

Rivotril® 2mg tablets

(clonazepam)

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Rivotril 2mg tablets but will be referred to as Rivotril throughout this leaflet. This medicine is also available in other strength as Rivotril 0.5mg tablets.

In this leaflet:

1. What Rivotril is and what it is used for
2. Before you take Rivotril
3. How to take Rivotril
4. Possible side effects
5. How to store Rivotril
6. Further information

1. What Rivotril is and what it is used for

Rivotril contains a medicine called clonazepam. This belongs to a group of medicines called 'benzodiazepines'.

Rivotril is used to treat epilepsy in infants, children and adults.

- It lowers the number of fits (seizures) that you have.
- Any fits that you do have will be less serious.

2. Before you take Rivotril

Do not take Rivotril if you are allergic (hypersensitive) to:

- Clonazepam or any of the other ingredients of Rivotril (listed in Section 6: 'Further information').
- Other 'benzodiazepine' medicines. These include diazepam, flurazepam and temazepam.

Do not take Rivotril if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rivotril.

Do not take Rivotril if:

- You have breathing problems or lung disease.
- You have severe liver problems.
- You have a condition called 'myasthenia gravis' (where your muscles become weak and get tired easily).
- You have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).
- You have problems with alcohol or drug (prescription or recreational) use.

Do not take Rivotril if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rivotril.

Take special care with Rivotril

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

Check with your doctor or pharmacist before taking Rivotril if:

- You have liver, kidney or lung problems.
- You have ever had depression.
- You have ever tried to kill yourself.
- A close friend or relative has recently died.
- You regularly drink alcohol or take recreational drugs or you have had problems with alcohol or drug use in the past.
- You have spinal or cerebellar ataxia (where you may become shaky and unsteady, have slurred speech or rapid eye movements).
- You have a rare, inherited blood problem called 'porphyria'.
- You are elderly or debilitated (weak); your doctor may adjust your dose.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Rivotril.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Rivotril can affect the way some other medicines work.

Also some other medicines can affect the way Rivotril works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to treat epilepsy, such as carbamazepine, hydantoins, phenobarbital, phenytoin, primidone or sodium valproate.
- Cimetidine (used to treat stomach problems and heartburn).
- Rifampicin (an antibiotic used to treat infections).
- Medicines used to make you sleep (hypnotics).
- Medicines that help with anxiety (tranquillisers).
- Pain-killers (analgesics) and medicines to relax your muscles (muscle relaxants).

Other medicines and Rivotril

Concomitant use of Rivotril and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Rivotril together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Operations

If you are going to have an anaesthetic for an operation or for dental treatment, it is important to tell your doctor or dentist that you are taking Rivotril.

Taking Rivotril with

Do not drink alcohol may cause side effects

Pregnancy and bre

You must not take Rivotril if you are pregnant or are breastfeeding. Rivotril is known to pass into breast milk.

Driving and using r

Talk to your doctor or pharmacist before you start taking Rivotril. This is particularly when you are taking Rivotril for the first time. The medicine can affect your ability to drive. You may feel dizzy.

- Do not drive while you are taking Rivotril.
- It is an offence to drive a motor vehicle if you are unfit to drive through illness.
- However, you will not be prosecuted if you can show that it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dependence

When taking this medicine there is a risk of dependence which increases with the dose and duration of treatment and also in patients with a history of alcohol and/or drug abuse.

Important information about some of the ingredients of Rivotril

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Rivotril

Always take Rivotril exactly as your doctor has told you. You should check with your doctor if you are not sure.

- Your doctor will start you on a low dose of Rivotril and gradually increase it over 2 to 4 weeks until the right dose has been found for you.
- Your doctor will usually tell you to split your daily dose into three equal amounts which you will take at evenly spaced times throughout the day.
- If the daily dose cannot be split equally, take the largest dose at bedtime.
- Once your doctor has found the right dose for you, they may tell you to take Rivotril as a single dose in the evening.

Adults and children over 12 years

- The usual starting dose is 1mg a day, or less.
- This will be increased gradually (usually to between 4mg and 8mg a day). The maximum dose is 20mg a day.

The elderly

- The usual starting dose is 0.5mg a day, or less.
- This will be increased gradually (usually to between 4mg and 8mg a day). The maximum dose is 20mg a day.

Infants (aged 0 to 1 year)

- The usual starting dose is 0.25mg a day, or less.
- This will be increased gradually (usually to between 0.5mg and 1mg a day).

