

**PACKAGE LEAFLET**

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

### **Dalmane 15 and 30 mg Hard Capsules**

Flurazepam monohydrochloride

**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 Dalmane 15 mg or 30 mg hard capsules, which will be called Dalmane capsules throughout this leaflet.

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

1. What Dalmane capsules are and what they are used for
2. What you need to know before you take Dalmane capsules
3. How to take Dalmane capsules
4. Possible side effects
5. How to store Dalmane capsules
6. Contents of the pack and other information

## **1. WHAT DALMANE CAPSULES ARE AND WHAT THEY ARE USED FOR**

Dalmane capsules contain the active ingredient flurazepam, which belongs to a group of medicines called benzodiazepines.

Dalmane capsules are used for severe insomnia (sleeplessness).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DALMANE CAPSULES**

Do not take Dalmane capsules:

- If you have a condition called myasthenia gravis (very weak or tired muscles)
- If you have severe breathing difficulties
- If you have sleep apnoea syndrome (breathing problems when asleep)
- If you have severe pulmonary insufficiency
- If you have severe liver disease
- If you have a mental illness
- If you are allergic to flurazepam
- If you are allergic to other similar drugs (benzodiazepines)
- If you are allergic to any of the other ingredients of Dalmane capsules (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Dalmane capsules:

- If you have a history of alcohol or drug abuse
- If you develop amnesia (forget things)
- If your behaviour changes, e.g. you become angry or agitated or have strange thoughts
- If you have breathing problems
- If you have liver disease
- If you are mentally unwell
- If you suffer from depression or anxiety
- If you are elderly (risk of confusion or clumsiness causing you to fall or injure yourself).

Withdrawal: treatment should be gradually withdrawn. Withdrawal symptoms occur with Dalmane capsules even when normal doses are given for short periods of time. See Section 3, 'If you stop taking Dalmane capsules'.

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 alcoholism and drug abuse.

Tolerance: if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor. Dalmane capsules may become less effective with repeated use.

### **Children**

Dalmane capsules are not recommended in children.

### **Other medicines and Dalmane capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you take these capsules with some other medicines, the effect of these capsules or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

- Strong painkillers (e. g. morphine)
- Drugs used to treat mental illness (e.g. zotepine)
- Sedative agents (medicines used to treat anxiety and to help you sleep, e. g. triazolam, midazolam)
- Drugs used to treat epilepsy (e. g. phenobarbital, phenytoin)
- Anaesthetics (e.g. lignocaine)
- Antidepressants (e. g. amitriptyline)
- Sedative antihistamines (to treat allergies)
- Medicines that affect the liver (e. g. the antibiotic rifampicin and cimetidine, a medicine used to treat stomach problems).

It may still be all right for you to be given Dalmane capsules and your doctor will be able to decide what is suitable for you.

Concomitant use of Dalmane 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 Dalmane 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.

### **Dalmane capsules with alcohol**

Do not drink alcohol while you are taking Dalmane capsules. Alcohol may increase the sedative effects of Dalmane capsules and make you very sleepy.

### **Pregnancy and breast-feeding**

You should not take Dalmane capsules while pregnant or breastfeeding as it might harm the baby.

If you take Diazepam tablets late in pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties.

If taken regularly during late pregnancy, your baby may develop withdrawal symptoms.

Avoid taking Dalmane if you are breast-feeding as Dalmane capsules passes into breast-milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

Dalmane capsules may cause sleepiness, amnesia (forgetfulness), poor concentration and poor co-ordination. These effects are more likely if you do not get enough sleep. If you develop any of these symptoms you should not drive or operate machinery.

#### **Dalmane capsules contain lactose**

Dalmane capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Dalmane capsules.

### **3. HOW TO TAKE DALMANE CAPSULES**

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

The usual doses are as follows:

#### **Adults**

The total daily dosage is 15 to 30 mg before bedtime.

#### **Older or debilitated patients**

If you are an older or debilitated patient, your doctor may give you a lower dose. The dose should not be more than 15 mg.

Treatment should be started with the lowest recommended dose.

The maximum dose should not be exceeded. The length of treatment varies from a few days to two weeks with a total maximum of four weeks (including tapering off process).

