

PATIENT INFORMATION LEAFLET

Dalmane 15 mg and 30 mg Capsules

Flurazepam (as monohydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effect and this becomes serious, tell your doctor or pharmacist.

In this leaflet:

1. What Dalmane is and what it is used for
2. Before you take Dalmane Capsules
3. How to take Dalmane Capsules
4. Possible side effects
5. How to store Dalmane Capsules
6. Further information

1. WHAT DALMANE IS AND WHAT IT IS USED FOR

Dalmane belongs to a group of medicines known as benzodiazepines, which are tranquillisers (medicines that have a calming effect). Dalmane shortens the time taken to fall asleep and lengthens the duration of sleep.

Dalmane Capsules are used for the short term treatment of sleeplessness (also known as insomnia) when it is severe. It can help overcome difficulties in getting to sleep and may help if you wake up frequently in the middle of the night.

Dalmane Capsules help you to sleep but do not cure the underlying cause of your insomnia, which you should discuss with your doctor.

2. BEFORE YOU TAKE DALMANE CAPSULES

Do not take Dalmane if you:

- are allergic (hypersensitive) to flurazepam or any of the other ingredients of Dalmane Capsules (these are listed in section 6, "Further Information").
- are allergic (hypersensitive) to any medicine known as a benzodiazepine (e.g. nitrazepam, diazepam, chlordiazepoxide, or temazepam).
- suffer from lung disease.
- suffer from difficulty breathing while awake or asleep.
- suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily).
- are suffering from a psychiatric illness or a personality disorder (severe mental problems).
- have a liver condition.
- suffer from porphyria.
- suffer from spinal and cerebellar ataxia.

Dalmane Capsules are not for use in anyone under 18 years of age.

Take special care with Dalmane

Tell your doctor before you take these capsules if you:

- have a long-term lung, liver or kidney condition.
- suffer from depression or have recently suffered the death of a close friend or relative.
- regularly drink alcohol or abuse drugs. You must not drink alcohol or use drugs while taking Dalmane.
- are pregnant or breast-feeding. Refer to section **Pregnancy and breast-feeding** below.
- are suffering or have suffered from a mental illness.

Dalmane capsules relax the muscles, therefore elderly patients should take extra care when they get up at night as there is a risk of falls and consequently of injuries including hip fractures.

Taking Dalmane with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is **extremely important**, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved. In particular, tell your doctor if you are taking any of the following medicines:

- antidepressants, sleeping tablets, neuroleptics, hypnotics, tranquillisers, or other such medicines that act on the brain and nerves.
- medicines used to relieve pain or anaesthetics.

- medicines for treating epilepsy (e.g. phenytoin and phenobarbital).
- medicines that affect the liver (e.g. the antibiotic rifampicin and cimetidine, medicines used to treat stomach problems); St. John's Wort.
- anti-viral medicines (e.g. ritonavir)
- antihistamines (used for treating allergies) that cause drowsiness (e.g. chlorphenamine).
- medicines to treat high blood pressure (e.g. beta blockers, cardiac glycosides, moxonidine).
- theophylline or aminophylline; medicines which make breathing easier.
- valerian, a herbal medicine.

as these medicines can potentiate the actions of benzodiazepines.

Concomitant use of Dalmane Capsules 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 Capsules 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.

Taking Dalmane with food and drink

Do not drink alcohol for as long as you are taking Dalmane Capsules as this will increase the effects of the medicine, and this can be dangerous.

Pregnancy and breast-feeding

Tell your doctor before taking Dalmane Capsules if you are pregnant, think that you are pregnant or intend to become pregnant during treatment. Your doctor will then decide whether you should take this medicine. Tell your doctor before taking Dalmane Capsules if you are breast-feeding. Avoid taking Dalmane if you are breast-feeding as Dalmane passes into breast-milk.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness and breathing and feeding difficulties. Also, your unborn baby may be at risk of developing dependency to this medicine and after birth may be at some risk of developing withdrawal symptoms.

Driving and using machines

Dalmane Capsules may cause side effects such as reduced alertness, confusion, tiredness, dizziness, poor muscle co-ordination and double vision.

This may affect your ability to drive and operate machinery. Do not drive or operate machinery if you experience any of these side effects.

The medicine can affect your ability to drive. Do not drive while taking this medicine until you know how it affects you.

It may be an offence to drive if your ability to drive safely is affected. 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.

There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>

Important information about some of the ingredients of Dalmane

Dalmane Capsules contain lactose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DALMANE CAPSULES

Your doctor will find the lowest dose to control your symptoms. The dose that your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.

