**APPROVED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S5**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**CLONAM 0.5 (Tablets)**

Each tablet contains 0,5 mg clonazepam.

**CLONAM 2 (Tablets)**

Each tablet contains 2 mg clonazepam.

**Read all of this leaflet carefully before you start taking CLONAM.**

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

## 1. WHAT CLONAM CONTAINS

The active substance is clonazepam.

Each **CLONAM 0.5** tablet contains 0,5 mg clonazepam.

Contains lactose.

The other ingredients are anhydrous lactose, ferric oxide red (E 172), ferric oxide yellow (E 172), magnesium stearate, microcrystalline cellulose, pregelatinised starch.

Each **CLONAM 2** tablet contains 2 mg clonazepam.

Contains lactose.

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

## 2. WHAT CLONAM TABLETS ARE USED FOR:

**CLONAM** is used for the treatment of seizures or fits in children and adults.

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

## 3. BEFORE YOU TAKE CLONAM

**Do not take CLONAM if:**

- You are allergic to clonazepam or any of the other ingredients of **CLONAM** tablets (see **WHAT CLONAM CONTAINS**).
- You are allergic to other benzodiazepines, such as diazepam, chlordiazepoxide, bromazepam, or flurazepam for example.
- You have breathing problems or suffer from lung disease.
- You have pressure build up in the eye (glaucoma).
- You have a severe liver condition.
- You muscles become weak and get tired easily (myasthenia gravis).
- Your breathing stops for short periods while you are asleep (sleep apnoea).
- You are shaky and unsteady, have slurred speech or have rapid eye movements.
- You are taking other medicines for fits, medicines to help you sleep, pain medicines, medicines to calm you, or medicines for depression or lithium.
- You have an addiction to medicines, recreational substances or alcohol.

**Take special care with CLONAM if:**

- You find that there is an increase in the amount of salivary or bronchial mucous (phlegm). This occurs in small children.Ensure the airways remain free of secretions.
- You have been told by your doctor that you have intolerance to some sugars (e.g. glucose, lactose, galactose). Contact your doctor before taking **CLONAM.**
- You have kidney or liver problems.
- You have a history of anxiety, depression or suicidal attempts. Depression may occur in

patients treated with **CLONAM.** If, at any time, you have thoughts of harming or killing yourself, contact your doctor immediately.

- You are taking any other medicines that affect your central nervous system as the effects of **CLONAM** may be increased.
- You consume alcohol, as alcohol can provoke epileptic seizures or modify the effects of **CLONAM** or give rise to unpredictable side effects.
- You are an epileptic (suffer from seizures) and you find there is an increase in the number of seizures (fits) you are having.
- You find you are becoming dependent on **CLONAM**, i.e. you need higher doses to get the same effect as compared to when you initially started the medicine. The risk of dependence (addiction) increases with higher doses and/or long-term treatment; or in patients who have a history of alcohol or substance abuse.
- You reduce your dose or stop taking **CLONAM**, as suddenly stopping treatment or a decrease in dose can cause your fits to return or cause withdrawal symptoms. Symptoms of withdrawal may include shaking (tremor), sweating, agitation, problems sleeping, feeling anxious, headaches, muscle pain, feeling tense and restless, confusion, feeling irritable or having seizures (fits). In severe cases, it can include a feeling of losing contact with reality, having feelings that your thoughts and actions are not your own, tingling and feeling numb in your arms and legs, feeling sensitive to light, noise or physical contact or seeing or hearing things that are not really there.
- You experience behavioural disturbances such as being aggressive, excited, irritable, nervous, agitated or anxious or you develop eating disorders such as anorexia (eating too little) or hyperphagia (overeating).
- You are elderly, as your dose of **CLONAM** may need to be adjusted by your doctor.

**Taking CLONAM with food and drink**

**CLONAM** may be taken with or without food.

You should not drink alcohol whilst taking **CLONAM** as this may provoke epileptic seizures or it may increase the effects of **CLONAM.**

**Pregnancy and Breastfeeding**

It is better not to take **CLONAM**, if you are pregnant or breastfeeding.

If advised to take **CLONAM** during late pregnancy or during labour, your baby might have a low body temperature, floppiness, breathing and feeding difficulties and an irregular heart beat.

**CLONAM** passes into breast milk. If you are breastfeeding, **CLONAM** should be avoided.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

**Driving and using machinery**

As a general rule, epileptics are not allowed to drive. **CLONAM** may cause drowsiness or dizziness and may, therefore affect your ability to be alert. Driving, operating machinery and carrying out other hazardous activities should therefore be avoided altogether or at least for the first few days of treatment. 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 CLONAM**

**CLONAM** contains lactose which may affect patients who are lactose intolerant, suffer from hereditary galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

**Taking other medicines with CLONAM:**

Always tell your healthcare professional if you are taking other medicine (This includes

complementary or traditional medicines).

The effects of **CLONAM** may be lessened by the simultaneous intake of the following medicines:

- Barbiturates, hydantoins or carbamazepine (medicines used to treat epilepsy),
- Rifampicin (an antibiotic used to treat infections).

The effects of **CLONAM** may be increased by the simultaneous intake of the following medicines:

- Phenytoin or primidone (medicines used to treat epilepsy).
- Medicines used to make you sleep.
- Medicines used to help with anxiety (tranquillisers).
- Pain killers or medicines to relax your muscles
- Cimetidine (used for stomach problems and heartburn)
- Alcohol and anaesthetics

Taking **CLONAM** with Valproic acid can cause seizures or fits.