Small children (aged 1 to 5 years)

- The usual starting dose is 0.25mg a day, or less.
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Older children (aged 5 to 12 years)

- The usual starting dose is 0.5mg a day, or less.
- This will be increased gradually (usually to between 3mg and 6mg a day).

If you take more Rivotril than you should

- If you take more Rivotril than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you may feel drowsy, sleepy, light-headed, have a lack of co-ordination or be less responsive than normal.

If you forget to take Rivotril

- If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

Stopping Rivotril

If you receive long term treatment with Rivotril (are given the medicine for a long time) you may become dependent upon this medicine and get withdrawal symptoms (see Section 4).

- Do not stop taking your tablets without talking to your doctor. If you do, your fits may return and you may get withdrawal symptoms (see Section 4: 'Possible side effects').
- If the dose of Rivotril you take has to be reduced, or stopped, this must be done gradually. Your doctor will let you know how to do this.

If someone else takes your Rivotril by mistake, they should talk to a doctor or go to a hospital straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Variation 0022: To add a new marketed product name 'Clonazepam B AND S 2mg tablets' with consequential changes to the leaflet and labels with FMD labelling requirements.

Variation 0023: To add the manufacturer name and address 'Recipharm Leganes S.L.U., Calle Severo Ochoa, 13, Leganes, 28914 Madrid, Spain.' with consequential changes to the leaflet and labels with FMD labelling requirement.

Variation 0025: To add the pack size '105 Tablets' with consequential changes to the leaflet and labels with FMD labelling requirement.

4. Possible side effects

Like all medicines Rivotril can cause side effects, although not everybody will get them.

Important side effects to look out for:

Allergic reactions

If you get an allergic reaction, **see a doctor straight away.**

The signs may include:

- Sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.
- Skin rash or itching.

Effects on the heart

If you notice any of the following effects, **see a doctor straight away.**

The signs may include:

- Breathlessness, swelling of the ankles, cough, tiredness and a racing heart.
- Chest pain which may spread to your neck and shoulders and down your left arm.

Effects on behaviour

If you notice any of the following effects, **talk to your doctor** as they may want you to stop taking Rivotril. The signs may include:

- Being aggressive, excited, irritable, nervous, agitated, hostile or anxious.
- Problems sleeping, nightmares and vivid dreams.
- Mental problems such as seeing or hearing things that are not really there (hallucinations), delusions (believing in things that are not real) and problems with your speech.
- Types of fits (seizures) that you have not had before.

Infants and children

- If an infant or small child is taking Rivotril, watch them carefully. This is because they could develop breathing problems, coughing or choking. This can be caused by too much saliva being made.
- Early puberty in children. This is reversible after stopping treatment with Rivotril.

Elderly patients

Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones.

Other possible side effects

When you start taking Rivotril you may notice the following effects:

- Feeling drowsy and tired.
- Feeling dizzy and light-headed.
- Weak or floppy muscles or jerky movements (poor co-ordination).
- Feeling unsteady when walking.

If you notice any of these effects, talk to your doctor. Your doctor may be able to help you by giving you a lower dose of Rivotril and then increasing it slowly.

The following may occur at any time during your treatment

Mind and nervous system

- Poor concentration, confusion and a feeling of being lost (disorientation).
- Feeling restless.
- Difficulty remembering new things.
- Headache.
- Depression.
- Slowing or slurring of speech.
- Poor co-ordination, including feeling unsteady when walking.
- An increase in how often you have fits.

Liver, kidney and blood

- Changes in how well your liver is working (shown by blood tests).
- Loss of bladder control.
- Blood problems. The signs include feeling tired, bruising easily, being short of breath and nose bleeds. Your doctor may want you to have blood tests from time to time.

Stomach and gut

- Feeling sick (nausea).
- Stomach upset.

Eyes

- Double vision.
- Jerky movements of the eyes (nystagmus).

Breathing

- Breathing problems (respiratory depression). Early signs include suddenly noisy, difficult and uneven breathing. Your skin may become blue.

Skin and hair

- Skin rashes, hives (lumpy rash) and itchy skin.
- Changes to the colour of your skin.
- Hair loss (the hair usually grows back).

Sexual

- Loss of sex drive.
- Difficulty getting or keeping an erection (erectile dysfunction).

Withdrawal symptoms

Using benzodiazepines like Rivotril may make you dependent on the medicine. This means that if you stop treatment quickly or reduce the dose too quickly, you may get withdrawal symptoms.

