

PATIENT INFORMATION LEAFLET

Mogadon 5 mg Tablets

Nitrazepam

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.

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1. What Mogadon is and what it is used for
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This medicine contains nitrazepam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

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.

Mogadon Tablets are used for the short term treatment of sleeplessness (also known as insomnia) when it is severe. Mogadon Tablets help you to sleep but do not cure the underlying cause of your insomnia, which you should discuss with your doctor.

This medicine has been prescribed to you and should not be given to anyone else.

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

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").
- are allergic (hypersensitive) to any medicine known as a benzodiazepine (e.g. flurazepam, 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 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.
- suffer from depression or have recently suffered the death of a close friend or relative.
- are suffering or have suffered from a mental illness.
- are pregnant or breast-feeding.

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake. You must not drink alcohol or use drugs while taking Mogadon.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Mogadon to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Because Mogadon Tablets relax the muscles, 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 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, barbiturates, antipsychotics, hypnotics, anxiolytics, tranquillisers or sleeping tablets, or other such medicines that act on the brain and nerves.
- Medicines used to relieve pain or anaesthetics.
- Antihistamines (used for treating allergies) that cause drowsiness (e.g. chlorphenamine).
- Medicines for treating epilepsy (e.g. phenytoin and phenobarbital).
- Medicines that affect the liver (e.g. the antibiotic rifampicin, cimetidine, omeprazole; medicines used to treat stomach problems, disulfiram and St John's wort).
- Sodium oxybate used in patients with narcolepsy.
- Theophylline or aminophylline; medicines to make breathing easier.

Concomitant use of Mogadon tablets 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 tablets 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 Mogadon Tablets with food and drink

Do not drink alcohol for as long as you are taking Mogadon Tablets. Alcohol will increase the effects of the tablets and this can be dangerous.

Pregnancy and breast-feeding

Tell your doctor before taking Mogadon Tablets 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 Mogadon Tablets if you are breast-feeding. Avoid taking Mogadon Tablets if you are breast-feeding as Mogadon 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

Mogadon Tablets 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.

Important information about some of the ingredients of Mogadon Tablets

Lactose: Mogadon tablets 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 medicine.

3. HOW TO TAKE MOGADON TABLETS

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 Mogadon 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.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Mogadon is not for use in children.

The usual starting dose is 5 mg (one tablet). However, if you are elderly or suffer from a lung, liver or kidney condition, or are generally unwell, your starting dose will not usually be more than 2.5 mg (half a tablet).

You may not need to take this medicine every night.

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 interruptions for 7 to 8 hours after taking the tablets.

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

Mogadon Tablets may become less effective if you take them for more than four weeks. If you think that your medicine is no longer working or your insomnia does not improve, you should consult your doctor. Also, you may become dependent on the tablets if you use them at high doses and for long periods. Therefore, Mogadon Tablets are not suitable for long-term use and after a few weeks it is worth trying to get by without these tablets. This will help to prevent you becoming used to Mogadon and reduce the risk of dependence.

Withdrawal symptoms may occur when you stop taking Mogadon Tablets (see section below **When you stop taking Mogadon Tablets**). Do not stop taking Mogadon Tablets without speaking to your doctor.

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.

If you forget to take Mogadon

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 Mogadon Tablets

Your doctor will advise you when to stop taking the tablets.

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:

- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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, 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 difficulties/wheezing, feeling faint, weak and/or collapse.
- Allergic skin reaction including skin that is red or itchy, pale or red irregular raised patches with severe itching (hives), circular irregular red patches on the skin of the hands and arms (Erythema Multiforme) and severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-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, rages, hallucinations, nightmares and depression.

Common side effects:

- drowsiness during the day
- a feeling of emptiness
- reduced alertness
- confusion
- tiredness
- headache
- dizziness
- muscle weakness
- poor muscle co-ordination
- double vision
- depressed state

Rare side effects:

- giddiness
- reduced blood pressure
- stomach upsets
- skin rashes
- changes in your vision other than double vision
- changes in the level of sexual desire
- inability to pass urine
- spinning sensation
- nausea
- speech disorder

Frequency unknown:

- An abnormality of the blood (Blood disorder).
- Trouble falling and/or staying asleep, decline in mental abilities (memory and thinking skills), Dependence (at regular dose) – You may become dependent on the tablets and find it difficult to stop taking them. If you stop taking the tablets suddenly, you may suffer from withdrawal reactions (see section 3 “When you stop taking Mogadon Tablets” for withdrawal symptoms”)
- Unsteadiness, reduced muscle movement, tremor, memory loss, epileptic fits
- Breathing problems, increased bronchial secretions
- yellowing of the eyes and skin (jaundice)
- Muscle cramps
- There is a risk of falls and consequently fractures in the elderly.
- Irritability, rebound effect
- dependence and addiction (see section “How do I know if I am tolerant or addicted?”).

Drug Withdrawal

When you stop taking Mogadon, you may experience drug withdrawal symptoms, which include:

• headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Mogadon, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your prescriber recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 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. Do not use Mogadon Tablets after the expiry date which is stated on the bottle or blister and the outer carton after "EXP". 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 Mogadon Tablets contain

Active substance: Nitrazepam. Each tablet contains 5 mg of nitrazepam.

Other ingredients: Lactose, maize starch and magnesium stearate.

What Mogadon Tablets look like and contents of the pack

The white tablets are round with  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

Viatrix Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer

ICN Polfa Rzeszów S.A., ul. Przemysłowa 2, 35-105 Rzeszów Poland

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

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