

# PATIENT INFORMATION LEAFLET

## Clonazepam Orally Disintegrating Tablets USP KALM DT 0.25/0.5/1/2

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.

### What is in this leaflet:

1. What KALM DT is and what it is used for
2. What you need to know before you take KALM DT
3. How to take KALM DT
4. What are the possible side effects of KALM DT
5. How to store KALM DT
6. Contents of the pack and other information

### 1. What KALM DT is and what it is used for

KALM DT contains the active substance Clonazepam, which belongs to a group of medicines called benzodiazepines.

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

- ❖ It lowers the number of fits (seizures) that you have.

### 2. What you need to know before you take KALM DT

#### Do not take KALM DT

- ❖ If you are allergic to Clonazepam or any of the other ingredients of this medicine.
- ❖ If you have breathing problems or lung disease.
- ❖ If you have severe liver problems.
- ❖ If you have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking KALM DT.

### Warnings and precautions

Talk to your doctor or pharmacist before taking KALM DT

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, contact your doctor immediately.

Check with your doctor or pharmacist before taking KALM DT if:

- ❖ You have liver, kidney or lung problems.
- ❖ You have a condition called 'myasthenia gravis' (where your muscles become weak and get tired easily).
- ❖ You have ever had depression.
- ❖ You have ever tried to kill yourself.
- ❖ You regularly drink alcohol or take recreational drugs or you have had problems with alcohol or drug use in the past.
- ❖ You have ataxia (where you may become shaky and unsteady, have slurred speech or rapid eye movements).
- ❖ You have a rare, inherited blood condition 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 KALM DT.

### Other medicines and KALM DT

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines taken without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ❖ Other medicines to treat epilepsy, such as Carbamazepine, Lamotrigine, Hydantoin, Phenytoin, 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).

### Operation

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 KALM DT.

### KALM DT with alcohol

Do not drink alcohol while you are taking KALM DT. This is because it may cause side effects or cause your fits to return. Alcohol can also increase the effects of KALM DT, possibly leading to severe sedation that could result in coma or death.

### Pregnancy and breast-feeding

You must not take KALM DT if you are pregnant, might become pregnant or are breast-feeding, unless your doctor tells you to. KALM DT 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 KALM DT. 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.

### 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.

### 3. How to take KALM DT

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

- ❖ Your doctor will start you on a low dose of KALM DT 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 KALM DT as a single dose in the evening.

### Adults and children over 12 years

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

### Elderly

The usual starting dose is 0.5 mg a day, or less.

This will be increased gradually (usually to between 4 mg and 8 mg a day). The maximum dose is 20 mg a day.

### Infants (aged 0 to 1 year)

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

This will be increased gradually (usually to between 0.5 mg and 1 mg a day).

### Small children (aged 1 to 5 years)

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

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

### Older children (aged 5 to 12 years)

The usual starting dose is 0.5 mg a day, or less.

This will be increased gradually (usually to between 3 mg and 6 mg a day).

### If you take more KALM DT than you should

If you take more KALM DT 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 KALM DT

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.

### If you stop taking KALM DT

If you receive long term treatment with KALM DT you may become dependent upon this medicine and get withdrawal symptoms.

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.
- ❖ Diarrhoea.

### 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.
- ❖ Do not stop taking your tablets without talking to your doctor.

#### 4. What are the possible side effects of KALM DT

Like all medicines, this medicine can cause side effects, although not everybody gets 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 KALM DT.

The signs may include:

- ❖ Being aggressive, hyperactive, irritable, nervous, agitated, hostile or anxious.
- ❖ Problems sleeping, nightmares and abnormal 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.
- ❖ Inappropriate behaviour, emotional and mood changes.
- ❖ Types of fits (seizures) that you have not had before.

##### Infants and children

If an infant or small child is taking KALM DT, 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 KALM DT.

##### Other possible side effects

When you start taking KALM DT, 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 KALM DT 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

- ❖ Loss of bladder control.
- ❖ Blood problems. The signs include feeling tired, bruising easily, being short of breath and nose bleeds.

##### 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.

##### 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

- ❖ Changes in sex drive.
- ❖ Difficulty getting or keeping an erection (erectile dysfunction).

##### 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 of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

##### 5. How to store KALM DT

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 and blister/bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

The active ingredient is Clonazepam.

##### KALM DT 0.25

Each uncoated orally disintegrating tablet contains:

Clonazepam IP 0.25 mg

Colour: Iron Oxide Red

##### KALM DT 0.5

Each uncoated orally disintegrating tablet contains:

Clonazepam IP 0.5 mg

Colour: Sunset Yellow-Lake

##### KALM DT 1

Each uncoated orally disintegrating tablet contains:

Clonazepam IP 1 mg

Colour: Sunset Yellow-Lake

##### KALM DT 2

Each uncoated orally disintegrating tablet contains:

Clonazepam IP 2 mg

Colour: Iron Oxide Red

##### What KALM DT looks like and contents of the pack

**KALM DT 0.25** is light pink coloured, round shaped, flat, uncoated tablets with "Q" logo scored on one side. KALM DT 0.25 tablets are packed in Alu-Alu Blister. The pack size is 10x10 tablets in a printed paper carton with packing insert.

**KALM DT 0.5** is light orange coloured, round shaped, flat, uncoated tablets with "Q" logo scored on one side. KALM DT 0.5 tablets are packed in Alu-Alu Blister. The pack size is 10x10 tablets in a printed paper carton with packing insert.

**KALM DT 1** is light orange coloured, round shaped, flat, uncoated tablets with "Q" logo scored on one side. KALM DT 1 tablets are packed in Alu-Alu Blister. The pack size is 10x10 tablets in a printed paper carton with packing insert.

**KALM DT 2** is light pink coloured, round shaped, flat, uncoated tablets with "Q" logo scored on one side. KALM DT 2 tablets are packed in Alu-Alu Blister. The pack size is 10x10 tablets in a printed paper carton with packing insert.



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