

PACKAGE LEAFLET

Package leaflet: Information for the user

Mogadon
5 mg Tablets
Nitrazepam

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 effect not listed in this leaflet.

What is in this leaflet:

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

1. WHAT MOGADON TABLETS ARE AND WHAT THEY ARE USED FOR

Mogadon tablets contain the active ingredient nitrazepam, which belongs to a group of medicines called benzodiazepines. Mogadon tablets are used for severe insomnia (sleeplessness).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOGADON TABLETS

Do not take Mogadon tablets:

- If you are allergic (hypersensitive) to nitrazepam,
- If you are allergic to other similar drugs (benzodiazepines),
- If you are allergic to any of the other ingredients of Mogadon tablets (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you have a condition called myasthenia gravis
- If you have severe breathing difficulties
- If you have sleep apnoea syndrome (breathing problems when asleep)
- If you have severe liver disease
- If you suffer from acute pulmonary insufficiency

- If you have a mental illness

Warnings and precautions

Talk to your doctor or pharmacist before taking Mogadon tablets:

- If you have a history of alcohol or drug abuse
- If you intend to stop taking Mogadon tablets – you may develop withdrawal symptoms, e.g. headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability
- 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

Mogadon tablets relax muscles so there is a risk of falls and hip fractures particularly for elderly patients when they get up at night.

Mogadon tablets should not be stopped suddenly and the dose should be slowly reduced to help prevent rebound symptoms. These include headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

Tolerance and Dependence

Mogadon tablets may become less effective with repeated use and you may become dependent on them.

Children

Not recommended.

Other medicines and Mogadon tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

Drugs that have an effect on the brain – examples of these are:

- Strong painkillers such as morphine
- Drugs used to treat mental illness such as lithium
- Drugs used to treat epilepsy such as valproate
- Anaesthetics such as propofol
- Antidepressants such as citalopram
- Drugs used to treat anxiety such as lorazepam
- Sleeping tablets such as zopiclone
- Antihistamines that make you sleepy such as promethazine.

Concomitant use of Mogadon 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 Mogadon 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.

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

Mogadon tablets with alcohol

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

Pregnancy and breast-feeding

You should not take Mogadon tablets while pregnant or breast-feeding as it might harm the baby. Disturbed behavior has been reported in newborn babies.

If you take Mogadon tablets late in your 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. 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

Mogadon tablets may cause sleepiness, amnesia (forgetfulness), poor concentration and poor coordination. 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.

Mogadon tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Mogadon tablets.

3. HOW TO TAKE MOGADON TABLETS

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 5 to 10 mg before bedtime.

In hospitalised patients a single dose of 20 mg may be given.

Elderly

The usual dose is 2.5 mg taken before bedtime.

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.

If you take more Mogadon tablets than you should

Go to the accident and emergency department of your hospital immediately. Signs of overdose are sleepiness, confusion, and tiredness. In more severe cases, shallow breathing, unresponsiveness, and coma can occur.

If you stop taking Mogadon tablets

You should not stop taking Mogadon tablets without telling your doctor as he may wish to gradually reduce the number of tablets 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 Mogadon tablets 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:

Drowsiness during the day, numbed emotions, reduced alertness, confusion, tiredness, headache, dizziness, muscle weakness, lack of co-ordination, double vision, depression.

Other side effects like digestive tract disturbances, changes in sex drive and skin reactions have also been reported. Amnesia (forgetfulness) may occur and cause behaviour problems.

Side effects such as restlessness, agitation, irritability, aggressiveness, abnormal thoughts, rages, nightmares, hallucinations (seeing or hearing things), and adverse behavioural effects are known to occur. They are more likely in children and the elderly.

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

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 HPRC 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 MOGADON TABLETS

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

Store in the original package or bottle below 25°C.

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 Mogadon tablets contain:

Each tablet contains 5 mg of the active ingredient nitrazepam.

The other ingredients are: maize starch, lactose monohydrate, and magnesium stearate.

What Mogadon tablets look like and contents of the pack

Mogadon tablets are round, white tablets with "V" over "MOG5" marked on one side and with a single break-line on the other. Mogadon tablets come in a plastic bottle containing 30 tablets or a blister pack of 30 tablets.

Not all pack may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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