The symptoms can include:

- Problems sleeping.
- Muscle pain, shaking (tremor) and feeling restless.
- Feeling very anxious, tense, confused, irritable or agitated or changes in your mood.
- Increased sweating.
- Headache.

Less common withdrawal symptoms include:

- Feeling sensitive to light, noise and physical contact.
- Seeing or hearing things that are not really there (hallucinations).
- Tingling and feeling numb in your arms and legs.
- A feeling of losing contact with reality.

Injury

- Patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rivotril

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further information

What Rivotril contains

Each tablet contains 2mg clonazepam as the active ingredient.

The other ingredients are anhydrous lactose, magnesium stearate, pregelatinised maize starch and microcrystalline cellulose.

What Rivotril looks like and contents of the pack

The round, white tablets have 'ROCHE 2' imprinted on one face and two break bars on the other. All tablets are cross scored so that they can easily be broken into halves or quarters.

The tablets are supplied in blister packs of 60 and 105.

Manufactured by: Recipharm Leganes S.L.U., Calle Severo Ochoa, 13, Leganes, 28914 Madrid, Spain.

OR

Roche Farma, S.A., C/ Eratostenes, 19, Getafe, 28906 Madrid, Spain.

Procured from within the EU and repackaged by the Product

Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Rivotril® 2mg tablets; PL 18799/1401

POM

Leaflet date: 18.05.2022

Rivotril is a registered trademark of F. Hoffmann-La Roche AG.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 0208 515 3763 to obtain the
leaflet in a format suitable for you.**

Clonazepam B&S 2mg tablets

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- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
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The name of your medicine is Clonazepam B&S 2mg tablets but will be referred to as Clonazepam throughout this leaflet. This medicine is also available in other strength as Clonazepam 0.5mg tablets.

In this leaflet:

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1. What Clonazepam is and what it is used for

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Check with your doctor or pharmacist before taking Clonazepam if:

- You have liver, kidney or lung problems.
- You have ever had depression.
- You have ever tried to kill yourself.
- A close friend or relative has recently died.
- You regularly drink alcohol or take recreational drugs or you have had problems with alcohol or drug use in the past.
- You have spinal or cerebellar ataxia (where you may become shaky and unsteady, have slurred speech or rapid eye movements).
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- You are elderly or debilitated (weak); your doctor may adjust your dose.

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Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Clonazepam can affect the way some other medicines work.

Also some other medicines can affect the way Clonazepam works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to treat epilepsy, such as carbamazepine, hydantoins, phenobarbital, phenytoin, primidone or sodium valproate.
- Cimetidine (used to treat stomach problems and heartburn).
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- Medicines used to make you sleep (hypnotics).
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- Pain-killers (analgesics) and medicines to relax your muscles (muscle relaxants).

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Concomitant use of Clonazepam and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Clonazepam together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Operations

If you are going to have an anaesthetic for an operation or for dental treatment, it is important to tell your doctor or dentist that you are taking Clonazepam.

Taking Clonazepam with Alcohol

Do not drink alcohol while you are taking Clonazepam. This is because it may cause side effects or cause your fits to return.

Pregnancy and breast-feeding

You must not take Clonazepam if you are pregnant, might become pregnant or are breast-feeding, unless your doctor tells you to. Clonazepam is known to have harmful effects on the unborn child.

Driving and using machines

Talk to your doctor about driving and using machines or tools, whilst you are taking Clonazepam. This is because it can slow down your reactions, particularly when you start taking it. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dependence

When taking this medicine there is a risk of dependence which increases with the dose and duration of treatment and also in patients with a history of alcohol and/or drug abuse.

Important information about some of the ingredients of Clonazepam

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Clonazepam

Always take Clonazepam exactly as your doctor has told you. You should check with your doctor if you are not sure.

- Your doctor will start you on a low dose of Clonazepam and gradually increase it over 2 to 4 weeks until the right dose has been found for you.
- Your doctor will usually tell you to split your daily dose into three equal amounts which you will take at evenly spaced times throughout the day.
- If the daily dose cannot be split equally, take the largest dose at bedtime.
- Once your doctor has found the right dose for you, they may tell you to take Clonazepam as a single dose in the evening.

Adults and children over 12 years

- The usual starting dose is 1mg a day, or less.
- This will be increased gradually (usually to between 4mg and 8mg a day). The maximum dose is 20mg a day.

