

## SCHEDULING STATUS

**S5**

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**RIVOTRIL® 0,5 mg** Tablets

**RIVOTRIL® 2 mg** Tablets

**RIVOTRIL® 1 mg/ml** Injection

**RIVOTRIL® 2,5 mg/ml** Drops

Clonazepam

### Read all of this leaflet carefully before you start taking RIVOTRIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RIVOTRIL has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### 1. WHAT RIVOTRIL CONTAINS

*RIVOTRIL 2,5 mg/ml drops:* The drops contain 2,5 mg clonazepam per ml, i.e. 1 drop contains 0,1 mg clonazepam.

Other ingredients: brilliant blue FCF colourant (E133), saccharin sodium, peach flavour, propylene glycol.

*RIVOTRIL 0,5 mg tablets:* Each 0,5 mg tablet contains 0,5 mg clonazepam.

Other ingredients: lactose, maize starch, pregelatinised potato starch, iron oxide red (E172), iron oxide yellow (E172), talc, magnesium stearate.

*RIVOTRIL 2 mg tablets:* Each 2 mg tablet contains 2 mg clonazepam.

Other ingredients: lactose, pregelatinised potato starch, microcrystalline cellulose, magnesium stearate.

*RIVOTRIL 1 mg/1 ml Injection:* Each ampoule contains 1 mg clonazepam per ml, and 3 % benzyl alcohol as a preservative.

Contains 15 % *m/v* ethyl alcohol (undiluted ampoule). Other ingredient: propylene glycol.

1 ml water for Injection is used as a diluent. After adding the diluent, the solution for injection contains 1 mg clonazepam per 2 ml.

## **2. WHAT RIVOTRIL IS USED FOR**

RIVOTRIL contains clonazepam as the active substance, which belongs to a group of medicines known as benzodiazepines. Clonazepam has anticonvulsant properties, that is, it prevents seizures (fits).

RIVOTRIL is used for the treatment of epilepsy in infants, children and adults.

RIVOTRIL is used for the treatment of panic disorder, with or without fear of closed spaces.

## **3. BEFORE YOU TAKE RIVOTRIL**

### **Do not take RIVOTRIL:**

- If you are allergic to the group of medicines known as benzodiazepines, such as diazepam, chlordiazepoxide, bromazepam, or flurazepam for example.
- If you are allergic to any of the ingredients it contains.
- If you suffer from lung disease.
- If you suffer from myasthenia gravis (severe muscle tiredness).
- If you suffer from sleeping disorders, such as difficulty breathing while asleep.
- If you have a liver condition.
- RIVOTRIL ampoules should not be used to treat new born babies, especially those born prematurely.

### **Take special care with RIVOTRIL**

Make sure your doctor knows if you:

- have a lung, liver or kidney condition.
- regularly drink alcohol or use recreational medicines.
- suffer from a form of incoordination of the muscles called cerebellar ataxia.
- have a history of depression and/or suicide attempts.

### ***Important***

You must not drink alcohol whilst taking RIVOTRIL as this may provoke epileptic seizures.

### **Pregnancy and Breastfeeding**

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.

Clonazepam passes into breast milk therefore, if you are breast feeding, this medicine should be avoided. Your doctor will be able to discuss this with you. Mothers who are not breast feeding may use RIVOTRIL.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking RIVOTRIL.

### **Driving and using machinery**

RIVOTRIL may affect your ability to operate machinery. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This 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.

### **Important information about some of the ingredients of RIVOTRIL**

RIVOTRIL tablets contain lactose. If you have an intolerance to certain sugars, contact your doctor before using RIVOTRIL.

### **Taking other medicines with RIVOTRIL**

Take special care if you are taking any other medicines, including those not prescribed by your doctor. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved, as for example, when RIVOTRIL is used in combination with other anti-epileptic medicines e.g. hydantoins, phenobarbitone, sodium valproate. RIVOTRIL may also be affected by other medicines, e.g. those used to treat stomach problems (cimetidine) and certain antibiotics (rifampicin). The effects of RIVOTRIL may be increased by other anticonvulsant (antiepileptic) medicines, anaesthetics, hypnotics (sleep inducing medicines), tranquillisers, analgesics (medicines that relieve pain) as well as muscle relaxants. Taking phenytoin or primidone with RIVOTRIL may affect the amount of medicine in your blood. Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

## **4. HOW TO TAKE RIVOTRIL**

Do not share medicines prescribed for you with another person.

Always take RIVOTRIL exactly as your doctor tells you to. He/she 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 total daily dose should be taken as advised by your doctor in three or four divided doses at intervals throughout the day up to a maximum of 20 mg per day. Swallow the tablets with water.
- *Correct method of administration of RIVOTRIL drops:* The drops should be mixed with water, tea or fruit juice and administered with a spoon.
- Do not change the prescribed dose yourself. If you think the effect of RIVOTRIL is too weak or too strong, talk to your doctor.

