

RIVOTRIL®

Clonazepam (0.5 mg, 2 mg)

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1. What Rivotril is used for

Rivotril tablets are used for the treatment of epilepsy in infants, children and adults.

Your doctor, however, may have prescribed Rivotril for another purpose.

Ask your doctor if you have any questions why Rivotril has been prescribed for you.

This medicine may be addictive.

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

2. How Rivotril works

Rivotril belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

3. Before you take Rivotril

– When you must not take it

1. You have had an allergic reaction to Rivotril, any other benzodiazepine medicine or any ingredients listed at the end of this leaflet.
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
2. You have severe lung disease
3. You have severe liver disease.
4. The expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Rivotril, talk to your doctor.

– Before you start to take it

Tell your doctor if:

1. If you are pregnant or plan to become pregnant
It is not known whether Rivotril is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Rivotril when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
2. If you are breastfeeding or plan to breastfeed
Rivotril passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Rivotril is not recommended for use while breast-feeding.
3. If you have any other health problems including:
 - Liver, kidney or lung disease
 - Depression, psychosis or schizophrenia
 - Porphyria (a rare blood pigment disorder)

4. If you drink alcohol
Alcohol may increase the effects of Rivotril.

5. You are lactose intolerant

6. You are allergic to any other medicines, foods, dyes or preservatives.

– Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop

Some medicines may interfere with Rivotril. These medicines include:

- sleeping tablets, sedatives or tranquillisers

- Some medicines for depression.
- Other medicines to control epilepsy
- Medicines for allergies or colds eg. antihistamines
- pain relievers
- muscle relaxants
- anaesthetics
- cimetidine – a medicine used to treat ulcers

These medicines may be affected by Rivotril or may affect how well Rivotril works.

Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Rivotril.

If you have not told your doctor about any of the above, tell them before you start taking Rivotril.

4. How to take Rivotril

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

– How much to take

Take Rivotril exactly as your doctor has prescribed.

Your doctor will tell you how many Rivotril tablets to take each day.

The dose varies from person to person depending on age and the condition being treated.

The usual maintenance dose for adult is 3-6 mg daily. Infant and children may need to take less.

– How to take it

Swallow Rivotril tablets whole with a glass of water.

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- When to take it

Take Rivotril as directed by your doctor. It may be taken with or without food.

- How long to take it

Continue taking Rivotril until your doctor tells you to stop.

- If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not double a dose to make up for one you have missed.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

- If you take too much (overdose)

You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible).

If you take too much Rivotril you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

If you are not sure what to do, contact your doctor or pharmacist.

5. While you are using Rivotril

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Rivotril.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you become pregnant while taking Rivotril.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to do some blood tests and other tests from time to time to check on your progress and detect any unwanted side effects.

- Things you must not do

Do not drive or operate machinery until you know how Rivotril affects you.

Rivotril may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Rivotril before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Do not take Rivotril for a longer time than your doctor has prescribed.

Do not stop taking Rivotril or lower the dose without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of Rivotril before you can stop taking it completely.

Do not give Rivotril to anyone else even if they have the same condition as you.

Do not use Rivotril to treat other complaints unless your doctor says so.

- Things to be careful of

Be careful when drinking alcohol while taking Rivotril.

Combining Rivotril and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Rivotril.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

6. Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rivotril.

Rivotril helps most people with epilepsy but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Drowsiness, tiredness
- Dizziness, unsteadiness
- Loss of memory, inattentiveness, confusion, lack of concentration
- Headache, hangover feeling in the morning
- Slurred speech
- Unpleasant dreams

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

- Difficulties in breathing
- Sudden anxiety or excitation
- Hallucinations or delusions
- Severe sleep disturbances

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and disposal of Rivotril

- Storage

Keep your tablets in the original bottle to protect from light.

Take them out only when you want to consume them or they may not keep well.

Keep Rivotril in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

- Disposal

Medicinal products should not be poured down the drain or thrown into household waste. Ask your pharmacist how to dispose of packaging and medicinal products you do not need. This will help protect the environment.

8. Product Description

Rivotril 0.5 mg blister come in packs of 60's.

Rivotril 2 mg blister come in packs of 60's.

- What Rivotril looks like

Rivotril 0.5 mg Tablets are cylindrical, biplanar and of pale orange with a break-mark on one side and 0.5 on the other.

Rivotril 2 mg Tablets are cylindrical, biplanar and of white to slightly yellowish colour with a cross-breakmark on one side and 2 on the other.

- Ingredients

Active ingredient:

- Each 0.5 mg tablet contains 0.5 mg clonazepam
- Each 2 mg tablet contains 2 mg clonazepam

Inactive ingredients:

- Both 0.5 mg and 2 mg tablets contain lactose, maize starch and magnesium stearate (470).
- The 0.5 mg tablets also contain potato starch, talc and the colourings iron oxide red, CI 77491 (172) and iron oxide yellow, CI77492 (172)
- The 2mg tablets also contain microcrystalline cellulose (460)

- MAL Number

Rivotril Tablet 0.5 mg:

MAL19860961ACRZ

Rivotril Tablet 2.0 mg:

MAL19860962ACRZ

9. Manufacturer and Product Registration Holder

Made for CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany by Recipharm Leganés S.L.U., Leganés, Spain

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
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Malaysia

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