## 4. HOW TO TAKE CLONAM

Do not share medicines prescribed for you with any other person.

- Always take **CLONAM** tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- The dose your doctor prescribes for you will depend on the nature of your illness, your reaction to the medicine, your age and body weight.
- Your doctor will start you on a low dose of **CLONAM** and gradually increase it over 2 to 4 weeks until the right dose has been found for you.
- The total daily dose should be taken as advised by your doctor in three or four divided doses at intervals 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, you may be told to take **CLONAM** as a

single dose in the evening.

- Swallow the tablets with water.
- Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.
- Your doctor will tell you how long your treatment with **CLONAM** will last.
- Do not stop treatment without consulting your doctor. If you do, your symptoms may return and you may get withdrawal symptoms.

**If you take more CLONAM than you should:**

You may feel drowsy, sleepy, confused, lightheaded, have a lack of coordination, low muscle tone or be less responsive than normal.

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

**If you forget to take CLONAM**

If you forget to take a 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.

**Effect when treatment with CLONAM is stopped:**

- Do not stop **CLONAM** without talking to your doctor.
- If you do your fits may return and you may get withdrawal symptoms (See "**Take Special Care with..**").
- If the dose of **CLONAM** you take has to be lowered, or stopped, this must be done gradually. Your doctor will let you know how to do this.

## 5. POSSIBLE SIDE EFFECTS

Not all side effects reported for this medicine are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

**CLONAM** can have side effects.

If any of the following happens, stop taking **CLONAM** and tell your doctor immediately or go to the casualty department of your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in breathing or swallowing, eyes, lips and hands
- difficulty in breathing
- rash or itching
- increase in saliva or bronchial secretions (phlegm) in children.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CLONAM.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice the following:

*Frequent*

- drowsiness (more common in the elderly and with higher doses), dizziness, weak or floppy muscles, slowing or slurring of speech,
- tiredness and sleepiness,
- difficulty remembering new things,
- slow reaction,
- over-sedation,

- muscle weakness,
- loss of sex drive and impotence,
- dependence (require the medicine in higher doses) and withdrawal symptoms (experience unpleasant symptoms when the medicine is stopped). Withdrawal symptoms may include feeling sensitive to light or noise, 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).

*Less frequent:*

- allergic reactions and swelling of the deep layers of the skin,
- nausea (feeling sick), diarrhoea, abdominal pains or stomach cramps,
- feeling depressed or having difficulty concentrating,
- feeling restless or confused,
- a feeling of being lost,
- feeling excited or irritated,
- feeling aggressive or agitated,
- feeling nervous, hostile or anxious,
- having problems sleeping, nightmares and vivid dreams,
- feelings of losing contact with reality, seeing or hearing things that are not really there (hallucinations),
- new type of seizures (fits),
- becoming over excited and very angry,
- headaches,
- seizures (fits),
- memory loss,
- tiredness,

- heart failure (heart cannot pump enough blood) or arrest (heart stops beating),
- low muscle tone,
- not being able to carry out movements with normal accuracy,

These effects occur early in treatment but do not last and disappear as treatment continues.

They can be avoided by slowly increasing the dose, which your doctor will do.

- a reduction in blood platelets,
- skin rash,
- swelling of the throat,
- hair loss (the hair usually grows back),
- changes in skin colour,
- double vision or jerky movements of the eyes,
- falls and fractures in the elderly,
- abnormal liver function tests,
- loss of bladder control,
- difficulty getting or keeping an erection.

*The following side effect does occur but not very often:*

early sexual development in children (this is reversible)

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

## 6. STORING AND DISPOSING OF CLONAM

- Store at or below 25°C.
- Protect from light.
- Do not remove the blister from the carton until required for use.
- Keep all medicines out of reach children.

- Do not use this medicine after their use-by (expiry) date which is printed on the box and the blister strip.
- If the tablets are out of date return them to your pharmacist.
- Do not dispose of medicines by flushing them down the drain or down the toilet. Ask your pharmacist how to dispose of medicines no longer required.

## 7. PRESENTATION OF CLONAM:

**CLONAM 0.5** Tablets are available as clear, PVC/PVDC-Aluminium foil blister strips with VMCH heat seal coating containing either 7, 14 or 10 tablets per blister each in a pack size of 84, 90 or 100 tablets packed in an outer carton.

**CLONAM 2** Tablets are available as clear, PVC/PVDC-Aluminium foil blister strips with VMCH heat seal coating containing either 7, 14 or 10 tablets per blister each in a pack size of 84, 90 or 100 tablets packed in an outer carton.

## 8. IDENTIFICATION OF CLONAM

**CLONAM 0.5** Tablets: Peach coloured, flat, circular, bevelled tablets with cross-scored on one side, plain on the other side.

**CLONAM 2** Tablets: White to off white, flat, circular, bevelled tablets with cross-scored on one side, plain on the other side.

## 9. REGISTRATION NUMBERS

**CLONAM 0.5:** 45/2.5/0820

**CLONAM 2:** 45/2.5/0821

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

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## 11. DATE OF PUBLICATION

## DATE OF REVISION