Injection:

- RIVOTRIL is usually administered by a doctor or nurse into a vein. It should always be used as directed by a doctor.
- The normal adult dose is 1 mg (2 ml) by slow intravenous injection. The normal dose in children is 0,5 mg (1 ml) by slow intravenous injection. The dose given to the elderly will differ from the normal adult dose.
- Alternatively, up to 3 mg may be given by intravenous infusion.

### **If you take more RIVOTRIL than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

### **If you forget to take RIVOTRIL**

If you forget to take one dose, you should never make up for it by doubling the dose next time. Instead, you should simply continue with the next dose when it is due.

Do not take a double dose to make up for a forgotten dose.

## **Effects when treatment with RIVOTRIL is stopped**

Your doctor will advise you when to stop taking RIVOTRIL. As treatment with RIVOTRIL may last all your life, you must always tell your doctor if you want to stop taking RIVOTRIL or other medicines you are taking, as sudden discontinuation of treatment can cause the reappearance of seizures as well as withdrawal symptoms. After a period of usage it is advisable to reduce dosage gradually. Sometimes withdrawal effects occur if the medicine is stopped suddenly and these may include sleep disturbances, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, irritability, sweating, tremor, headaches and agitation. In serious cases, withdrawal effects can also include being oversensitive to light, noise and physical contact, hallucinations, tingling and numbness and a feeling of being unreal.

## **5. POSSIBLE SIDE-EFFECTS**

**Not all side effects reported for RIVOTRIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIVOTRIL, consult your doctor, pharmacist or other healthcare professional for advice.**

**If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.**

Some patients will feel drowsy or tired, especially at the start of treatment and may experience muscle weakness, dizziness, light-headedness, floppiness of the muscles or bad coordination and unsteadiness when walking. In rare cases breathing difficulties may occur. Your doctor can help to avoid most of these effects by adjusting the dose. Poor concentration, restlessness, confusion, disorientation and memory loss may also occur when taking RIVOTRIL.

In infants and small children increased salivation and 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. Other unwanted effects which can also occur more rarely include: hives or itching, swelling of the soft tissue, especially around the eyes, lips and hands, hair loss, changes in your skin colouring, nausea, headache, loss of sexual desire, impotence, urinary incontinence, early sexual development in children, stomach upsets or allergic reactions including severe hypersensitivity and shock.

With long-term RIVOTRIL treatment, the following may occur: increase in seizures (only with certain forms of epilepsy), slowing or slurring of speech, reduced co-ordination of movements or changes in vision (e.g. double vision, involuntary jerky movements of the eye).

Depression may occur in patients treated with RIVOTRIL.

In rare cases changes in your blood and liver function may occur and your doctor will monitor for these. Development of physical and psychological dependence may make it difficult to come off or stop treatment. Changes in behaviour may occur including aggression, excitement, irritability, nervousness, hostility, agitation, anxiety, sleep disturbances, nightmares, vivid dreams, psychotic disorders, severe behavioural disturbances, and new types of seizure may occur. If these symptoms occur, you must inform your doctor **immediately**. He/she may want you to stop taking this medicine.

If you are concerned about these or any other unwanted side effects, talk to your doctor.

## 6. STORING AND DISPOSAL OF RIVOTRIL

**Tablets and Ampoules:** Store at or below 30 °C in the original package, to protect from light.

**Drops:** Store at or below 25 °C in the original package, to protect from light.

RIVOTRIL should not be used after the expiry date shown on the container.

Store out of reach and of children.

## 7. PRESENTATION OF RIVOTRIL

*RIVOTRIL ampoule pack:* packs of 5 ampoules active substance and 5 ampoules Water for Injection.

*RIVOTRIL drops 2,5 mg per ml* (1 drop contains 0,1 mg active substance) in a 10 ml dropper bottle.

*RIVOTRIL 0,5 mg Tablets:* packs of 60's, 90's and 100's.

*RIVOTRIL 2 mg Tablets:* packs of 60's, 90's and 100's.

Not all packs may be marketed.

## 8. IDENTIFICATION OF RIVOTRIL

*RIVOTRIL 1 mg/ml Ampoules:* 1 ml clonazepam in 1 ml solvent, each accompanied by an ampoule containing 1 ml water as a diluent.

*RIVOTRIL 2,5 mg/ml Drops:* clear to almost clear blue solution contained in 10 ml amber glass dropper bottles.

*RIVOTRIL 0,5 mg Tablets:* orange, single-scored tablets marked "0.5".

*RIVOTRIL 2 mg Tablets:* white to slightly yellowish, double-scored tablets marked ".2".

## 9. REGISTRATION NUMBER

RIVOTRIL 1 mg/ml Ampoules F/2.5/187

RIVOTRIL 2,5 mg/ml Drops F/2.5/188

RIVOTRIL 0,5 mg Tablets F/2.5/189

RIVOTRIL 2 mg Tablets F/2.5/190

#### **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Pharmaco Distribution (Pty) Ltd.

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#### **11. DATE OF PUBLICATION**

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