1. WHAT MOGADON IS AND WHAT IT IS USED FOR

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

If you experience any side effect and this becomes serious, tell your doctor or pharmacist.

2. BEFORE YOU TAKE MOGADON TABLETS

Do not take Mogadon Tablets if you:

- are allergic (hypersensitive) to nitrazepam or any of the other medicines involved. In particular, tell your doctor if you are taking any of the following medicines:
  - Antidepressants, other tranquillisers or sleeping pills, 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).

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

Mogadon Tablets are not for use in anyone under 18 years of age.

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

The medicine has been prescribed to treat a medical or dental condition and it may be an offence to drive if your ability to drive safely is affected. However, you would not be committing an offence if:

- 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 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.

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

In this leaflet:

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

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.

Mogadon Tablets are not for use in anyone under 18 years of age.

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.

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.
- have abused alcohol or drugs. You must not drink alcohol or use drugs while taking Mogadon.
- are pregnant or breast-feeding.
- have a severe psychiatric illness or a personality disorder (severe mental problems).
- have a severe liver condition.

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, other tranquillisers or sleeping pills, 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).
Nitrazepam. Each tablet contains 5 mg.

The usual starting dose is 5 mg or one tablet. However, if you are elderly or suffer from a hang, 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 any time of day.

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).

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

When you stop taking Mogadon Tablets, withdrawal symptoms may occur. These may include:

- a recurrence of sleep problems
- depression
- nervousness
- extreme anxiety
- tension
- restlessness
- confusion

In severe cases the following symptoms may occur:

- changes in behaviour
- numbness and tingling of the extremities
- 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, Mogadon Tablets can cause side effects, although not everybody gets them.

Changes in behaviour may occur rarely. These changes may include:

- aggression, excitation, confusion, restlessness, agitation, irritability, rages, hallucinations, nightmares and depression.
- changes in your vision other than double vision
- changes in the level of sexual desire
- changes in behaviour
- over-sensitivity to light, noise and touch
- hallucinations
- fits
- muscle weakness
- tension
- nervousness
- depression
- a recurrence of sleep problems
- reduced alertness
- doubled vision
- inability to pass urine
- yellowing of the eyes and skin (jaundice)
- an abnormality of the blood (blood dyscrasias)
- muscle weakness
- poor muscle co-ordination
- dizziness
- headache
- muscle weakness
- mood changes
- irritability
- sweating
- diarrhoea
- headaches

Common side effects:

- nervousness
- restlessness
- tiredness
- confusion
- depression
- anxiety
- a recurrence of sleep problems
- changes in behaviour
- over-sensitivity to light, noise and touch
- hallucinations
- fits
- muscle weakness
- tension
- nervousness
- depression
- a recurrence of sleep problems
- reduced alertness
- confusion
- dizziness

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

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 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 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.

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.

Mogadon Tablets are not for use in children. Mogadon Tablets 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 “MOG5” 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, 35-959 Rzeszów, Poland

For any information about this medicine, please contact the Marketing Authorisation Holder. This leaflet was last revised in 05/2018.