

## PRODUCT MONOGRAPH

 **RIVOTRIL®**

clonazepam

0.5 mg and 2 mg Tablets

Anticonvulsant

Hoffmann-La Roche Limited  
7070 Mississauga Road  
Mississauga, Ontario, Canada  
L5N 5M8

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## PART III: CONSUMER INFORMATION

 **RIVOTRIL®**  
clonazepam tablets

**This leaflet is part III of a three-part "Product Monograph" published when RIVOTRIL was approved for sale in Canada and is designed specifically for Consumers.**

**Please read this information before you start to take your medicine. Keep this leaflet until you have finished all your tablets, as you may need to read it again. If you are helping someone else to take RIVOTRIL, read this leaflet before you give the first tablet.**

**This leaflet is a summary and will not tell you everything about RIVOTRIL. Contact your doctor or pharmacist if you have any questions about the drug.**

### ABOUT THIS MEDICATION

#### What the medication is used for:

RIVOTRIL is used for the treatment of certain types of seizures.

If you are 65 years or older, talk to your doctor before starting RIVOTRIL. RIVOTRIL may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

#### What it does:

RIVOTRIL contains the active ingredient clonazepam, which belongs to a group of medicines known as benzodiazepines. RIVOTRIL has anticonvulsant properties which help to manage seizures.

#### When it should not be used:

- If you are allergic to the group of medicines known as benzodiazepines (examples: diazepam, chlordiazepoxide, bromazepam, or flurazepam)
- If you are allergic to the medicinal ingredient (clonazepam)
- If you are allergic to any of the other non-medicinal ingredients it contains (see 'What the non-medicinal ingredients are')
- If you suffer from lung disease.
- If you have a liver condition.
- If you have glaucoma.
- If you have myasthenia gravis.
- If you suffer from sleep apnea

#### What the medicinal ingredient is:

clonazepam.

#### What the non-medicinal ingredients are:

**Tablets 0.5 mg:** cornstarch, iron oxide red, iron oxide yellow, lactose, magnesium stearate, potato starch and talc.

**Tablets 2 mg:** cornstarch, lactose, magnesium stearate and microcrystalline cellulose.

#### What dosage forms it comes in:

RIVOTRIL is available as:

0.5 mg, pale orange, cylindrical, scored tablet, with ROCHE 0.5 engraved on one face, scored on the other.

2.0 mg, white, cylindrical, scored tablet, edges bevelled, with ROCHE •2• on one side, cross-scored on the other.

The 0.5 mg tablets are available in bottles of 100 and 500 tablets. The 2.0 mg tablets are available in bottles of 100 tablets.

### WARNINGS AND PRECAUTIONS

#### Serious Warnings and Precautions

**Addiction, Abuse and Misuse:** Even if you take RIVOTRIL exactly as you were told to, you are at risk for abuse, misuse, addiction, physical dependence and withdrawal. Abuse and misuse can result in overdose or death, especially if you take RIVOTRIL with:

- Opioids
- Alcohol or
- Illicit drugs

#### Your doctor should:

- Talk to you about the risks of treatment with RIVOTRIL as well as other treatment (including non-drug) options
- Assess your risk for these behaviours before prescribing RIVOTRIL
- Monitor you while you are taking RIVOTRIL for the signs and symptoms of misuse and abuse. If you feel like you are craving RIVOTRIL, or not using it as directed, talk to your doctor right away.

**Store RIVOTRIL in a secure place to avoid theft or misuse.**

**Withdrawal:** If you suddenly stop taking RIVOTRIL, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see the Withdrawal section below)

- Always contact your doctor before stopping, or lowering your dose of RIVOTRIL or changing your medicine