The elderly

- The usual starting dose is 0.5mg a day, or less.
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- The usual starting dose is 0.25mg a day, or less.
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Older children (aged 5 to 12 years)

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If you take more Clonazepam than you should

- If you take more Clonazepam than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you may feel drowsy, sleepy, light-headed, have a lack of co-ordination or be less responsive than normal.

If you forget to take Clonazepam

- If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

Stopping Clonazepam

If you receive long term treatment with Clonazepam (are given the medicine for a long time) you may become dependent upon this medicine and get withdrawal symptoms (see Section 4).

- Do not stop taking your tablets without talking to your doctor. If you do, your fits may return and you may get withdrawal symptoms (see Section 4: 'Possible side effects').
- If the dose of Clonazepam you take has to be reduced, or stopped, this must be done gradually. Your doctor will let you know how to do this.

If someone else takes your Clonazepam by mistake, they should talk to a doctor or go to a hospital straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Clonazepam can cause side effects, although not everybody will get them.

Important side effects to look out for:

Allergic reactions

If you get an allergic reaction, **see a doctor straight away.**

The signs may include:

- Sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.
- Skin rash or itching.

Effects on the heart

If you notice any of the following effects, **see a doctor straight away.**

The signs may include:

- Breathlessness, swelling of the ankles, cough, tiredness and a racing heart.
- Chest pain which may spread to your neck and shoulders and down your left arm.

Effects on behaviour

If you notice any of the following effects, **talk to your doctor** as they may want you to stop taking Clonazepam. The signs may include:

- Being aggressive, excited, irritable, nervous, agitated, hostile or anxious.
- Problems sleeping, nightmares and vivid dreams.
- Mental problems such as seeing or hearing things that are not really there (hallucinations), delusions (believing in things that are not real) and problems with your speech.
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Infants and children

- If an infant or small child is taking Clonazepam, watch them carefully. This is because they could develop breathing problems, coughing or choking. This can be caused by too much saliva being made.
- Early puberty in children. This is reversible after stopping treatment with Clonazepam.

Elderly patients

Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones.

Other possible side effects

When you start taking Clonazepam you may notice the following effects:

- Feeling drowsy and tired.
- Feeling dizzy and light-headed.
- Weak or floppy muscles or jerky movements (poor co-ordination).
- Feeling unsteady when walking.

If you notice any of these effects, talk to your doctor. Your doctor may be able to help you by giving you a lower dose of Clonazepam and then increasing it slowly.

The following may occur at any time during your treatment

Mind and nervous system

- Poor concentration, confusion and a feeling of being lost (disorientation).
- Feeling restless.
- Difficulty remembering new things.
- Headache.
- Depression.
- Slowing or slurring of speech.
- Poor co-ordination, including feeling unsteady when walking.
- An increase in how often you have fits.

Liver, kidney and blood

- Changes in how well your liver is working (shown by blood tests).
- Loss of bladder control.
- Blood problems. The signs include feeling tired, bruising easily, being short of breath and nose bleeds. Your doctor may want you to have blood tests from time to time.

Stomach and gut

- Feeling sick (nausea).
- Stomach upset.

Eyes

- Double vision.
- Jerky movements of the eyes (nystagmus).

Breathing

- Breathing problems (respiratory depression). Early signs include suddenly noisy, difficult and uneven breathing. Your skin may become blue.

Skin and hair

- Skin rashes, hives (lumpy rash) and itchy skin.
- Changes to the colour of your skin.
- Hair loss (the hair usually grows back).

Sexual

- Loss of sex drive.
- Difficulty getting or keeping an erection (erectile dysfunction).

Withdrawal symptoms

Using benzodiazepines like Clonazepam may make you dependent on the medicine. This means that if you stop treatment quickly or reduce the dose too quickly, you may get withdrawal symptoms.

The symptoms can include:

- Problems sleeping.
- Muscle pain, shaking (tremor) and feeling restless.
- Feeling very anxious, tense, confused, irritable or agitated or changes in your mood.
- Increased sweating.
- Headache.

Less common withdrawal symptoms include:

- Feeling sensitive to light, noise and physical contact.
- Seeing or hearing things that are not really there (hallucinations).
- Tingling and feeling numb in your arms and legs.
- A feeling of losing contact with reality.

Injury

- Patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).

Reporting of side effects

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5. How to store Clonazepam

Keep out of the sight and reach of children.

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Clonazepam B&S 2mg tablets; PL 18799/1401

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