

RIVOTRIL[®]

Contains the active ingredient clonazepam

Consumer Medicine Information

What is in this leaflet

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 taking RIVOTRIL against the benefits they expect it will have 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 and tablets are used for the treatment of epilepsy in infants, children and adults.

RIVOTRIL injection is also used to treat status epilepticus (prolonged or repeated fits or seizures without any recovery between 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 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.

Before you take RIVOTRIL

Do not take RIVOTRIL if:

- 1. you have had an allergic reaction to RIVOTRIL, any other benzodiazepine medicine 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 (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:

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

- 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 may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. RIVOTRIL is not recommended for use while breastfeeding.

- 3) if you have any other health problems including:**

- liver, kidney or lung disease
 - high or low blood pressure
 - myasthenia gravis (severe muscle weakness)
 - sleep apnoea (a condition where you have temporary stops in breathing during sleep)
 - glaucoma (a condition where you have high pressure in the eye)
 - depression, psychosis or schizophrenia
 - porphyria (a rare blood pigment disorder)
- 4) if you drink alcohol**
Alcohol may increase the effects of RIVOTRIL.

- 5) if you are lactose intolerant**

- 6) if 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 healthfood 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
- disulfiram - a medicine used in alcohol abuse

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

How to take 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 4 and 8 mg

daily. Infants and children may need to take less.

How to take it

Swallow the RIVOTRIL tablets whole with a glass of water.

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

When to take it

Take RIVOTRIL as directed by your doctor.

RIVOTRIL may be taken with or without food.

How long to take RIVOTRIL

Continue taking RIVOTRIL until your doctor tells you to stop.

If you forget to take RIVOTRIL

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 RIVOTRIL (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much RIVOTRIL, 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.

While you are taking 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 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 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 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

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.

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 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 taking RIVOTRIL

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep RIVOTRIL in a cool dry place where the temperature stays below 25 °C. Do not store it, 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 tablets that are left over.

Product Description

What RIVOTRIL looks like

RIVOTRIL 0.5 mg Tablets are round, pale orange with a score

break on one side and ROCHE 0,5 on the other.

RIVOTRIL 2 mg Tablets are round, whitish, with a score break on one side and ROCHE 2 on the other.

RIVOTRIL Drops are a clear colourless to greenish yellow liquid.

RIVOTRIL Injection contains a clear colourless to greenish yellow liquid.

Ingredients

Active ingredient - clonazepam

- each 0.5 mg tablet contains 0.5 mg clonazepam
- each 2 mg tablet contains 2 mg clonazepam
- each 1 mL drops contains 2.5 mg clonazepam
- each 1mL ampoule for injection contains 1 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 (553) and the colourings iron oxide red, CI 77491 (172) and iron oxide yellow, CI 77492 (172)
- the 2 mg tablets also contain microcrystalline cellulose (460)
- the drops contain saccharin sodium (954), propylene glycol (1520), glacial acetic acid (260) and peach flavour 85 502
- the injection contains ethanol, benzyl alcohol, propylene glycol (1520) and glacial acetic acid (260).

RIVOTRIL tablets are gluten free.

RIVOTRIL 0.5 mg Tablets come in packs of 100.

RIVOTRIL 2 mg Tablets come in packs of 100.

RIVOTRIL Drops come in packs of 10mL.

RIVOTRIL Injection comes in packs of 5 ampoules.

Manufacturer

RIVOTRIL is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number

- RIVOTRIL 0.5 mg Tablets
AUST R 13759
- RIVOTRIL 2 mg Tablets
AUST R 42373
- RIVOTRIL 2.5 mg/mL Oral
Liquid AUST R 13758
- RIVOTRIL 1 mg/1 mL
Injection
AUST R 13757

This leaflet was prepared on 1 September 2009.