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2. Brexpiprazole

Brexpiprazole

Pronunciation: *breks-PIP-ray-zole***Generic name:** brexpiprazole**Brand name:** [Rexulti](#)**Dosage form:** oral tablet**Drug class:** [Atypical antipsychotics](#)Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Mar 16, 2025.[Uses](#) [Side effects](#) [Before taking](#) [Directions](#) [Dosage](#) [What to avoid](#) [FAQ](#)

What is brexpiprazole?

Brexpiprazole is used to treat major depressive disorder in adults (in addition to other medications), schizophrenia in adults and children aged 13 years and older, and agitation that may happen with dementia due to Alzheimer's disease. It is an oral tablet taken once a day.

Brexpiprazole belongs to the drug class called [atypical antipsychotics](#).

Brexpiprazole first gained FDA approval on July 10, 2015 under the brand name [Rexulti](#). There is a [generic brexpiprazole](#) but it is only approved for adults with depression or schizophrenia. The brand Rexulti has additional approvals for adolescents 13 years and older with schizophrenia and for Alzheimer's disease-related agitation.

Mechanism

Brexpiprazole works by correcting the imbalance of natural chemical messengers (neurotransmitters), such as dopamine and serotonin in the brain. This imbalance is thought to be associated with several psychiatric disorders such as schizophrenia, depression, and agitation associated with Alzheimer's disease.

Brexpiprazole uses

Brexpiprazole is an atypical antipsychotic used:

- along with antidepressant medicines to treat major depressive disorder (MDD) in adults
- to treat schizophrenia in adults and children ages 13 years and older
- to treat agitation that may happen with dementia due to Alzheimer's disease.

Brexpiprazole should not be used as an "as needed" treatment for agitation that may happen with dementia due to Alzheimer's disease.

Clinical trials have not been conducted in children so it is not known if brexpiprazole is safe and effective for the treatment of MDD in children under the age of 18 or for the treatment of schizophrenia in children under 13 years.

Brexpiprazole side effects

The most common side effects of brexpiprazole are:

- weight gain (see [Why does Rexulti cause weight gain?](#) for more information)
- sleepiness
- dizziness
- common cold symptoms
- restlessness or feeling like you need to move (akathisia).

Serious side effects and warnings

Brexpiprazole carries a **Boxed Warning** for an increased risk of death in elderly patients with dementia-related psychosis.

Increased risk of death in elderly people with dementia-related psychosis. Trials have reported medicines like brexpiprazole can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). Brexpiprazole is not approved for dementia-related psychosis **without** agitation that may happen with Alzheimer's disease.

Increased risk of suicidal thoughts and actions. Brexpiprazole and antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. Depression and other mental illnesses are the most important causes of suicidal thoughts and actions.

- Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when brexpiprazole or the antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worsening depression
- new or worsening anxiety
- feeling very agitated or restless
- panic attacks

- trouble sleeping (insomnia)
- new or worsening irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity or talking (mania)
- other unusual changes in behavior or mood.

Other **serious side effects** of brexpiprazole include the following.

Cerebrovascular problems (these involve the blood vessels of the brain), including stroke, in elderly people with dementia-related psychosis that can lead to death.

Neuroleptic malignant syndrome (NMS), which is a rare and life-threatening reaction to antipsychotic drugs. Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS:

- high fever
- stiff muscles
- confusion
- changes in your pulse, blood pressure, heart rate, and breathing
- increased sweating.

Uncontrolled body movements (tardive dyskinesia). Brexpiprazole may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking brexpiprazole. Tardive dyskinesia may also start after you stop taking brexpiprazole.

Brexpiprazole may also cause problems with your metabolism such as:

- **High blood sugar** (hyperglycemia) and diabetes. Increases in blood sugar can happen in some people who take brexpiprazole. Extremely high blood sugar can lead to coma or death. Your healthcare provider should check your blood sugar before you start, or soon after you start brexpiprazole and then regularly during long term treatment with brexpiprazole. Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with brexpiprazole:
 - feel very thirsty
 - feel very hungry
 - feel sick to your stomach
 - need to urinate more than usual
 - feel weak or tired
 - feel confused, or your breath smells fruity
- **Increased fat levels** (cholesterol and triglycerides) in your blood. Your healthcare provider should check the fat levels in your blood before you start, or soon after you start brexpiprazole, and then periodically during treatment with brexpiprazole.

- **Weight gain.** You and your healthcare provider should check your weight before you start and often during treatment with brexpiprazole.

Unusual and uncontrollable (compulsive) urges. Some people taking brexpiprazole have had strong unusual urges, to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges include sexual urges, shopping, and eating or binge eating. If you or your family members notice that you are having new or unusual strong urges or behaviors, talk to your healthcare provider.

Low white blood cell count. Your healthcare provider may do blood tests during the first few months of treatment with brexpiprazole.

Decreased blood pressure (orthostatic hypotension) and fainting. You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position.

Falls. Brexpiprazole may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.

Seizures (convulsions). Brexpiprazole may increase your risk of seizures.

Problems controlling your body temperature so that you feel too warm. See “What should I avoid while taking brexpiprazole?”

Difficulty swallowing that can cause food or liquid to get into your lungs.

Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. See “What should I avoid while taking brexpiprazole?”

Brexpiprazole may **harm an unborn baby**.

These are not all the possible side effects of brexpiprazole. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA1088.

 [Brexpiprazole side effects](#) (more detail)

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Before taking

Do not take brexpiprazole if you are allergic to brexpiprazole, Rexulti, or any inactive ingredient in the tablets.

