In particular, tell your doctor or pharmacist if
Rivotril works. Also some other medicines can affect the way
affect the way some other medicines work. The name of your medicine is Rivotril 0.5mg Tablets but will be referred to as Rivotril throughout this leaflet. This medicine is also available in other strength of Rivotril 2mg Tablets.

In this leaflet:
1. What is Rivotril and is it used for
2. How to take Rivotril
3. Possible side effects
4. Before you take Rivotril
5. Taking other medicines
6. Further information

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.
- You are allergic to alcohol or drug (prescription or recreational) use.
- You have had an allergic reaction to 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:
- You are elderly or frail.
- 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 use.
- You have had an allergic reaction to Rivotril if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rivotril.

Special care with Rivotril:
- You have ever had depression.
- You have ever had an alcoholic or drug (prescription or recreational) use.
- You have ever had drug abuse.
- You have a condition called ‘myasthenia gravis’ (where your muscles become weak and get tired easily).
- You have a hereditary blood disorder.
- You have an intolerance to some sugars, talk to your doctor before taking Rivotril.

How to take Rivotril:
- You should take Rivotril exactly as your doctor has told you. You should check with your doctor if you are not sure.
- You will start taking Rivotril at bedtime. Once your doctor has found the right dose for you, they may tell you to take Rivotril as required.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines such as:
- Other medicines to treat epilepsy, such as carbamazepine, hydantoin, phenobarbital, phenytoin, primidone or sodium valproate.
- Other medicines to treat sleep disorder, such as tarazepam, secobarbital, nitrazepam, triazolam.
- Some medicines used to treat tuberculosis (mainly to isoniazid).
- Rifampicin (an antibiotic used to treat infections).
- Medicines used to make you sleep ( hypnotics).
- Medicines that help with anxiety (anxiolytics).
- Pain-killers (analgesics) and medicines to relax your muscles (muscle relaxants).

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

Taking Rivotril with Alcohol
Do not drink alcohol while you are taking Rivotril. This is because it may cause side effects which are more likely to occur, particularly when you start taking it. If you are in any doubt about what 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:
  - You have been prescribed this medicine to treat a medical problem and Your doctor has taken it into account in the instructions given by the prescriber or in the information provided with the medicine
  - 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 Rivotril.

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 that you should be careful about eating if you have a condition called ‘galactosaemia’ (where you may become shaky or have fits if you eat milk or milk products).

The usual starting dose is 0.5mg a day. The maximum dose is 8mg a day.

For children aged 6 to 11 years

0.5mg tablets
The medicine contains lactose, which is a type of sugar that you should be careful about eating if you have a condition called ‘galactosaemia’ (where you may become shaky or have fits if you eat milk or milk products).

This will be increased gradually (usually to between 3mg and 6mg a day). The maximum dose is 20mg a day.

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.

Infants (aged 0 to 1 year)

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.

Small children (aged 1 to 5 years)

The usual starting dose is 0.25mg a day, or less.

This will be increased gradually (usually to between 1mg and 3mg a day).

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).

Please read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again in the future.
- 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 you think 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 0.5mg Tablets but will be referred to as Rivotril throughout this leaflet.

This medicine is also available in other strength of Rivotril 2mg Tablets.

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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.

Talk to special care with Rivotril:
- You have a rare, inherited blood disorder.
- You have a condition called ‘myasthenia gravis’ (where your muscles become weak and get tired easily).
- You have a hereditary blood disorder.
- You have an intolerance to some sugars, talk to your doctor before taking Rivotril.

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Small children (aged 1 to 5 years)

The usual starting dose is 0.25mg a day, or less.

This will be increased gradually (usually to between 1mg and 3mg a day).

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).

Patient Information Leaflet
If you take more Rivotril than you should,
- talk to a doctor straight away.
- go to a hospital straight away.
- do not 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 lose your sense of smell, all of which are less responsive than normal.
- if you forget to take Rivotril,
- take the tablets at the next time and continue as you would normally.
- do not take a double dose (two skips at the same time) to make up for a forgotten dose.

Stopping Rivotril
If you stop a long term treatment with Rivotril (are given the medicine for a long time) you may become dependent upon this medication. You may find it difficult to get withdrawal symptoms (see Section 4).

- Do not stop taking your tablets without talking to your doctor. If you do, yourfits 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 may be done gradually. Your doctor will let you know how to do this.
- If someone else takes your Rivotril tablets by mistake, they should take 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 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 cause choking.
    - 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.
    - rapid heartbeat.

- Mood and nervous system
  - if you notice any of these effects, talk to your doctor. Your doctor may be able to help you by giving you a lower dosage 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.
  - Slurred or slurred speech.
  - Poor co-ordination, including feeling unsteady when walking.

- An increase in how often you have fits.
- Liver, kidney and blood
  - you may need to do blood tests (shown by blood tests).
  - Loss of bladder control.
  - Depression. 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).
  - Bloating.
  - Eyes
    - Double vision.
    - Jerky movements of the eyes (nystagmus).
- Breathing
  - Breathing problems (respiratory depression). Early signs include sudden noticeable tiredness and uneven breathing.
  - Your skin may become blue.
  - Skin
    - Skin rashes, hives (lumpy rash) anditchy 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).

If your swelling symptoms include:
- Be aware of your symptoms.
- Using benzodiazepines like Rivotril may make symptoms like swelling and tiredness worse.
  - 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, irritability or agitation, or changes in your mood.
    - Increased sweating.

- Headache
  - Loss of common withdrawal symptoms include:
    - Fussiness or irritability, loss of coordination, loss of balance, loss of muscle control.
    - Seizures.
    - Seizures may be a problem especially if you have had seizures before.

- Long term treatment with benzodiazepines can cause side effects.

5. Further information
- What Rivotril tablets look like and are made of:
  - Each tablet contains 0.5mg clonazepam as the active ingredient.
  - It contains the inactive ingredients, lactose, maize starch, pregelatinised maize starch, magnesium stearate, talc, yeast, red iron oxide (E172) and yellow iron oxide (E172).

- How to store Rivotril tablets:
  - Keep Rivotril tablets in their original pack.
  - Keep Rivotril tablets at room temperature. Do not store in fridge or freezer.
  - Keep Rivotril tablets out of the reach of children.

- How to dispose of Rivotril tablets:
  - Do not use Rivotril after the expiry date on the pack.
  - Do not throw away any left over tablets.

- Blood tests
  - In some cases, your doctor may want you to have blood tests from time to time, to make sure Rivotril is helping you.

- Adverse reactions
  - If you experience any of the following side effects:
    - windburn, or red spots.
    - fever, itching or swelling (lumps or hives).
    - blistering, peeling or loosening of skin.
    - Sudden swelling of the hands, feet and mouth. This may make it difficult to breathe or cause choking.
    - Fastening of the skin.

- Reporting of side effects
  - If you experience any of these side effects, talk to your doctor, pharmacist or nurse. 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
  - By reporting side effects, you can help provide more information on the safety of this medicine.