PATIENT INFORMATION LEAFLET

DALMAPAM 15 MG HARD CAPSULES
DALMAPAM 30 MG HARD CAPSULES

Flurazepam (as flurazepam 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.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT DALMAPAM CAPSULES ARE AND WHAT THEY ARE USED FOR

Dalmapam 15 mg and 30 mg hard capsules (called Dalmapam capsules in this leaflet) belong to a group of medicines called benzodiazepines. They are used in the short-term treatment of severe sleeplessness (insomnia) when the disorder is severe, as it can help overcome difficulties in getting to sleep or if you wake up frequently during the night.

2. BEFORE YOU TAKE DALMAPAM CAPSULES

Do NOT take the capsules if you:
- are allergic (hypersensitive) to flurazepam or other benzodiazepines, or to any of the other ingredients in the capsules (*see Section 6 and end of Section 2*)
- have severe breathing difficulties
- suffer from lung disease
- suffer from muscle weakness and abnormal tiring of the muscles (myasthenia gravis)
- suffer from temporary pauses in breathing while awake or during sleep (sleep apnoea syndrome)
- suffer from severe liver disease
- are suffering from psychiatric illness or personality disorder
- chronic psychosis

Take special care
Talk to your doctor before taking these capsules if you:

- have a kidney or liver condition
- have a history of alcohol or drug abuse
- are suffering from depression or anxiety associated with depression or a recent bereavement of a close relative or friend.
- regularly drink alcohol or abuse drugs. You must not drink alcohol or use drugs while taking Dalmapam.
- suffer from spinal and cerebellar ataxia

Dalmapam capsules should not be used alone to treat psychiatric illness, depression or anxiety.
Rare behavioural effects including paradoxical aggressive outbursts, excitement, confusion, restlessness, agitation, irritability, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and the uncovering of depression with suicidal tendencies can occur in patients with personality disorders.
Elderly patients should take extra care when taking Dalmapam when they get up at night as there is a risk of falls and consequent injuries.

If you are taking these capsules for a few weeks they may lose their effectiveness. You may become dependent on them if your dose or length of treatment increases, or if you have a history of alcohol or drug abuse. Side effects such as restlessness, agitation and irritability may occur particularly in children and the elderly. If any of these happen, treatment should be stopped.

If you stop taking these capsules suddenly, you may experience depression, nervousness, headaches, diarrhoea, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, rebound insomnia, sweating, and irritability. In severe cases you may develop reality confusion, heightened sense of hearing, numbness and tingling of the extremities, sensitivity to light, noise and physical contact, hallucinations or epileptic fits. Your sleeplessness and anxiety may return. You should consult your doctor, who will decrease your dose gradually.

You may experience loss of memory. This usually occurs 1-2 hours after taking the capsules, therefore they should be taken at night before sleep.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:
- tranquillisers, sleep-inducing drugs and other such medications which act on the brain and nervous system
- antipsychotics e.g. haloperidol used to treat schizophrenia
- antidepressants
- certain pain relief medicines (e.g. morphine, pethadine)
- anaesthetics
- epilepsy medicines (e.g. phenytoin and phenobarbital)
- antihistamines that could make you drowsy (e.g. chlorphenamine)
- some compounds which stop certain liver enzymes from working (e.g. rifampicin, omeprazole, disulfuram and cimetidine)
- medicines to treat high blood pressure (e.g. beta-blockers)
- theophylline or aminophylline which are used to make breathing easier

Taking with food and drink
Do not drink alcohol whilst taking these capsules, as it may enhance the sedative effect.

Driving and using machinery
Dalmapam capsules may make you sleepy, cause memory loss, affect your concentration or make your muscles weaker.
This may affect your ability to drive and operate machinery. Do not drive or operate machinery if you experience any of these side effects. Do not drive until you know how the medicine affects you

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, think you may be pregnant or planning to become pregnant. Your doctor will then decide whether or not you should take this medicine.
Dalmapam capsules should only be taken by pregnant women only if advised by a doctor because they may harm the unborn baby. If you think you may be pregnant, speak to your doctor as soon as possible.
Dalmapam capsules must not be given to breast-feeding mothers because flurazepam passes into breast-milk.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Important information about some of the ingredients of this medicine
Dalmapam capsules contain:

- **Lactose:** if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these capsules.

3. HOW TO TAKE DALMAPAM CAPSULES

Always take Dalmapam capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will prescribe the most suitable dose for you and you will be checked at the start of treatment to ensure you have the correct dose and treatment length.
The capsules should be taken just before going to bed and swallowed with water without chewing.

Adults: the usual daily dose for insomnia is 15 to 30 mg
The duration of the treatment varies from a few days to 2 weeks. It should not exceed 4 weeks, including a gradual dose reduction.

If you take these capsules for longer, then they may lose their effectiveness, or you may become dependent (*see Section 2: Take special care*). Your doctor will advise you how long to take the capsules for.

Elderly or weak patients: The initial dose should not exceed 15 mg

Children: Not Recommended

Special patient groups: if you suffer from liver or kidney function problems, or have long term breathing problems, your dose will be reduced.

If you take more Dalmapam capsules than you should
If you, or someone else, have taken more capsules than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you. Symptoms of overdose include loss of ability to co-ordinate muscular movement, extreme tension of the muscles, low blood pressure, shallow breathing and rarely coma.

If you forget to take a dose
If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining doses at the correct time. Do not take a double dose to make up for a missed dose.

If you stop taking Dalmapam capsules
Do not stop taking these capsules without asking your doctor first. Your dose needs to be reduced gradually otherwise you may experience unwanted side effects (*see Section 2: Take special care*).

4. POSSIBLE SIDE EFFECTS

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

STOP taking Dalmapam capsules and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:
- difficulty breathing or swallowing,
- swelling of the face, lips, tongue or throat,
- severe itching of the skin, with a red rash or raised bumps.

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

Common: may effect up to 1 in 10 people
- drowsiness during the day
- a feeling of emptiness
- reduced alertness
- confusion
- tiredness
- headache
- dizziness
- muscle weakness
- poor muscle co-ordination
- double vision
- forgetfulness
- bitter taste

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

Rare: may effect up to 1 in 1,000 people

- giddiness
- hypersensitivity
- 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 especially at night

Very rare: may effect up to 1 in 10,000 people
- increased liver enzymes

The following side effects have also been reported (Frequency unknown)
- blood disorder
- hallucination, 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.

The following reactions are more likely to occur in children and the elderly:
- restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, severe mental disorders (psychoses), inappropriate behaviour.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DALMAPAM CAPSULES

Keep out of the sight and reach children. Do not store above 25˚C. Store in the original packaging. Do not use the capsules after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month. Medicines should 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 Dalmapam capsules contain:
- the **active ingredient:** flurazepam (as flurazepam monohydrochloride) 15 mg or 30 mg per capsule
- **other ingredients:** lactose monohydrate (*see also end of Section 2 for further information on lactose*), microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate and talc.

- **capsule shell:** black iron oxide (E172), titanium dioxide (E171) and gelatin. The 15 mg capsules also contain yellow iron oxide (E172).
- **printing ink:** shellac glaze, red iron oxide (E172), propylene glycol (E1520), strong ammonia solution and potassium hydroxide.

What Dalmapam capsules look like and contents of the pack
Dalmapam 15 mg capsules are ivory/light grey hard gelatin capsules, marked “FLU 15”.
Dalmapam 30 mg capsules are grey and black hard gelatin capsules, marked “FLU 30”.

The capsules contain a white powder. They are available in packs of 30 capsules.

Marketing Authorisation Holder and Manufacturer
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