**RIVOTRIL with Opioids: Taking RIVOTRIL with opioid medicines can cause:**

- Severe drowsiness
- Decreased awareness
- Breathing problems
- Coma
- Death

**Withdrawal:**

- If you suddenly stop your treatment, lower your dose too fast, or switch to another medication, you can experience withdrawal symptoms that can range from mild to severe or life threatening. Some of your withdrawal symptoms can last for months after you stop RIVOTRIL.
- Your risk of going through withdrawal is higher if you are taking RIVOTRIL for a long time or at high doses. However, symptoms can still occur if you are taking RIVOTRIL as directed for a short period of time or slowly reducing the dose.
- The symptoms of withdrawal often resemble the condition that you are being treated for. After stopping your treatment, it may be hard to tell if you are experiencing withdrawal or a return of your condition (relapse).
- Tell your doctor **right away** if you experience any symptoms of withdrawal after changing or stopping your treatment.
- Severe symptoms of withdrawal include:
  - Feeling like you cannot move or respond (catatonia)
  - Severe confusion, shivering, irregular heart rate and excessive sweating (delirium tremens)
  - Feeling depressed
  - Feeling disconnected from reality (dissociation)
  - Seeing or hearing things that are not there (hallucinations)
  - Overactive behaviour and thoughts (mania)
  - Believing in things that are not true (psychosis)
  - Convulsions (seizures), including some that do not stop
  - Thoughts or actions or suicide
- For other symptoms of withdrawal, see the **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM** table (below).
- To reduce your chances of going through withdrawal:
  - Always contact your doctor before stopping or reducing your dose of RIVOTRIL or changing medications

- Always follow your doctor's instructions on how to reduce your dose carefully and safely
- Tell your doctor **right away** if you experience any unusual symptoms after changing or stopping your treatment

**RIVOTRIL with Opioids:** Taking RIVOTRIL with opioid medicines can cause severe drowsiness and breathing problems.

- Tell your doctor if you:
  - Are taking opioid medicines
  - Are prescribed an opioid medicine after you start taking RIVOTRIL
- RIVOTRIL may affect your ability to be alert. Do NOT drive or operate heavy machinery or do tasks that require special attention until you know how taking an opioid medicine and RIVOTRIL affects you. This effect of RIVOTRIL may be made worse if you take alcoholic drinks. If you increase your dose or change the timings of when you take your medication this may also modify your reactions.

**Falls and Fractures:** Benzodiazepines like RIVOTRIL can cause you to feel sleepy, dizzy and affect your balance. This increases the risks of falling, which can cause fractures or other fall related-injuries, especially if you:

- Take other sedatives
- Consume alcohol
- Are elderly or
- Have a condition that causes weakness or frailty
- Benzodiazepines such as RIVOTRIL are not recommended for the primary treatment of psychotic illness
- Memory loss may occur when RIVOTRIL is used at therapeutic doses.
- Do not take this medicine if you are pregnant, or might become pregnant, unless advised by your doctor. Contact your doctor if you think you may be pregnant, or are intending to become pregnant. If you are pregnant or thinking about becoming pregnant, ask your healthcare provider about joining the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling (1-888) 233-2334 (toll free). Women who are pregnant and planning to take an antiepileptic drug should call the pregnancy registry to enable collection of valuable data about its use in pregnancy. Information on the registry can also be found at the website: <http://www.aedpregnancyregistry.org/>
- RIVOTRIL passes into breast milk. Therefore, if you

are breast feeding, this medicine should be avoided. Your doctor will discuss this with you.

- A small number of people being treated with anti-epileptics such as RIVOTRIL have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor immediately.

**BEFORE you use RIVOTRIL talk to your doctor or pharmacist if you:**

- Have a lung, liver or kidney condition.
- Have glaucoma.
- Are taking or plan on taking ANY other drugs (including herbal preparations, drugs you purchase without prescriptions, and those not prescribed by your doctor).
- Regularly drink alcohol or use recreational drugs.
- Suffer from a form of incoordination of the muscles called spinal or cerebellar ataxia.
- Have a history of depression and/or suicide attempts.
- Have rare hereditary problems of galactose intolerance.
- Have ever had a problem with:
  - Substance use, including prescribed or illegal drugs, or
  - Alcohol
- Have ever had seizures or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)

**INTERACTIONS WITH THIS MEDICATION**

**Serious Drug Interactions**

**Taking RIVOTRIL and opioids may cause:**

- Severe drowsiness
- Trouble breathing
- Coma
- Death

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

Some medicines may interfere with RIVOTRIL. These medicines include:

- medicines to control seizures

- narcotics and narcotic pain relievers (opioids, e.g., morphine, codeine; see **Serious Warnings and Precautions box**)
- muscle relaxants
- sleeping medication
- medicines to treat your mood, such as monoamine oxidase inhibitors, tricyclic antidepressants, phenothiazines
- phenytoin, phenobarbital, carbamazepine, and valproate.

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.

**If you have not told your doctor about any of the above, tell him/her before you start taking RIVOTRIL.**

You must not consume alcohol while taking RIVOTRIL as its effects may worsen side effects that some patients experience with RIVOTRIL.

