REXULTI® film-coated tablets

Brexipiprazole (0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg)

What is in this leaflet

What REXULTI is used for

REXULTI film-coated film-coated tablets contain the active substance brexpiprazole.

REXULTI is a prescription medicine used to treat adults aged 18 and older who suffer from:

- Major depressive disorder (MDD): REXULTI is used in addition to your antidepressant medicine, when your doctor determines that the antidepressant alone did not adequately treat your depression.
- Schizophrenia: REXULTI is used to treat symptoms of schizophrenia. Your doctor may continue to prescribe REXULTI even when you are feeling better in order to prevent the re-emergence of symptoms.
- to treat agitation associated with Alzheimer's dementia (AAD).

How REXULTI works

REXULTI belongs to a group of medicines called antipsychotic agents. REXULTI helps to correct a chemical imbalance in the brain which is associated with schizophrenia. In Depression REXULTI is used as adjunct treatment to add to the action of antidepressants to restore the chemical imbalance in the brain that is thought to occur in depression.

You and your doctor have decided on REXULTI to help relieve the symptoms of your condition. Although REXULTI cannot cure schizophrenia, it can help to keep the symptoms of schizophrenia under control and reduce the risk of relapse as you continue treatment. In depression REXULTI can help to reduce symptoms in patients that do not respond optimally to current treatment with antidepressants.

Before you use REXULTI

When you must not use it

Do not take REXULTI: if you are allergic to brexpiprazole or any of the other ingredients of this medicine (listed in Section 8).

Pregnancy and lactation

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

The effect of REXULTI on your unborn baby is not known. Using REXULTI in the last trimester of pregnancy may cause muscle movement problems, medicine withdrawal symptoms, or both of these in your newborn.

It is not known if brexpiprazole passes into breast milk. You and your doctor should decide if you will take REXULTI during breastfeeding.

Before you start use it

Warnings and precautions

Various medicines of the group to which REXULTI belongs have been associated with an increased rate of death when used in elderly patients with dementia.

Before taking REXULTI, tell your doctor if you:

- are an elderly person with dementia (loss of memory and other mental abilities);
- have or are at risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking REXULTI and regularly during treatment.;
- have high levels of cholesterol, triglycerides, LDL-cholesterol, or low levels of HDL cholesterol;
- have or had seizures (convulsions);
- have or had low or high blood pressure;
- have or had heart problems or a stroke;
- have liver or kidney problems;
- have difficulties with swallowing

REXULTI film-coated tablets contain lactose

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

Taking other medicines

Other medicines and REXULTI

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Your doctor can tell you if it is safe to take REXULTI with your other medicines. Do not start or stop any medicines while taking REXULTI without talking to your doctor first.

Taking REXULTI film-coated tablets with other medicines may require changes to your dose of REXULTI film-coated tablets. It is especially important to mention to your doctor if you take any of the following:

- Blood pressure-lowering medicines,
- Medicines to correct heart rhythm (e.g. quinidine),

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- Antidepressants (e.g. paroxetine, fluoxetine) or herbal remedy for depression (e.g. St John's Wort),
- Medicines to treat fungal infections (e.g. ketoconazole),
- Antibiotic medicines (e.g. rifampicin, clarithromycin),
- Certain medicines to treat HIV infection (e.g. ritonavir),
- Medicines to treat epilepsy (e.g. carbamazepine)

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with REXULTI film-coated tablets, you should see your doctor.

How to use REXULTI

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

Try to take your REXULTI film-coated tablets at the same time each day. Swallow your film-coated tablets whole with water. Do not split, chew, or crush the film-coated tablets.

How much to use

Major Depressive Disorder:
The recommended dose in Major Depressive Disorder is 2 mg once daily. In order to reduce the risk of side effects the dose is increased gradually to reach the recommended dose.

The usual starting dose is 0.5 mg or 1 mg once daily for the first week, which is then increased gradually up to the target recommended dose of 2 mg.

Schizophrenia:
The recommended dose in Schizophrenia is 2-4 mg once daily. In order to reduce the risk of side effects the dose is increased gradually to reach the recommended dose.

