Mogadon 5 mg Tablets

Nitrazepam

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

1. What Mogadon is and what it is used for

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

Telling your doctor or pharmacist that you are taking Mogadon Tablets (see section 4). In particular, tell your doctor if you are:

• allergic (hypersensitive) to any medicine known as a benzodiazepine
• allergic (hypersensitive) to nitrazepam or any of the other ingredients of Mogadon Tablets
• suffering from lung disease.

2. BEFORE YOU TAKE MOGADON TABLETS

Do not take Mogadon Tablets if:

• you are allergic (hypersensitive) to nitrazepam or any of the other ingredients of Mogadon Tablets (these are listed in section 6, ‘Further Information’)
• you are allergic (hypersensitive) to any medicine known as a benzodiazepine (e.g. flurazepam, diazepam, chlordiazepoxide or temazepam).

• suffer from difficulty breathing while awake or asleep.
• suffer from myasthenia gravis (a condition in which the muscles become weak and tires easily).
• are suffering from a psychiatric illness or a personality disorder (severe mental problems).
• have a severe liver condition.

Mogadon Tablets are not for use in anyone under 18 years of age. Take special care with Mogadon Tablets. Tell your doctor before you take these tablets if you:

• have a long-term lung, liver or kidney disease.
• have suffered from depression or have recently suffered the death of a close friend or relative.
• are suffering or have suffered from a mental illness.
• have had alcohol or drugs. You must not drink alcohol or use drugs while taking Mogadon.
• are pregnant or breast-feeding.

Tell your doctor before you take Mogadon Tablets if you:

• suffer from difficulty breathing while awake or asleep.
• suffer from depression or have recently suffered the death of a close friend or relative.
• are suffering or have suffered from a mental illness.
• have had alcohol or drugs. You must not drink alcohol or use drugs while taking Mogadon.

3. HOW TO TAKE MOGADON TABLETS

Your doctor will find the lowest dose to control your symptoms. You may not need to take this medicine every night.

The usual starting dose is 5 mg (one tablet). However, if you are elderly or suffer from certain medical conditions, the starting dose may be lower.

Swallow the tablet(s) whole with water or another non-alcoholic drink.

Take the medicine just before going to bed. Make sure that you can sleep without these tablets. This will help to prevent you becoming used to Mogadon and reduce the risk of dependence.

Concomitant use of Mogadon tablets and opioids (strong pain killers, medicines for substitution therapy and some centrally-acting medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, concomitant use of Mogadon tablets would usually be contraindicated with such treatment options are not possible. However, if your doctor does prescribe the Mogadon tablets together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Tell your doctor about all opioid medicines you are taking, and follow your doctor’s dose recommendation closely. It could help to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tak...
If you take more Mogadon Tablets than you should
If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

When you stop taking Mogadon Tablets
Your doctor will advise you when to stop taking the tablets. Do not stop taking Mogadon tablets abruptly. You may experience withdrawal effects if your treatment is stopped suddenly.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Mogadon Tablets can cause side effects, although not everybody gets them.

Stop taking the medicine and/or seek urgent medical advice immediately if you notice the following:

• Serious allergic reactions which may include swelling of the face including throat and tongue, breathing difficulty/shouting, fainting, faint and/or collapse.

• Allergic skin reaction including skin that is red or itchy, pale or red irregular raised patches with severe itching (urticaria), circular irregular red patches on the skin of the hands and arms (Erythema Multiforme) and severe form of skin rash with flaking, fever, blisters or ulcers (Steven Johnson syndrome).

Changes in behaviour may occur rarely. If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine. These changes may include aggression, excitement, confusion, restlessness, agitation, irritability, rage, hallucinations, nightmares and depression.

Common side effects:
- drowsiness during the day
- a feeling of emptiness
- reduced alertness
- confusion
- restlessness
- headache
- inability to pass urine
- changes in vision other than double vision

Rare side effects:
- dizziness
- muscle weakness
- poor muscle co-ordination
- double vision
- depressed state
- speech disorder
- incontinence
- numbness and tingling of the extremities
- fits

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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 the medicine. You may need additional help. Your doctor will be able to discuss this with you.

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.

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

If you forget to take Mogadon Tablets
If you forget to take Mogadon Tablets, take the missed dose as soon as possible and then continue with the next dose when it is due.

5. HOW TO STORE MOGADON TABLETS
Store Mogadon Tablets out of the sight and reach of children.

Store the bottle or blister in the original outer carton in order to protect from light.

Store Mogadon Tablets in a dry place below 25°C.

The white tablets are round with „M” marked on one side and a line across the other so that they can be broken in half easily.

Mogadon Tablets come in packs of 30 tablets.

Marketing Authorisation Holder
Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer
ICN Polfa Rzeszów S.A., ul. Przemysłowa 2, 35-930 Rzeszów Poland

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

This leaflet was last revised in January 2023.
Nazwa produktu: Mogadon 5 mg
TAB/Nitrazepam/
Kolor nadruku: Black
Kraj (ISO): GB
Nr wykrojnika: SPEC NO -
Opracowane przez: Katarzyna Wojdanowska
Kod Wytwórcy: -
Nr korekty: Proof No 2
Data: 26-01-2023
Kod farmaceutyczny: Pharmacode 514
Miniature one-track: Kode Wersji: P1EU08
Inny kod: ART-234-03
Rozmiar czcionki: Minimum 9 pt
Wymiar ulotki: PIL size 480 x 180 mm (35,5 x 180 mm)
Krój czcionki: Minion Pro Font Family
Gramatura papieru: 45 g/m²
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Akceptacja Techniczna

Akceptacja Działu ds. Rejestracji
Regulatory Affairs Dept. Approval