Grapefruit juice may increase blood levels of RIVOTRIL, therefore you should avoid drinking grapefruit juice while you are taking RIVOTRIL.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

Always take the tablets exactly as your doctor tells you to. Your doctor will prescribe a suitable dose for you. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and body weight. The table below shows the different doses that your doctor may prescribe according to your age. Your doctor will start you on an initial low dose and gradually increase it until the desired effect is achieved.

	Initial Dose	Maintenance Dose
Adults	1.5 mg/day or less in divided doses	8-10 mg/day in divided doses
Children (up to 10 years or 30kg)	0.01-0.03 mg/kg/day in divided doses	0.1-0.2 mg/kg/day in divided doses

The total daily dose should be taken as advised by your doctor.

Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

Your doctor will advise you when to stop taking the

medicine. Your doctor will slowly decrease your dose and will tell you when to stop taking the medicine. Always follow your doctor's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.

### **Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### **Missed Dose:**

Take the missed dose of RIVOTRIL as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take 2 doses at the same time.

## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medications RIVOTRIL can cause some side effects. For most patients these side effects are likely to be minor and temporary as your body adjusts to the medicine. However, some may be serious. Consult your doctor or pharmacist as soon as you can if you do not feel well while taking RIVOTRIL.

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Some muscle weakness and dizziness.
- Increased salivation.
- Movement control and balance issues.

Less common possible side effects are:

- Increased secretion from the lungs may occur. Children should therefore be watched carefully as this might cause difficulties in breathing and/or severe choking and coughing.
- In rare cases changes in your blood and liver may occur and your doctor will monitor for these.
- Falls and fractures

Withdrawal-related side effects:

- With long-term RIVOTRIL treatment development of physical and psychological dependence may occur. If treatment is stopped suddenly symptoms of withdrawal may occur, including: shaking, sweating, agitation/restlessness, sleep disturbances, anxiety (possibly extreme), headaches, muscle pain, tension, restlessness, confusion and irritability. In severe cases of withdrawal, symptoms may include numbness and tingling of the extremities, hallucinations (see or hear

things that are not there), increased sensitivity to light, noise and physical contact.

## **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Rare	Unusual behavioural problems (aggression, rage), sudden anxiety or excitation; restlessness, agitation, irritability; hallucinations (see or hear things that are not there) or delusions; severe sleep disturbances, nightmares, inappropriate behaviour.		✓	
	Allergic reactions (red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes)			✓
	Depression Symptoms may include: difficulty sleeping, changes in weight, feelings of worthlessness, guilt, regret,		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	helplessness or hopelessness, withdrawal from social situations, family gatherings and activities with friends, reduced libido (sex drive).			
Uncommon	Suicidal Thoughts or Actions: Thoughts, plans and actions taken for the purpose of killing or harming yourself.		✓	
Unknown	<b>Overdose:</b> extreme sleepiness, confusion, slurred speech, slow reflexes, slow shallow breathing, coma, loss of balance and coordination, uncontrolled rolling of the eyes, and low blood pressure.			✓
	<b>Respiratory Depression:</b> slow, shallow or weak breathing.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	<b>Withdrawal:</b> Severe symptoms include: <b>Catatonia:</b> feeling like you cannot move or respond <b>Delirium</b> <b>Tremens:</b> severe confusion, shivering, irregular heart rate and excessive sweating <b>Feeling depressed</b> <b>Dissociation:</b> feeling disconnected from reality <b>Hallucinations:</b> seeing or hearing things that are not there <b>Mania:</b> overactive behaviour and thoughts <b>Psychosis:</b> believing in things that are not true <b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking <b>Thoughts or actions of suicide</b> <b>Other symptoms</b>		✓	

# SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>include:</b> Stomach cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or restless; severe anxiety or panic-attacks; headache; sensitivity to light, noise or physical contact; shaking; vomiting; trouble sleeping; feeling irritable; muscle pain or stiffness; a burning or prickling feeling in the hands, arms, legs or feet; sweating.			

***This is not a complete list of side effects. For any unexpected effects while taking RIVOTRIL, contact your doctor or pharmacist.***

## HOW TO STORE IT

- Keep RIVOTRIL in a cool dry place stored at room temperature (15-30°C) in the original package provided by the health care professional.
- Keep this medicine out of sight and reach of children.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

## MORE INFORMATION

**Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.**

This document plus the full product monograph, prepared for health professionals can be found at: [www.rochecanada.com](http://www.rochecanada.com) or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388 (Drug Information).

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