

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REXULTI?

REXULTI contains the active ingredient brexpiprazole. REXULTI is used to treat adults with schizophrenia and agitation associated with dementia due to Alzheimer's disease (AAD) in patients who are unresponsive to non-pharmacological interventions. For more information, see Section [1. Why am I using REXULTI?](#) in the full CMI.

2. What should I know before I use REXULTI?

Do not use if you have ever had an allergic reaction to REXULTI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use REXULTI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REXULTI and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use REXULTI?

- Your doctor will tell you how much to take each day. It depends on your condition or whether you take any other medicines.
- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.

More instructions can be found in Section [4. How do I use REXULTI?](#) in the full CMI.

5. What should I know while using REXULTI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using REXULTI. • If you become pregnant while taking REXULTI tell your doctor immediately.
Things you should not do	• Do not give REXULTI to anyone else, even if they have the same condition as you. • Do not stop taking REXULTI or lower the dosage without checking with your doctor. If you stop taking REXULTI suddenly, your condition may worsen. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how REXULTI affects you. • REXULTI may cause dizziness, light-headedness, or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	• Tell your doctor if you drink alcohol. • You should avoid alcohol while taking REXULTI as it could magnify the side effects.
Looking after your medicine	• Store it in a cool dry place below 30°C, away from moisture, heat, or sunlight. • Keep REXULTI in the original container, and in safe place where children cannot reach it.

For more information, see Section [5. What should I know while using REXULTI?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: drowsiness, diarrhoea, indigestion, weight increase, shaking, inability to stand or sit still, feeling dizzy or fainting, impulsive behaviours or urges, sleep walking and related behaviours.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

serious allergic reaction; abnormal movements of the tongue, or other uncontrolled movements; sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions; suicidal thoughts and actions or talk about death, suicide, self-harm or harm to others - especially sudden changes in mood, behaviours, thoughts or feelings; swelling, pain or redness in the leg, chest pain or difficulty in breathing. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

REXULTI®

Active ingredient(s): *brexpiprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using REXULTI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REXULTI.**

Where to find information in this leaflet:

1. [Why am I using REXULTI?](#)
2. [What should I know before I use REXULTI?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use REXULTI?](#)
5. [What should I know while using REXULTI?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using REXULTI?

REXULTI contains the active ingredient brexpiprazole.

REXULTI belongs to a group of medicines called antipsychotic agents.

REXULTI is used to treat adults with schizophrenia and agitation associated with dementia in Alzheimer's disease (AAD) in patients who are unresponsive to non-pharmacological intervention.

Schizophrenia is a mental illness characterised by symptoms such as:

- hallucinations; hearing, seeing or sensing things that are not there
- suspiciousness, mistaken beliefs
- incoherent speech and behaviour, emotional flatness.

People with this condition may also feel depressed, guilty, anxious, or tense.

Although REXULTI cannot cure schizophrenia, it can help to keep the symptoms under control and reduce the risk of relapse as you continue treatment. The cause of schizophrenia is not understood.

Alzheimer's disease is a common cause of dementia which leads to a decline in mental ability. Dementia associated with Alzheimer's disease can cause behavioural changes such as agitation and aggression.

Medicines like REXULTI and other similar medicines help to control the symptoms of schizophrenia and AAD through their actions in the brain.

2. What should I know before I use REXULTI?

Warnings

Do not use REXULTI if:

- you are allergic to brexpiprazole, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines (such as medicines of the same class).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions as listed below
- take any medicines including other antipsychotic agents for any other conditions
- have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- dementia (loss of memory or other mental abilities) and you are elderly
- neuroleptic malignant syndrome - a reaction to some medicines with a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma
- tardive dyskinesia - a reaction to some medicines with abnormal movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs
- high or low blood pressure
- rapid heartbeat and a drop in blood pressure when getting up
- problems with your heart or blood vessels, including stroke, "mini" stroke, or family history of heart or blood vessel problems
- heart disorders such as heart failure or ischemic heart disease.
- epilepsy, seizures or fits
- suicidal thoughts or behaviour
- problems with your oesophagus (food pipe/gullet) such as difficulty in swallowing
- high blood sugar or diabetes mellitus or a family history of diabetes or high blood sugar
- high cholesterol, triglycerides, LDL - cholesterol or low levels of HDL-cholesterol
- blood clots, or you have any of the risk factors for developing blood clots mentioned in this leaflet
- past experience with excessive gambling or other compulsive behaviours
- have or had low white blood cell count
- sleep apnoea (a sleep disorder where your breathing is interrupted during sleep).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Prior to starting treatment with REXULTI your doctor will assess you for and treat any reversible factors which might lead to agitation such as pain, infection, delirium.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

REXULTI is not recommended for use during pregnancy. If you need to take REXULTI during your pregnancy, your doctor will discuss the benefits and risks of taking it with you. The effect of REXULTI on your unborn baby is not known. Using REXULTI in the last three months of pregnancy may cause muscle movement problems, medicine withdrawal symptoms or both of these in a newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is recommended that you do not breastfeed while taking REXULTI, as it is not known if REXULTI passes into breast milk and, therefore, there is a possibility that the breastfed baby may be affected.

Blood clots and associated risk factors

Tell your doctor if you have had blood clots, or you have any of the following risk factors for developing blood clots:

- family history of blood clots
- 65 years of age or older
- smoking
- obese
- recent major surgery such as hip or knee replacement
- immobility due to air travel or other reason
- you take oral contraceptives

Use in Children

REXULTI should not be given to children and adolescents under 18 years of age as safety and efficacy has not been established in this age group.

Patients over 65 years

If you are over 65 years of age you may have an increased chance of getting side effects.

Elderly patients with dementia may suffer serious side effects such as stroke, pneumonia, or heart problems. These serious side effects can be life threatening.

