

## **Package Leaflet: Information for the user**

### **Clobazam Thame 5mg/5ml Oral Suspension Clobazam Thame 10mg/5ml Oral Suspension clobazam**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- ▶ 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- ▶ If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Clobazam Thame 5mg/5ml or 10mg/5ml Oral Suspension but will be referred to as Clobazam throughout this leaflet.

#### **What is in this leaflet:**

- 1. What Clobazam is and what it is used for**
- 2. What you need to know before you take Clobazam**
- 3. How to take Clobazam**
- 4. Possible side effects**
- 5. How to store Clobazam**
- 6. Contents of the pack and other information**

#### **1. What Clobazam is and what it is used for**

This medicine contains the active substance clobazam which belongs to a group of medicines called benzodiazepines.

It works by having a calming effect on the brain.

#### **Clobazam can be used for:**

- ▶ The short-term treatment of the symptoms of severe anxiety in adults
- ▶ Epilepsy (fits) in adults and children aged over 2 years (together with other treatments).
- ▶ Short term treatment of hyperarousal and agitation in patients with schizophrenic or other psychotic illness (only in combination with other treatments as benzodiazepines alone are not effective in these patients)

#### **2. What you need to know before you take Clobazam**

##### **Do not take Clobazam if:**

- ▶ You are allergic to clobazam, other benzodiazepine medicines or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- ▶ You are breast-feeding.
- ▶ You have ever had problems with drugs or alcohol dependence in the past.
- ▶ You suffer from an illness that causes muscle weakness (called 'myasthenia gravis').
- ▶ You have severe liver problems.
- ▶ You have severe breathing problems.
- ▶ You stop breathing for short periods during sleep (called 'sleep apnoea syndrome').
- ▶ The patient is under 2 years old, except if the doctor decides this is necessary.

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

### **Warnings and Precautions**

**Note:** Make sure that you receive the same clobazam medicine **every time** you collect your prescription unless your doctor has agreed to change to a different clobazam medicine. If the appearance of this medicine is not the same as usual or if the dosage instructions have changed, speak to your doctor or pharmacist as soon as possible to make sure you have the right medicine.

Talk to your doctor or pharmacist before taking Clobazam if:

- ▶ You have problems with controlling your movements (called ‘spinal or cerebellar ataxia’).
- ▶ You have depression, irrational fears and obsessions.
- ▶ You have delusions (believing things which are not true) or hallucinations (sensing things which are not there).
- ▶ You have liver or kidney problems. Your doctor will decide whether to reduce the dose of Clobazam.
- ▶ You have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with Clobazam as there is an increased risk of experiencing side effects.
- ▶ You are over 65. This is due to increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that may result in serious injury.
- ▶ You have difficulty digesting medicines. In some patients, liver may not metabolise (break down) medicines adequately. In these patients the medicine may remain in the body for a longer period of time. This may result in side effects. If you are known to poorly metabolise certain medicines please speak to your doctor.

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

#### *Suicidal thoughts*

Tell your doctor straight away if you start thinking about suicide or harming yourself. Some patients have had suicidal thoughts while taking medicines containing clobazam, especially if they were also depressed.

#### *Psychotic or ‘Paradoxical’ reactions*

It is known that with the use of clobazam restlessness, agitation, irritability, aggression, delusions, rage, nightmares, hallucinations, deceptive thoughts (psychosis), inappropriate behaviour and other adverse behavioural effects may occur. If this happens you should stop taking Clobazam and contact your doctor. These reactions are more common in children and elderly patients.

#### *Dependence, withdrawal and tolerance*

You may become dependent on Clobazam if you take it for a long period of time or with high dose, particularly if you have a history of heavy alcohol or drug use. This means that you may feel that you need to continue treatment with Clobazam in order to feel well (known as psychological dependence). You should therefore take Clobazam for as short time as possible.

If you suddenly stop taking Clobazam you may experience worsening of the symptoms you were originally being treated for, as well as mood changes, anxiety, sleep disturbance,

headache, increased dreaming, tension, confusion, excitability, hallucinations, muscle pain, numbness of the limb, tingling, sweating, tremor, nausea, sensitivity to light, increased sensitivity to sound, sensitivity to light or restlessness.

This is known as withdrawal symptoms and can be avoided by slowly reducing your dose. If you are worried about dependence or withdrawal please talk to your doctor.

If you take Clobazam for a long period of time for treatment of epilepsy it is possible that you may become tolerant to it, meaning that it will not be as effective as it was when you first started taking it. If you feel that Clobazam is no longer helping to control your symptoms please talk to your doctor, they may suggest you take a short break from this medicine.