Before taking brexpiprazole, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had heart problems or a stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar or a family history of diabetes or high blood sugar.
- have or have had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol
- have or have had seizures (convulsions)
- have or have had kidney or liver problems
- have or have had a low white blood cell count
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

Brexpiprazole may harm your unborn baby. Taking brexpiprazole during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. Talk to your healthcare provider about the risk to your unborn baby if you take brexpiprazole during pregnancy.

Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with brexpiprazole.

There is a pregnancy exposure registry for women who are exposed to brexpiprazole during pregnancy. If you become pregnant during treatment with brexpiprazole, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/>.

Breastfeeding

It is not known if brexpiprazole passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with brexpiprazole.

 [Brexpiprazole pregnancy and breastfeeding warnings](#) (more detail)

How should I take brexpiprazole?

Take brexpiprazole exactly as your healthcare provider tells you to take it. Your healthcare provider may change your dose if needed. Do not change the dose or stop taking brexpiprazole without first talking to your healthcare provider.

- Take brexpiprazole 1 time each day.

- Brexpiprazole may be taken with or without food.

i [Brexpiprazole patient tips](#) (more detail)

Brexpiprazole dosing

The dosage of Brexpiprazole varies depending on the condition being treated and the age of the patient.

The dosage may need to be adjusted for moderate to severe liver disease, kidney disease, and interacting medications. See the [brexpiprazole prescribing information](#) for more details.

Note that generic brexpiprazole is only approved for depression and schizophrenia in adults, not for all the uses Rexulti is approved for.

Indication	Form	Starting dosage	Target dosage	Maximum dosage
Major depressive disorder	Rexulti	0.5 or 1 mg daily	2 mg daily	3 mg daily
	Generic brexpiprazole			
Schizophrenia (adults)	Rexulti	1 mg daily	2 to 4 mg daily	4 mg daily
	Generic brexpiprazole			
Schizophrenia (age 13-17 years)	Rexulti	0.5 mg daily	2 to 4 mg daily	4 mg daily
Agitation associated with dementia	Rexulti	0.5 mg daily	2 mg daily	3 mg daily

i [Detailed Brexpiprazole dosage information](#)

What should I avoid while taking brexpiprazole?

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

Do not become too hot or dehydrated during treatment with brexpiprazole.

- Do not exercise too much.
- In hot weather, stay inside in a cool place if possible.
- Stay out of the sun.
- Do not wear too much clothing or heavy clothing.
- Drink plenty of water.

What happens if I take too much brexpiprazole?

If you take too much brexpiprazole, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What other drugs affect brexpiprazole?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Brexpiprazole and other medicines may affect each other causing possible serious side effects. Brexpiprazole may affect the way other medicines work, and other medicines may affect how brexpiprazole works. Especially tell your healthcare provider if you take:

- Strong CYP2D6 or CYP3A4 inhibitors, such as clarithromycin, diltiazem, erythromycin, itraconazole, ketoconazole, paroxetine, fluoxetine, or bupropion. Administer half the recommended dosage of brexpiprazole
- Strong/moderate CYP2D6 with strong/moderate CYP3A4 inhibitors: Administer one-quarter of the recommended dosage of brexpiprazole
- strong/moderate CYP3A4 inhibitors and you are a known CYP2D6 poor metabolizer: Administer one-quarter of the recommended dosage of brexpiprazole
- Strong CYP3A4 inducers, such as phenobarbital, phenytoin, rifampicin, St. John's Wort, or glucocorticoids. Double the recommended dosage of brexpiprazole and further adjust based on the clinical response.

Your healthcare provider can tell you if it is safe to take brexpiprazole with your other medicines. Do not start or stop any medicines during treatment with brexpiprazole without first talking to your healthcare provider. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Storage

Store brexpiprazole tablets at room temperature between 68°F to 77°F (20°C to 25°C). Keep out of the reach of children.

Ingredients

Brexpiprazole is available as the brand Rexulti and as generic brexpiprazole.

Active ingredient: brexpiprazole

Inactive ingredients (**Rexulti brand**): lactose monohydrate, corn starch, microcrystalline cellulose, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, hypromellose, and talc. For color: titanium dioxide, iron oxide, and ferrosoferric oxide.

Inactive ingredients (generic brexpiprazole [**Ajanta Pharma USA Inc.**]): lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose unspecified, low-substituted hydroxypropyl cellulose unspecified, magnesium stearate, Hypromellose unspecified, talc, titanium dioxide, propylene glycol, ferric oxide red

Inactive ingredients (generic brexpiprazole [**Amneal Pharmaceuticals NY LLC**]): ferric oxide red, ferric oxide yellow, ferrosoferric oxide, hypromellose unspecified, lactose monohydrate, microcrystalline cellulose, magnesium stearate, corn starch, talc, titanium dioxide.

Who makes brexpiprazole?

Rexulti (the brand of brexpiprazole) is manufactured through a partnership between two pharmaceutical companies:

- Otsuka Pharmaceutical (Tokyo, Japan)

- Also makes Abilify, Samsca, and other medications
- Lundbeck (Copenhagen, Denmark)
 - Also makes Lexapro, Vyepti, and other medications.

These companies have a long-standing partnership in developing psychiatric medications, with Rexulti being one of their major joint products.

Generic brexpiprazole is packaged by Ajanta Pharma USA Inc. and Amneal Pharmaceuticals NY LLC.

Popular FAQ

How does Rexulti work?



References

1. [Brexiprazole Prescribing Information Amneal Pharmaceuticals NY LLC.](#)
2. [Brexiprazole Prescribing Information Ajanta Pharma USA Inc.](#)
3. [Rexulti \(brexpiprazole\) Package Insert](#)
4. [Rexulti \(brexpiprazole\) Prescribing Information](#)

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	Risk data available	
CSA Schedule*		
N/A	Not a controlled drug	▼
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