Other medicines and Clonazepam
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, pimozide 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 (anxiolytics).
- Pain-killers (analgesics) and medicines to relax your muscles (muscle relaxants).

Concomitant use of Clonazepam and opioids (strong pain killers, medicines for breakthrough pain) 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.

If you are going to have an anaesthetic (where you may become shaky and confused), it is important to tell your doctor or pharmacist before taking Clonazepam.

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

Pregnancy and breast-feeding
You must not take Clonazepam if you are 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 benzodiazepine abuse.

Clonazepam contains:
This medicine also contains ethanol (96%). This means that 1ml contains 6.46mg of alcohol. This is same as 1.6ml of beer or 0.66ml of wine per 5ml dose.

3. How to take Clonazepam
Always take Clonazepam exactly as your doctor has told you. You should check this 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 spread your daily dose into four equal amounts which you will take at evenly spaced times throughout the day.
- Once your doctor has found the right dose for you, they may tell you to take Clonazepam as a single dose in the evening.

Starting dose:
Clonazepam Thame 0.5mg/5ml Oral Solution is recommended for starting dose.

- Adults: The usual starting dose is 10ml (1mg) a day, or less.
- Elderly: the usual starting dose is 5ml (0.5mg) a day, or less.

Maintenance dose:
Clonazepam Thame 2mg/5ml Oral Solution is recommended for maintenance dose.

Adaptation: Elderly.
The starting dose will be increased gradually as maintenance dose (usually to between 10ml (1mg) and 20ml (2mg) a day). The maximum dose is 50ml (20mg) a day.

Route and method of administration
This medicinal product must be taken orally.

- Use the 10ml oral syringe with 1ml increments (use a 4ml measure if you are taking 2mg/5ml intermediate graduation).

Instructions for the use of syringe:
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1).
- b) Insert the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible air bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres prescribed by your doctor (figure 5C).
- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the syringe holder (figure 6B).
- e) Empty the contents of the syringe into the patient’s mouth by pushing the piston to the bottom of the syringe (figure 7A) without removing the bottle with the plastic screw cap. Wash the syringe with water (figure 8).
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

Mental and nervous system
- Poor concentration, confusion and a feeling of being lost (disorientation).
- Feeling restless.
- Difficulty remembering new things.
- Headache.
- Slowing or slurring of speech.
- Poor attention, 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
Use 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 sedative (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 you can help provide more information on the safety of this medicine.

5. How to store Clonazepam
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or bottle label after ‘Exp’. The expiry date refers to the last day of that month.
- This medicinal product does not require any special temperature storage conditions.
- Keep the bottle tightly closed.
- Keep the bottle in the outer carton in order to protect from light.
- Discard 30 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicine via waste water or household waste. Ask: bottle(s) change or dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clonazepam contains
- The active substance is Clonazepam.

For 0.5mg/5ml: Each 5ml Solution contains 0.5mg Clonazepam.

For 2mg/5ml: Each 5ml Solution contains 2mg Clonazepam.

The other ingredients are ethanol (96%) and medium chain triglycerides.

What Clonazepam looks like and contents of the pack
- Clonazepam is clear, colourless to pale yellow colour oral solution supplied in an amber glass bottle with tamper-evident, child resistant plastic screw cap and a 10ml oral syringe with 0.25ml graduation for measuring the required dose and a syringe adapted.

Clonazepam oral solution is supplied in 10ml bottles.

Marketing Authorisation Holder:
- Therme Laboratories, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

Manufacturer:
- SIMVIS PHARMACEUTICALS S.A.
- Asklipiou 4-6, Kryoneri, Attiki, 14568, Greece

If this leaflet is hard to see or read, you can call (0) 208 515 3700 for help.

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