Always take Dalmane exactly as your doctor has told you. Do not change the prescribed dose yourself. You should check with your doctor or pharmacist if you are not sure how to take this medicine. If you think that the effect of your medicine is too weak or too strong, talk to your doctor.



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The usual starting dose is 15 mg which may be increased to a maximum of 30 mg.

Take the medicine just before going to bed. Make sure that you can sleep without interruptions for 7 to 8 hours after taking the capsules. Swallow the capsule(s) whole with water or another non-alcoholic drink.

Treatment will not normally be continued for more than four weeks.

This is because Dalmane Capsules may become less effective if you take them for more than four weeks. If you think that your medicine is no longer working, you must consult your doctor.

Also, you may become dependent on the capsules if you use them at high doses and for long periods. Therefore, Dalmane Capsules are not suitable for long-term use and after a few weeks it is worth trying to get by without these capsules. This will help to prevent you becoming used to Dalmane and reduce the risk of dependence. Discuss with your doctor prior to stopping taking Dalmane. See section **“When you stop taking Dalmane”** below.

If you take more Dalmane than you should

If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

If you forget to take Dalmane

Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

When you stop taking Dalmane

Your doctor will advise you when to stop taking the capsules. Do not stop taking Dalmane capsules abruptly. You may experience withdrawal effects if your treatment is stopped suddenly. This is less likely if your dose is gradually reduced towards the end of your treatment.

Withdrawal symptoms may include:

- depression
- nervousness
- extreme anxiety
- tension
- restlessness
- confusion
- mood changes
- a recurrence of sleep problems
- irritability
- sweating
- diarrhoea
- headaches
- muscle pain

In severe cases the following symptoms may occur:

- changes in behaviour
- numbness and tingling of the extremities
- over-sensitivity to light, noise and touch
- hallucinations
- fits

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dalmane can cause side effects, although not everybody gets them.

It is very important that you immediately seek medical advice if you develop any of the following symptoms:

A severe allergic (anaphylaxis) or serious allergic reaction which causes swelling of your face or throat (angioedema), difficulty breathing, thoughts of selfharm, yellowing of the eyes and skin (jaundice), abnormality in the blood (blood dyscrasias) with symptoms such as weakness, pale skin, bleeding problems, sore throat and frequent infections. Changes in behaviour can also occur rarely. These changes may include aggression, excitement, confusion, restlessness, agitation, irritability, rage, hallucinations, nightmares and depression. **If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine.**

Tell your doctor or pharmacist if you develop any of the following side effects:

Common:

- drowsiness during the day
- a feeling of emptiness
- reduced alertness
- confusion
- tiredness
- headache
- dizziness
- muscle weakness
- poor muscle co-ordination
- double vision
- dependence
- forgetfulness
- bitter taste
- speech disorder
- loss of balance

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

Rare:

- giddiness
- reduced blood pressure
- stomach upsets and nausea
- skin rashes
- problems with your vision (other than double vision)
- changes in the level of sexual desire
- inability to pass urine
- vertigo
- breathing difficulties, particularly at night

Very rare:

- increased liver enzymes.

The following side effects have also been reported (Frequency unknown):

- blood disorders
- hallucinations, dependence, withdrawal syndrome, rebound effect, depression
- paradoxical reactions (e.g. anxiety, sleep disorders, insomnia, nightmares, restlessness, agitation, irritability, aggression, delusion, psychoses, abnormal behaviour, emotional disturbances, suicide attempt, suicidal ideation).
- tremor, stiffness and slow movement.

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

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

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. HOW TO STORE DALMANE CAPSULES

- Store Dalmane Capsules out of the sight and reach of children.
- Store Dalmane Capsules in a dry place below 25°C.
- Do not use Dalmane Capsules after the expiry date which is stated on the blister and the outer carton after “EXP”. The expiry date refers to the last day of that month.
- Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dalmane contains

Active substance: Flurazepam (as monohydrochloride). Each capsule contains the equivalent of 15 mg or 30 mg of flurazepam.

Other ingredients: Lactose, talc, magnesium stearate, gelatin and colouring agents iron oxide black (E 172) and titanium dioxide (E 171). In addition, the 15 mg capsules contain the colouring agent iron oxide yellow (E 172).

What Dalmane looks like and contents of the pack

- Dalmane 15 mg capsules are grey and yellow and are marked with “ICN 15”.
- Dalmane 30 mg capsules are black and grey and are marked with “ICN 30”.
- Both capsule strengths come in packs of 30 capsules.

Marketing Authorisation Holder

Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

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

For any information about this medicine, please contact the Marketing Authorisation Holder.

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