#### **Children**

Not recommended

#### **If you take more Dalmane capsules than you should**

Go to the accident and emergency department of your hospital immediately. Signs of overdose are sleepiness, lack of co-ordination and slurred speech. The effects are more likely to be severe if the capsules are taken with alcohol or other drugs that affect the brain.

#### **If you stop taking Dalmane capsules**

You should not stop taking Dalmane capsules without telling your doctor as he may wish to gradually reduce the number of capsules you take before stopping them completely.

Treatment should be gradually withdrawn otherwise the symptoms you are being treated for may return more intensely than before (difficulty in sleeping and anxiety). The risk of this happening is greater when you stop taking Dalmane capsules suddenly.

Withdrawal symptoms may include: headaches, difficulty in sleeping, muscle pain, extreme anxiety, tension, restlessness, confusion, irritability, mood changes.

In severe cases the following symptoms may occur: changes in behaviour, loss of the sense of reality, feeling unreal or detached from life, hallucinations, numbness and tingling of the extremities, fits, over-sensitivity to light, noise and touch.

If you have taken benzodiazepines for a long time, the reduction in your dosage will be over a longer period of time than would normally be required when you stop taking this medicine. You may need additional help. Your doctor will be able to discuss this with you.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

**Common:** may affect up to 1 in 10 people

- drowsiness during the day
- headache
- a feeling of emptiness and lack of emotional well-being
- dizziness
- reduced alertness
- muscle weakness
- confusion
- poor muscle co-ordination
- tiredness
- Sensation of unpleasant taste
- Memory loss
- double vision

These effects are likely to occur at the start of treatment and usually disappear after a while.

**Rare:** may affect up to 1 in 1,000 people

- giddiness
- Hypersensitivity
- inability to pass urine
- reduced blood pressure
- yellowing of the skin and/or eyes (jaundice)
- stomach upsets and nausea
- skin rashes
- abnormality in the blood
- Vertigo
- Difficulty in breathing (particularly at night)
- problems with your vision (blood dyscrasias) (other than double vision)
- changes in the level of sexual desire

Changes in behaviour can also occur rarely. These changes may include aggression, excitement, confusion, restlessness, agitation, irritability, rage, hallucinations, nightmares, dependence, withdrawal symptoms, rebound effect, anxiety, sleep disorders such as insomnia, delusions, abnormal behaviour, psychotic disorder, emotional disturbances, suicide ideation, suicide attempt and depression. If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine. Other side effects may include blood disorders, drug induced movement disorder, jaundice and increased hepatic enzymes.

If you are woken up soon after taking the medicine your memory may be temporarily affected.

If you are an older patient, you may be more susceptible to side effects. If this happens, tell your doctor and he/she may decide to change your dose.

You may become dependent on Dalmane capsules and abuse has been reported. Withdrawal symptoms: see Section 3, 'If you stop taking Dalmane capsules.'

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### Reporting of side effects

If you get any 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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE DALMANE CAPSULES**

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

Blisters: Store in the original package below 25°C.

Bottles/containers: Store below 25°C. Keep the container tightly closed.

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 Dalmane capsules contain:**

Each capsule contains 15 or 30 mg of the active ingredient flurazepam monohydrochloride.

The other ingredients are: lactose monohydrate, talc, magnesium stearate, gelatin, black iron oxide (E 172) and titanium dioxide (E 171).

Dalmane 15 mg capsules also contain: Yellow iron oxide (E 172). Printing ink: Shellac, Red iron oxide (E 172), Ammonia Solution, Potassium Hydroxide, Propylene glycol

### **What Dalmane capsules look like and contents of the pack**

Dalmane 15 mg capsules opaque grey cap and opaque yellow body with 'ICN15' printed in red on both cap and body.

Dalmane 30 mg capsules are opaque black cap and opaque grey body with 'ICN30' printed in red on both cap and body.

Dalmane capsules come in blister packs, amber glass bottles, polythene bags in tins, plastic containers, white plastic securitainers, and small plastic bottles, containing 30 capsules.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Mylan IRE Healthcare Limited,  
Unit 35/36, Grange Parade,  
Baldoye Industrial Estate,  
Dublin 13,  
Ireland

### **Manufacturer**

Labiana Pharmaceuticals S.L.U.,  
Casanova, 27-31,  
08757-Corbera de Llobregat  
Barcelona, Spain

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