Tell your doctor if you are concerned.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with REXULTI and affect how it works.

- medicines and herbal remedies used to treat depression and anxiety (e.g., Saint John's Wort, fluoxetine and paroxetine)
- anticonvulsants used to treat epilepsy or seizures
- medicines used to treat high blood pressure
- medicines used to treat heart rhythm disturbances
- medicines used to treat blood disorders (e.g., ticlopidine)
- medicines used to treat bacterial, fungal or viral infections (e.g., terbinafine and itraconazole).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REXULTI.

4. How do I use REXULTI?

How much to take

- Your doctor or pharmacist will tell you how much you will need to take each day. This will depend on your condition and whether you are taking any other medicines.
- Follow the instructions provided and use REXULTI until your doctor tells you to stop.
- The label put on the carton by the pharmacist will tell you how much you should take. If you take the wrong dose, REXULTI may not work as well as expected and your disease may not improve.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

When to take REXULTI

- Unless your doctor gives you other directions, you should take REXULTI only once a day.
- REXULTI should be taken at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take REXULTI

- REXULTI tablets should be swallowed whole and washed down with a glass of water.
- REXULTI can be taken with or without food.

If you forget to use REXULTI

REXULTI should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- This may increase the chance of you getting an unwanted side effect.
- If you are not sure what to do, ask your doctor or pharmacist.

- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much REXULTI

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Close medical supervision and monitoring is required until you have recovered. You may experience a heart signalling disorder (a condition called QT prolongation) if you take too much REXULTI that will need monitoring. Symptoms may include fainting, palpitations and seizures.

5. What should I know while using REXULTI?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking REXULTI.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking REXULTI.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking REXULTI.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will assess the efficacy of treatment to determine the need for continued treatment and the appropriate dosage.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Call your doctor straight away if you:

- Notice anything that is making you feel unwell
- Notice any side effects as mentioned in this leaflet and they concern you
- Become pregnant while taking REXULTI

Things you should not do

- Do not take REXULTI to treat any other complaints unless your doctor tells you to.
- Do not give REXULTI to anyone else, even if they have the same condition as you.
- Do not stop taking REXULTI or lower the dosage without checking with your doctor.
- If you stop taking REXULTI suddenly, your condition may worsen. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

REXULTI and body temperature

Make sure you keep cool in hot weather and keep warm in cool weather.

REXULTI may affect the way your body reacts to temperature changes. It may prevent sweating, even during heatwaves. You may feel dizzy or faint if you are too hot. To stay cool in hot weather, try to do the following:

- drink plenty of water
- wear light clothing
- spend time in air-conditioned environments (or keep windows open and use electric fans)
- take cool baths or showers and avoid hot baths and saunas
- try to restrict exercise or heavy work to cool parts of the day

Driving or using machines

Be careful before you drive or use any machines or tools until you know how REXULTI affects you.

REXULTI may cause dizziness, light-headedness, or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid drinking alcohol while you are taking REXULTI.

You should avoid alcohol while taking REXULTI as it could magnify the side effects.

Looking after your medicine

- Keep REXULTI in the original container.
- If you take it out of its original container it may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30°C, away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

There is no evidence that REXULTI is addictive.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• drowsiness • diarrhoea • indigestion • weight increase • shaking • inability to stand or sit still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing legs • feeling dizzy or fainting, especially when getting up from a lying or sitting position • impulsive behaviours or urges (including gambling) • sleep walking and related behaviours (including sleep related eating disorder). • strong urge to urinate that doesn't go away or a burning feeling while urinating. If these symptoms occur you should speak to your doctor or healthcare professional.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or rash, itching or hives) • tardive dyskinesia - abnormal movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs • neuroleptic malignant syndrome - sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions • suicidal thoughts and actions or talk about death, suicide, self-	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
• harm or harm to others - pay close attention to any changes, especially sudden changes, in mood, behaviours, irritability, agitation, thoughts or feelings • swelling, pain or redness in the leg, chest pain or difficulty in breathing	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REXULTI contains

Active ingredient (main ingredient)	• brexpiprazole
Other ingredients (inactive ingredients)	• lactose monohydrate • maize starch • microcrystalline cellulose • hypolose • magnesium stearate • OPADRY complete film coating system 03A465005 BROWN • OPADRY complete film coating system 03A430000 ORANGE • OPADRY complete film coating system 03A420002 YELLOW • OPADRY complete film coating system 03A410000 GREEN • OPADRY complete film coating system 03A400000 PURPLE • OPADRY complete film coating system 03A480004 WHITE
Potential allergens	• lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What REXULTI looks like

REXULTI is available in six tablet strengths:

REXULTI 0.25 mg AUST R 273225- Light brown, round, shallow convex, bevel-edged tablet, debossed with BRX and 0.25 on one side*

REXULTI 0.5 mg AUST R 273222 - Light orange, round, shallow convex, bevel-edged tablet, debossed with BRX and 0.5 on one side

REXULTI 1 mg AUST R 273220 - Light yellow, round, shallow convex, bevel-edged tablet, debossed with BRX and 1 on one side

REXULTI 2 mg AUST R 273223 - Light green, round, shallow convex, bevel-edged tablet, debossed with BRX and 2 on one side

REXULTI 3 mg AUST R 273221 - Light purple, round, shallow convex, bevel-edged tablet, debossed with BRX and 3 on one side

REXULTI 4 mg AUST R 273224 - White, round, shallow convex, bevel-edged tablet, debossed with BRX and 4 on one side

*REXULTI 0.25 mg tablet is not marketed.

Who distributes REXULTI

Lundbeck Australia Pty Ltd

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REXULTI is co-marketed by Lundbeck Australia and Otsuka Australia Pharmaceutical:

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This leaflet was prepared in October 2024.