The usual starting dose is 1 mg once daily for the first 4 days. This is increased to 2 mg from Day 5 through 7. From Day 8 the dose may be increased up to 4 mg once a day.

The maximum recommended daily dosage is 4 mg.

The recommended dose for the continuation of treatment to prevent re-emergence of symptoms is 2-4 mg once daily.

Treatment of Agitation Associated with Alzheimer's Dementia

The recommended starting dosage for Rexulti for the treatment of AAD is 0.5mg taken orally once daily on Days 1 to 7. The dosage should be titrated on Days 8 through 14 to 1mg, and on Day 15 to 2mg. The recommended target dose is 2mg once daily. After at least 14 days at 2mg once daily, the dose can be increased to the maximum recommended daily dose of 3mg, if clinically warranted.

Periodically reassess to determine the continued need for maintenance treatment and appropriate dosage.

Your doctor will advise on the best dose for you.

- *When to use it*

  Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue using *REXULTI* for as long as your doctor recommends.

If you take more REXULTI than you should
If you have taken too many REXULTI film-coated tablets, contact your doctor right away even if there are no symptoms. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

If you forget to take REXULTI
Take the missed dose as soon as you remember. If you are close to your next dose, just skip the missed dose and take your next dose at your regular time. Do not take a double dose to make up for a forgotten dose.

If you stop taking REXULTI
If you stop taking REXULTI you may experience re-emergence of your symptoms. It is no recommended to stop taking REXULTI without prior consultation with your doctor

REXULTI with food and alcohol
REXULTI can be taken regardless of meals.
Alcohol should be avoided

Children and adolescents

Do not use this medicine in children and adolescents under 18 years of age. The safety and effectiveness in these patients was not evaluated.

While you are using it

- tell your doctor if you have any of these symptoms of high blood sugar: feel very thirsty, feel sick to your stomach, need to urinate more than usual, feel very hungry, feel weak or tired, feel confused, or your breath smells fruity;
- tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat;
- tell your doctor immediately it you experience involuntary, irregular muscle movements, especially in the face, such as tongue and lips;
  tell your doctor immediately if you are having any thoughts or

feelings about harming yourself. Suicidal thoughts and behaviour have been reporte3ehaveng antipsychotic treatment;
- avoid getting over-heated or dehydrated. Do not over-exercise and drink plenty of water.
- tell your doctor immediately if you have problems with impulse control (i.e. urge to gamble, spend money, and eat or other urges or sex addiction).

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *REXULTI* to anyone else, even if they have the same symptoms or condition as you.

Driving and using machines

Do not drive a car, operate machinery, or do other dangerous activities until you know how REXULTI affects you. REXULTI may make you feel drowsy.

Side effects

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

Talk to your doctor or pharmacist if you experience:

- Increases in blood sugar level and/or symptoms of high blood sugar (e.g increased thirst, increased hunger, and frequent urination)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during sleep (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

Adjunct MDD

Adverse reactions reported in 2% or more of treated patients:

Vision blurred (blurry vision), constipation, dry mouth, fatigue, sore throat, cough, stuffy or runny nose, weight increased, increased appetite, inner reestlessness, dizziness, sleepiness, tremor (trembling, shaking), anxiety, insomnia, restlessness.

Adverse Reactions Reported in less than 2% of treated Patients:

Unusual heartbeat, abnormal blinking or eyelid tic, toothache, increased production of saliva, urinary tract infection, increased blood prolactin (increased levels of a hormone called "prolactin"), decreased blood cortisol (decreased levels of a hormone called "cortisol"), increase in a liver enzyme called aspartate aminotransferase, muscle spasms, tension, night sweats, high blood pressure and extrapyramidal disorder (involuntory movments, slow and impaired voluntory movements, and changes in muscle tone).

Schizophrenia

Adverse reactions reported in 2% or more of treated patients:

Diarrhea, Nausea, weight increased, increased blood Creatine Phosphokinase (increased levels of an enzyme called "Creatine Phosphokinase"), back pain, inner restlessness, dizziness and tremor (trembling, shaking).

