**Mogadon®**

**Patient Information Leaflet**

Tables 5 mg Nitrazepam

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**WHAT IS MOGADON?**

Mogadon contains the active ingredient nitrazepam, which belongs to a group of medicines known as benzodiazepines. Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep.

The white tablets are round with V MOG 5 marked on one side and a line across the other so that they can be broken in half easily.

They contain 5 mg nitrazepam and the other ingredients: lactose monohydrate, maize starch and magnesium stearate.

The tablets come in packs of 30.

The Product Authorisation holder is Valeant Pharmaceuticals Ltd., Cedarwood, Chineham Business Park, Crookham Lane, Basingstoke, Hampshire, RG24 9WD, UK. The manufacturer is ICN Pols Rzeszów S.A., ul. Przemysłowa 2, 37-999 Rzeszów, Poland.

**WHAT IS MOGADON USED FOR?**

Mogadon is used for the short term treatment of severe sleeplessness (also known as insomnia). It can help overcome any difficulties in getting to sleep, but does not cure the underlying cause of your insomnia.

**WHEN MUST MOGADON NOT BE USED?**

- If you are allergic to the group of medicines known as benzodiazepines, e.g. diazepam, chlordiazepoxide, nitrazepam, temazepam.
- If you are allergic to Mogadon or any of the ingredients it contains.
- If you suffer from lung disease.
- If you suffer from myasthenia gravis (severe muscle tiredness).
- If you are suffering from a psychiatric illness or a personality disorder.
- If you suffer from sleeping disorders such as difficulty breathing while asleep.
- If you have a liver condition.

Mogadon must not be given to children.

**WHEN SHOULD YOU BE EXTRA CAREFUL WHILE TAKING MOGADON?**

Make sure your doctor knows if you:

- Have a lung, liver or kidney condition.
- Are taking any other medicines, including those not prescribed by your doctor.
- Are elderly, or suffer from a lung, liver or kidney condition.

The effects of Mogadon may be increased by tranquilisers, anti-epileptics, hypnotics (sleep-inducing drugs), antihistamines and analgesics (painkillers, anti-inflammatory drugs, anti-arthritis drugs) used in the treatment of allergies (anti-histamines) and epilepsy (anti-epileptics).

When Mogadon is used in combination with antihistamines, drugs, side-effects may occur more frequently and your doctor may decide to adjust your dose. In addition, cimetidine (a medicine used to treat stomach problems) and ranitidine (an anti-acid) are also known to affect Mogadon.

- If you suffer from depression or have recently suffered the death of a close friend or relative.
- Regularly drink alcohol or use recreational drugs.
- Prolonged use of Mogadon may lead to tolerance. If you think that your medicine is no longer working, you should consult your doctor.

**MAY MOGADON BE TAKEN DURING PREGNANCY OR WHILE BREAST-FEEDING?**

You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. Your doctor will then decide whether you should take this medicine. 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, difficulty breathing while asleep, and how does treatment with Mogadon end?”

**HOW SHOULD MOGADON BE TAKEN?**

Always take the tablets as your doctor tells you. He/she will prescribe a suitable dose for you. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight. The normal starting dose is 5 mg. However, if you are elderly, or suffer from a lung, liver or kidney condition your starting dose will not be more than 2.5 mg (half a tablet).

- If you are suffering from a psychotic disorder your dose should not exceed 5 mg.

**Prolonged use of Mogadon may lead to dependence. If you think that your medicine is no longer working, you should consult your doctor.**

**IMPORTANT**

Mogadon may make you sleepy or affect your concentration. This may affect your performance at skilled tasks, e.g. driving and operating machinery.

Alcohol will increase the sedative effects of Mogadon and should therefore be avoided for as long as you are using this medicine.

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 medicinal product.

Mogadon tablets contain magnesium. Therefore, if you have been told by your doctor that you have an intolerance to magnesium, contact your doctor before taking this medicinal product.

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- If you are suffering from a psychotic disorder your dose should not exceed 5 mg.
• Your doctor will find the lowest dose to control your symptoms. You may not need to take this medicine every night. Treatment will not normally be continued for more than four weeks.

• Take the medicine just before going to bed and swallow the tablet whole with water or another non-alcoholic drink.

• After taking Mogadon, you should ensure that you have 7 to 8 hours uninterrupted sleep.

• If you forget to take one dose, you should never make up for the missed dose by doubling the dose next time, instead you should simply continue with the next dose when it is due.

• Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

• If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

WHEN AND HOW DOES TREATMENT WITH MOGADON END?

Your doctor will advise you when to stop taking the medicine. Please remember that it is not suitable for long-term use and that, after a few weeks, it is worth trying to get by without it. This will help to prevent you becoming used to it and reduce the risk of dependence.

After a period of usage it is advisable to reduce the dosage gradually. Sometimes withdrawal effects occur if the medicine is stopped suddenly and these may include depression, nervousness, extreme anxiety, tension, restlessness, confusion, mood changes, rebound insomnia (a recurrence of sleep problems), irritability, sweating, diarrhoea, headaches and muscle weakness.

Also your original problem may return when your treatment is stopped, and you may be anxious, restless and have mood changes. This is less likely if your dose is gradually reduced towards the end of your treatment.

In the unusual case where patients have taken benzodiazepines for a long time, a longer period will be needed over which their dosage will be reduced. Special help may be needed. Your doctor will be able to discuss this with you.

WHAT ARE THE POSSIBLE UNWANTED EFFECTS OF MOGADON?

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

Side effects include drowsiness during the day, feeling of emptiness, reduced alertness, confusion, tiredness, headache, dizziness, muscle weakness, poor muscle coordination and changes in vision. These effects are likely to occur at the start of treatment and usually disappear after a while.

You may become dependent on Mogadon, this could lead to withdrawal symptoms if your treatment is stopped.

In rare cases, changes in behaviour, including aggression, excitement, confusion, restlessness, agitation, irritability, rages, hallucinations and nightmares may occur. If these symptoms occur you must inform your doctor. He/she may want you to stop taking this medicine.

Other unwanted effects which can also occur rarely include:

• Dizziness.
• Reduced blood pressure.
• Stomach upsets.
• Skin rashes.
• Changes in vision.
• Changes in the level of sexual desire.
• Inability to pass urine/holding of urine in the bladder.
• Jaundice -yellowing of the eyes and skin.
• Blood disorders -resulting in severe tiredness and possible infections.
• Depression.

If you are concerned about these or any other unwanted effects talk to your doctor.

HOW SHOULD MOGADON BE STORED?

• Do not store above 25ºC.
• Keep blister in the outer carton in order to protect from light.
• Keep this medicine out of the reach and sight of children.
• This medicine must not be used after the date (EXP) printed on the pack. Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.
• REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them if their symptoms are the same as yours.

HOW CAN YOU HELP YOURSELF TO SLEEP BETTER?

Changes in your daily habits can often lead to improved natural sleep. Try the following suggestions:

• Do not drink any caffeine-containing drinks in the evening, such as cola, coffee or tea.
• Do not have a heavy evening meal.
• Pursue relaxing activities before retiring.
• Try to ensure the bedroom is quiet, well aired and only dimly lit.

If the above suggestions do not work, medication may help.

However, you must avoid taking sleep-inducing medicines for long periods and always discuss it with your doctor.

FURTHER INFORMATION

You can get further information on Mogadon from your doctor or pharmacist.

Mogadon Tablets are distributed in Ireland by Allipharm Services, Belgard Road, Tallaght, Dublin 24, Ireland.

DATE OF LAST REVIEW

July 2007