

Other side effects

Very common side effects (may affect more than 1 in 10 people):

- during blood tests your doctor may find higher amounts of prolactin in your blood.

Common side effects (may affect up to 1 in 10 people):

- rash,
- weight gain,
- akathisia (an uncomfortable feeling of inner restlessness and a compelling need to move constantly),
- dizziness,
- shaking,
- feeling sleepy,
- diarrhoea,
- nausea,
- pain in the upper abdomen,
- back pain,
- pain in arms or legs or both,
- during blood tests your doctor may find higher amounts of creatine kinase (also called creatine phosphokinase) in your blood (enzyme important for muscle function).

Uncommon side effects (may affect up to 1 in 100 people):

- allergic reaction (e.g., swelling in the mouth, tongue, face and throat, itching, hives),
- parkinsonism - medical condition with many various symptoms which include decreased or slow movements, slowness of thought, jerks when bending the limbs (cogwheel rigidity), shuffling steps, shaking, little or no facial expression, muscle stiffness, drooling,
- dizziness on standing up due to a drop in your blood pressure, which may cause fainting,
- cough,
- tooth decay or cavities (dental caries),
- flatulence,
- muscle pain,
- higher blood pressure,
- during blood tests your doctor may find higher amounts of triglycerides in your blood,
- during blood tests your doctor may find increases in liver enzymes.

Other side effects (it is not known how many people are affected):

- seizure,
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis),
- withdrawal symptoms in new-born babies if the mother has taken this medicine during pregnancy.
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - strong impulse to gamble excessively despite serious personal or family consequences
 - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
 - uncontrollable excessive shopping
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviours; he/she will discuss ways of managing or reducing the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store RXULTI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and on the outer carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What RXULTI film-coated tablets contain

- The active substance is brexpiprazole.
Each film-coated tablet contains 0.25 mg brexpiprazole.
Each film-coated tablet contains 0.5 mg brexpiprazole.
Each film-coated tablet contains 1 mg brexpiprazole.
Each film-coated tablet contains 2 mg brexpiprazole.
Each film-coated tablet contains 3 mg brexpiprazole.
Each film-coated tablet contains 4 mg brexpiprazole.

- The other ingredients are:

Tablet core:

Lactose monohydrate (see section 2 “RXULTI contains lactose”), maize starch, microcrystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylcellulose, magnesium stearate, purified water.

Tablet coat:

Hypromellose (E 464), talc (E 553b), titanium dioxide (E 171).

RXULTI 0.25 mg film-coated tablets

Iron oxide (E 172) (yellow, red, black)

RXULTI 0.5 mg film-coated tablets

Iron oxide (E 172) (yellow, red)

RXULTI 1 mg film-coated tablets

Iron oxide (E 172) (yellow)

RXULTI 2 mg film-coated tablets

Iron oxide (E 172) (yellow, black)

RXULTI 3 mg film-coated tablets

Iron oxide (E 172) (red, black)

What RXULTI film-coated tablets look like and contents of the pack

RXULTI 0.25 mg film-coated tablets

Light brown, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 0.25 on one side.

RXULTI 0.5 mg film-coated tablets

Light orange, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 0.5 on one side.

RXULTI 1 mg film-coated tablets

Light yellow, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 1 on one side.

RXULTI 2 mg film-coated tablets

Light green, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 2 on one side.

RXULTI 3 mg film-coated tablets

Light purple, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 3 on one side.

RXULTI 4 mg film-coated tablets

White, round, 6 mm in diameter, shallow convex and bevel-edged, debossed with BRX and 4 on one side.

RXULTI film-coated tablets are supplied in Aluminium/PVC blisters containing 10, 28 or 56 film-coated tablets.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<https://www.ema.europa.eu/>