Adverse Reactions Reported in less than 2% of treated Patients:

Upper abdominal pain, dental caries, uncomfortable feeling in the stomach, pain, high blood pressure, increased levels of fats called triglycerides in the blood, pain in arms and legs, muscle pain, drowsiness, cough, rash and extrapyramidal disorder (involuntory movments, slow and impaired voluntory movements, and changes in muscle tone).

Agitation in Alzheimers dementia

-Adverse reactions reported in 2% more of treated patients:

cold symptoms, urinary tract infection, insomnia, dizziness, headache, somnolence.

Both MDD, Schizophrenia and AAD

Other side effect may also occur with low frequency:

Stroke in elderly people, tardive dyskinesia (uncontrolled body movements), suicidal thoughts and actions, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness which may be a sign of a condition called Neuroleptic Malignant Syndrome (NMS), hyperglycemia (high blood sugar), elevated level of cholesterol, orthostatic hypotension (feeling lightheaded or faint when rising too quickly from a sitting or lying position), seizures (convulsions), difficulty swallowing.

Some people taking REXULTI have had unusual urges, such as gambling, eating that you cannot control (compulsive), compulsive shopping and other compulsive behaviours. If you or your family members notice that you are having unusual urges or behaviors, talk to your doctor.

These are not all the possible side effects of REXULTI. For more information, ask your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to

Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of REXULTI

- Storage

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 carton after EXP. The expiry date refers to the last day of that month.

Store REXULTI below 30°C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

REXULTI 0.25 mg film-coated tablet:

Round, shallow convex and bevel-edged, light brown, debossed with BRX and 0.25 one side

REXULTI 0.5 mg film-coated tablet:

Round, shallow convex and bevel-edged, light orange, debossed with BRX and 0.5 one side

REXULTI 1 mg film-coated tablet:

Round, shallow convex and bevel-edged, light yellow, debossed with BRX and 1 one side

REXULTI 2 mg film-coated tablet:

Round, shallow convex and bevel-edged, light green, debossed with BRX and 2 one side

REXULTI 3 mg film-coated tablet:

Round, shallow convex and bevel-edged, light purple, debossed with BRX and 3 one side

REXULTI 4 mg film-coated tablet:

Round, shallow convex and bevel-edged, white, debossed with BRX and 4 one side

REXULTI film-coated tablets are supplied in blisters packed in cartons containing 28 film-coated tablets.

Not all strengths may be marketed.

- Ingredients

Active ingredient(s):
The active substance is brexpiprazole. Each tablet contains 0.25 mg/ 0.5 mg / 1mg / 2 mg / 3 mg / 4 mg of brexpiprazole

Inactive ingredients:
lactose monohydrate, corn starch, microcrystalline cellulose, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, hypromellose, talc, titanium dioxide, iron oxide red (0.25 mg, 0.5 mg, 3 mg), iron oxide yellow (0.25 mg, 0.5 mg, 1 mg, 2 mg), ferrosoferric oxide (0.25 mg, 2 mg, 3mg).

- *MAL number(s):*

REXULTI 0.25 mg film-coated tablet:

MAL20026042ARZ

REXULTI 0.5 mg film-coated tablet:

MAL20026043ARZ

REXULTI 1 mg film-coated tablet:

MAL20026044ARZ

REXULTI 2 mg film-coated tablet:

MAL20026045ARZ

REXULTI 3 mg film-coated tablet:

MAL20026046ARZ

REXULTI 4 mg film-coated tablet:

MAL20026047ARZ

Manufacturer:

Otsuka Pharmaceutical Co., Ltd.
Second Tokushima Factory,
224-18, Hiraishi Ebisuno,
Kawauchi-cho,Tokushima-shi,
Tokushima 771-0182,Japan

Product Registration Holder:

Lundbeck Malaysia Sdn. Bhd. (1027116-X)
A-05-01, Oasis Square Jalan PJU 1A/7A,
Ara Damansara, 47301 Petaling Jaya,
Selangor Darul Ehsan

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