#### *Breathing difficulties*

Clobazam may cause respiratory depression, particularly when administered at high doses. Tell your doctor if you have respiratory failure, your doctor will decide whether to reduce the dose. In case of severe respiratory disturbance, clobazam may not be used.

#### *Serious skin problems*

Clobazam may cause serious skin reactions. You should talk to your doctor if you develop any rash unless it is clearly not drug related.

#### *Children*

Clobazam should only be used in children from 1 month to 2 years old, under exceptional situations, where there is a clear epilepsy indication.

### **Other medicines and Clobazam**

**Please tell your doctor or pharmacist** if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Clobazam can affect the way some other medicines work. Also, some medicines can affect the way Clobazam works.

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

- ▶ Medicines for epilepsy (such as phenytoin, carbamazepine, stiripentol or valproic acid).
- ▶ Medicines for depression (Monoamine Oxidase Inhibitors (MAOIs) such as phenelzine and isocarboxazid; tricyclic anti-depressants such as amitriptyline and nortriptyline; trazodone; Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine and paroxetine).
- ▶ Medicines for severe mental illness called ‘antipsychotics’ (such as chlorpromazine, haloperidol, clozapine and pimozide).
- ▶ Painkillers (such as medicines containing codeine, dihydrocodeine or morphine).
- ▶ Sleeping tablets (such as zolpidem).
- ▶ Tranquilisers (such as diazepam, temazepam or lorazepam).
- ▶ Muscle relaxants (such as baclofen).
- ▶ Antihistamines that make you sleepy (such as chlorphenamine, promethazine or diphenhydramine).
- ▶ Lithium - used for a mental illness called ‘manic-depressive illness’ (mood changes between a state of high excitability or exaggerated emotions and depression).
- ▶ Cimetidine - used to treat ulcers and heartburn.
- ▶ Erythromycin - used to treat infections caused by bacteria.
- ▶ Omeprazole - used to treat the symptoms of acid reflux such as heartburn or acid regurgitation.

- ▶ Ticlopidine - an antiplatelet medication used in patients with an increased risk of stroke.
- ▶ Fluconazole - used in the treatment of fungal conditions.
- ▶ Dextromethorphan - used to relieve dry, irritating coughs.
- ▶ Nebivolol - medicine used to treat high blood pressure.

Concomitant use of Clobazam 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 Clobazam 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 not sure if any of the above apply to you talk to your doctor or pharmacist.

### **Anaesthetics**

If you are going to have an anaesthetic, tell your doctor or anaesthetist that you are taking Clobazam. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants to give you.

### **Clobazam with food, drink and alcohol**

Do not drink alcohol while taking Clobazam. This is because there is an increased risk of sleepiness and other side effects.

### **Pregnancy, breast-feeding and fertility**

#### *Pregnancy*

Use of this medicine is not recommended during pregnancy and in women of childbearing potential not using contraception.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment. Do not stop taking Clobazam without talking to your doctor.

A large amount of data has not shown evidence of malformations associated with the use of benzodiazepines. However, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population.

Cleft lip and palate (sometimes called "harelip") is a deformation at birth caused by incomplete fusion of the palate and upper lip.

Reduced fetal movement and fetal heart rate variability may occur after taking Clobazam during the second and/or third trimester of pregnancy.

If Clobazam is taken at the end of pregnancy or during childbirth, your baby may show drowsiness (sedation), muscle weakness (hypotonia or floppy infant syndrome), a drop in

body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory depression sometimes severe).

If taken regularly in late pregnancy, your baby may get withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

### **Driving and using machines**

Clobazam has major influence on the ability to drive and use machines. You may feel sleepy or have concentration or memory problems after taking this medicine. You may also experience double vision or you may react more slowly to things. If this happens, do not drive or use any tools or machines.

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

### **Clobazam contains:**

This medicine contains **methyl parahydroxybenzoate (E218)**, which may cause allergic reactions (possibly delayed).

This medicine contains less than 1mmol **sodium** (23mg) per 5ml, that is to say essentially 'sodium-free'

## **3. How to take Clobazam**

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- ▶ If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
- ▶ Keep taking Clobazam until your doctor tells you to stop.
- ▶ Clobazam is usually given for 2 to 4 weeks. After that, your doctor will decide whether you should keep taking this medicine.

### **The recommended doses are:**

#### **5mg/5ml Doses:**

#### **Adults (Anxiety and Epilepsy)**

- ▶ Treatment of Anxiety: The usual dose is 20ml (20mg) to 30ml (30mg) each day.
- ▶ Treatment of Epilepsy: The starting dose is 5ml (5mg) to 15ml (15mg) each day. This can be taken as two separate doses or as a single dose at night. Your doctor may increase your dose to up to 60ml (60mg) each day. Your doctor may lower the dose to suit you.

