



New Zealand Consumer Medicine Information

RIVOTRIL[®]

Clonazepam: oral drops (2.5 mg/ml); injection (1 mg).

What is in this leaflet

Please read this leaflet carefully before you start using RIVOTRIL.

This leaflet answers some common questions about RIVOTRIL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using RIVOTRIL against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What RIVOTRIL is used for

RIVOTRIL drops are used for the treatment of epilepsy (fits) in infants, children and adults.

RIVOTRIL injection is also used to treat status epilepticus (severe epileptic attacks).

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

Your doctor, however, may have prescribed RIVOTRIL for another reason.

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

This medicine is available only with a doctor's prescription. RIVOTRIL can be habit forming (leading to addiction). The risks are greater for patients on higher doses or on long term treatment, or patients who have a history of alcohol or drug abuse.

Before you use RIVOTRIL

When you must not use it

Do not use RIVOTRIL if:

- 1. you have had an allergic reaction to RIVOTRIL, or any ingredients listed at the end of this leaflet**

Some symptoms of an allergic reaction may include:

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

2. **you have severe and chronic lung disease**
3. **you have severe liver disease**
4. **you have an addiction to drugs or alcohol**
5. **the package is torn or shows signs of tampering**
6. **the expiry date 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 using RIVOTRIL, talk to your doctor.

RIVOTRIL injection contains benzyl alcohol and must not be given to new born babies, especially premature babies.

Before you start to use it

Your doctor must know about all the following before you start to take RIVOTRIL.

Tell your doctor if:

1. **you are pregnant or plan to become pregnant**
It is possible that RIVOTRIL may be 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. **you are breastfeeding or plan to breastfeed**
RIVOTRIL may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. It is not recommended that you breastfeed whilst taking RIVOTRIL.
3. **you have any other health problems including:**
 - § liver, kidney or lung disease
 - § high or low blood pressure
 - § balance and/or co-ordination difficulties
 - § depression, psychosis or schizophrenia
 - § history of alcohol or drug abuse
 - § porphyria (a rare blood pigment disorder)
 - § myasthenia gravis (a disease that causes muscle weakness)
 - § sleep apnoea
 - §
4. **you drink alcohol**
You should not drink alcohol whilst taking RIVOTRIL. Alcohol may increase the effects of RIVOTRIL.
5. **you are allergic to any other medicines, foods, dyes or preservatives**

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

Tell your doctor or pharmacist before you take RIVOTRIL if you are concerned about becoming dependent on this medicine.

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. You should also tell any health professional who is prescribing a new medication for you that you are taking RIVOTRIL.

Some medicines may interfere with RIVOTRIL. These medicines include:

- § sleeping tablets, sedatives or tranquillisers
- § some medicines for depression, anxiety, schizophrenia or other mental illnesses
- § other medicines to control fits such as phenytoin (Dilantin[®]), phenobarbital (Phenobarbitone[®]), carbamazepine (Tegretol[®]), lamotrigine (Lamictal[®]) and sodium valproate (Epilim[®])
- § pain relievers
- § muscle relaxants
- § some antihistamines, used to treat allergies
- § some medicines used to treat Parkinson's disease
- § flumazenil (Anexate[®])
- § anaesthetics

These medicines may be affected by RIVOTRIL or may affect how well RIVOTRIL works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking RIVOTRIL.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use RIVOTRIL

How much to take

Take RIVOTRIL exactly as your doctor has prescribed.

Your doctor will tell you how much RIVOTRIL to take each day.

The dose varies from person to person depending on age and the condition being treated. The usual adult dose is between 3 and 6 mg daily. Infants and children may need to take less.

Your doctor may start you on a low dose and slowly increase it depending on your response.

How to take it

Oral Drops

RIVOTRIL oral drops should not be administered directly from the neck of the bottle into the mouth in case the dropper dislodges.

The oral drops should be given with a spoon and may be mixed with water, tea or fruit juice.

Injections

The RIVOTRIL injection is used to treat severe epileptic attacks (status epilepticus) and should only be administered by a doctor.

When to take it

Take RIVOTRIL as directed by your doctor.

RIVOTRIL 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 take a double 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.

RIVOTRIL is only intended for the use of the patient it has been prescribed for.

While you are using RIVOTRIL

Things you must do

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

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 RIVOTRIL is 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 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 or 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 could make your epilepsy worse or 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 take any other medicines whether they require a prescription or not without first telling your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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 to.

Things to be careful of

If you are elderly, unwell, drinking alcohol 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. Alcohol can change the way the medicine works. Your doctor may suggest that you avoid alcohol while you are taking RIVOTRIL.

In case of overdose

If you take too much (overdose)

If you think that you or anyone else has taken too much RIVOTRIL, immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

Keep telephone numbers for these places handy.

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

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
- § slurred speech
- § unpleasant dreams
- § muscle weakness
- § changes in mood, such as depression, anxiety, irritation, nervousness, hostility, aggression or agitation
- § inappropriate behaviour

These are the more common side effects of RIVOTRIL. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of RIVOTRIL if you experience any of the above side effects.

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

- § severe anxiety, aggression or agitation
- § hallucinations or delusions (seeing, hearing or feeling things that other people cannot)
- § suicidal thoughts
- § severe sleep disturbances
- § difficulty breathing
- § severe rash, itching or hives
- § swelling of the feet or ankles

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

If you suddenly stop taking Rivotril, or take a lower dose without checking with your doctor, you may experience withdrawal. Symptoms of withdrawal include shaking, sweating, agitation, trouble sleeping, anxiety, headaches, muscle pain, tension, restlessness, confusion, irritability or fits.

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

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.

After using RIVOTRIL

Storage

Keep RIVOTRIL in a cool dry place where the temperature stays below 30°C. Keep RIVOTRIL injection ampoules in outer carton to protect from light.

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

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep RIVOTRIL where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking RIVOTRIL, or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine that may be left over.

Product description

What it looks like

RIVOTRIL 2.5 mg/mL oral drops are a clear, blue or colourless to slightly green- yellow solution contained in a 10 mL amber glass bottle.

RIVOTRIL 1mg injection solution is a clear, colourless to slightly green-yellow solution contained in a 2 mL amber ampoule.

Ingredients

Rivotril 170503



Active ingredient

Clonazepam

- § each 1 mL of RIVOTRIL oral drops contains 2.5 mg clonazepam (1 drop = 0.1 mg clonazepam)
- § each RIVOTRIL injection ampoule contains 1 mg clonazepam

Inactive ingredients

- § RIVOTRIL oral drops contain saccharin sodium (954), propylene glycol (1520), glacial acetic acid (260), peach flavour PHL-014725 and brilliant blue FCF (E133, CI42090)
- § RIVOTRIL injection contains ethanol, benzyl alcohol, propylene glycol (1520) and glacial acetic acid (260)

Sponsor Details

RIVOTRIL is supplied in New Zealand by:

Roche Products (New Zealand) Limited
P O Box 109113 Newmarket
Auckland 1149
NEW ZEALAND

Customer enquiries: 0800 656 464

Date of Preparation

This leaflet was revised on 03 May 2017.