#### **Children (over 2 years) (Epilepsy)**

- ▶ The usual starting dose is 5mg (5ml) each day in children aged 6 years and above or 0.1mg/kg/day for younger children in divided doses or as a single dose at night.
- ▶ Your doctor will then adjust the dose according to your child's response.

#### **Elderly (Anxiety and Epilepsy)**

- ▶ Treatment of Anxiety: The usual dose for anxiety is 10ml (10mg) to 20ml (20mg) each day.

- ▶ Treatment of Epilepsy: In elderly patients your doctor will start a low initial dose with gradual increases.

### 10mg/5ml Doses:

#### Adults (Anxiety and Epilepsy)

- ▶ Treatment of Anxiety: 10ml (20mg) to 15ml (30mg) each day.
- ▶ Treatment of Epilepsy: Starting dose is 2.5ml (5mg) to 7.5ml (15mg) each day. This can be taken as two separate doses or as a single dose at night. Your doctor may increase your dose to up to 30ml (60mg) each day. Your doctor may lower the dose to suit you.

#### Children (over 2 years) (Epilepsy)

- ▶ The usual starting dose is 5mg (2.5ml) each day in children aged 6 years and above or 0.1mg/kg/day for younger children in divided doses or as a single dose at night.
- ▶ Your doctor will then adjust the dose according to your child's response.

#### Elderly (Anxiety and Epilepsy)

- ▶ Treatment of Anxiety: The usual dose for anxiety is 5ml (10mg) to 10ml (20mg) each day.
- ▶ Treatment of Epilepsy: In elderly patients your doctor will start a low initial dose with gradual increases.

#### Patients with hepatic or renal impairment (Anxiety and Epilepsy):

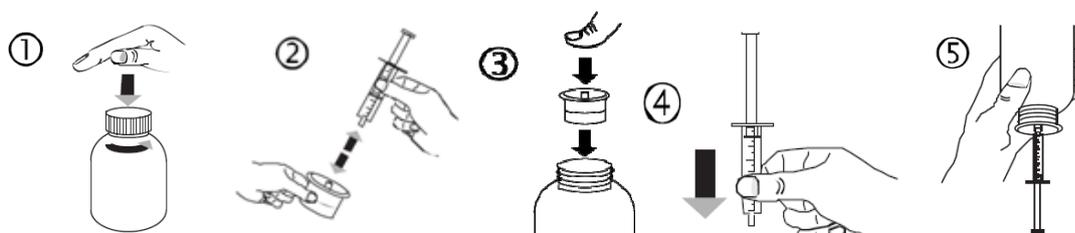
In patients with liver or kidney disease lower initial doses are required, with a gradual increase under careful observation of your doctor (see section "Warnings and precautions").

#### Method of administration

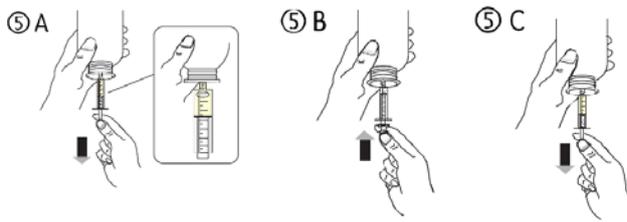
- ▶ Take this medicine by mouth.
- ▶ This product may settle during storage. Shake the bottle well before use.
- ▶ Use the measuring syringe provided in the pack to deliver the required dose.
- ▶ When you are taking medicines like Clobazam you should not use a different clobazam containing medicine except under your doctor's supervision.
- ▶ Clobazam can be taken with or without food.

#### Instructions for the use of syringe:

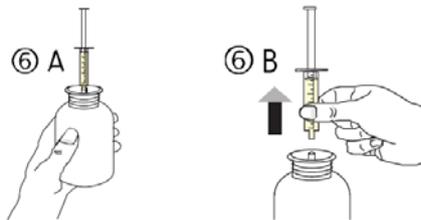
1. Open the bottle: press the cap down and turn it anticlockwise (Figure 1).
2. Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is fixed well. Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



3. Fill the syringe with a small amount of suspension by pulling the piston down (figure 5A), then push the piston up in order to remove any possible air bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).

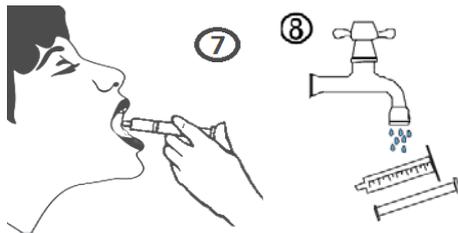


4. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



5. Put the end of the syringe into the mouth and push the plunger slowly back in to deliver the medicine into the mouth (figure 7).

6. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8) and store in a clean place.



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

If you take more Clobazam than you should, tell your doctor or go to your nearest hospital casualty department straight away. Do not drive yourself, because you may start to feel sleepy. Remember to take the medicine pack with you. This is so that the doctor knows what you have taken.

### **If you forget to take Clobazam**

- ▶ If you forget to take a dose, take it as soon as you remember.
- ▶ However, if it is nearly time for the next dose, skip the missed dose.
- ▶ Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Clobazam**

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Clobazam just because you feel better.

- ▶ When your doctor says that you can stop taking Clobazam, you need to do this gradually. Your doctor will help you to do this.
- ▶ Stopping the medicine can make you feel stressed (anxiety), confused or depressed. You may also lose your appetite and have difficulty sleeping. Tell your doctor if this happens.

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You may feel ill after taking this medicine, or notice unusual or unexpected symptoms. If this happens, tell your doctor.

**Tell your doctor straight away if you have any of the following side effects:**

- ▶ Feeling restless, have difficulty sleeping or nightmares
- ▶ Feeling irritable or anxious
- ▶ Believing things which are not true (delusions)
- ▶ Sensing things which are not there (hallucinations)
- ▶ Feeling suicidal (see section 2 'Suicidal thoughts')
- ▶ Increased possibility of tripping or falling especially in elderly patients.
- ▶ Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also, flu-like symptoms and fever. This may be something called 'Stevens Johnson Syndrome' which is a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also, a feeling of being generally unwell, fever, chills and aching muscles. This is something called 'Toxic epidermal necrolysis'.

Tell your doctor straight away if you get any of the side effects listed above. Your doctor may decide that your treatment needs to be stopped.

**Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days.**

The following side effects are more likely to happen at the start of treatment. They usually last for a short time:

- ▶ Headache
- ▶ Feeling sleepy, tired, drowsy or dizzy
- ▶ Reacting to things more slowly than usual
- ▶ Difficulty in staying awake or alert
- ▶ Dry mouth, constipation
- ▶ Shaking fingers
- ▶ Muscle weakness.

**Other side effects include:**

- ▶ Feeling sick
- ▶ Slurred or slow speech
- ▶ Breathing problems
- ▶ Loss of memory, confusion or trouble remembering things
- ▶ Skin rash
- ▶ Problems walking or other movement problems
- ▶ Falls
- ▶ Eye problems such as double vision and rapid uncontrolled movement of the eyes
- ▶ Unusual or out of character behaviour
- ▶ Becoming dependent on Clobazam (also called 'physical or mental dependence')
- ▶ Weight gain
- ▶ Loss of sexual drive.

If you take this medicine for a long time, you are more likely to get the following side effects:

- ▶ Feeling anxious
- ▶ Confusion, depression

- ▶ Loss of appetite
- ▶ Difficulty sleeping

### **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 HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Clobazam**

- ▶ 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 after EXP. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special storage conditions.
- ▶ For 5mg/5ml: Discard 30 days after first opening.
- ▶ For 10mg/5ml: Discard 60 days after first opening.
- ▶ Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Clobazam contains**

The active substance is clobazam.

For 5mg/5ml: Each 5ml of oral suspension contains 5mg clobazam.

For 10mg/5ml: Each 5ml of oral suspension contains 10mg clobazam.

The other ingredients are methyl parahydroxybenzoate (E218), citric acid monohydrate (E330), sodium citrate (E331), sucralose (E955), xanthan gum (E415) and purified water.

### **What Clobazam looks like and contents of the pack**

Clobazam is white to off-white viscous liquid supplied in an amber glass bottle with tamper-evident child resistant plastic screw cap and a 5ml polypropylene oral syringe with 0.1ml graduation mark and an adaptor for the syringe. Where higher doses are to be administered, dosing cups should be considered.

Clobazam is supplied in bottles containing 100ml and 150ml suspension.

Not all pack sizes may be marketed.

**POM**

### **Marketing Authorisation Holder:**

Syri Pharma Limited t/a Thame Laboratories  
Floor 0, 1 WML,  
1 Windmill Lane,  
Dublin 2, D02 F206, Ireland.

**Manufacturer:**

Pharmadox Healthcare Ltd,  
KW20A Kordin Industrial Park,  
Paola PLA 3000,  
Malta

OR

Delpharm Bladel B.V.  
Industrieweg 1,  
5531 AD, Bladel,  
Netherlands

**If this leaflet is hard to see or read, please call +353 1 437 0882 for help.**

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