PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DORMONOCT 2 mg TABLETS

Read all of this leaflet carefully before you start taking DORMONOCT:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DORMONOCT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT DORMONOCT CONTAINS:

The active substance is loprazolam.

Each tablet contains 2 mg of loprazolam as loprazolam mesylate.

Contains sugar (lactose monohydrate): 83,9 mg per tablet

The other ingredients are: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose and povidone.

WHAT DORMONOCT IS USED FOR:

Loprazolam belongs to a group of medicines called benzodiazepines. It works by having a calming effect on the brain.

DORMONOCT is used for:

1) Short-term treatment of insomnia (inability to sleep).
2) Sleep disturbances in elderly patients.
3) Pre-operative sleep disturbances.

DORMONOCT is only used when the disorder is severe, disabling or when the individual is subject to extreme stress.

BEFORE YOU TAKE DORMONOCT:

Do not take DORMONOCT:

- if you are hypersensitive (allergic) to loprazolam, benzodiazepines or any of the other ingredients of DORMONOCT. Signs of an allergic reaction include: a rash, itching, swallowing or breathing problems or swelling of your lips, face, throat or tongue
- if you have serious breathing problems (severe respiratory insufficiency)
- if you have a long term (chronic) condition in which the muscles become weak and tire easily (called myasthenia gravis)
- if you stop breathing for short periods during sleep (called sleep apnoea syndrome)
- if you have serious liver problems.

DORMONOCT should not to be given to children.

Take special care with DORMONOCT:

- if you are elderly or debilitated, as there is a risk of over-sedation, shallow breathing and unsteadiness when walking. The initial dosage should be reduced

- If you have shallow breathing (respiratory insufficiency), in order to avoid aggravation of the problem. The dosage should be reduced
- if you have lung problems
- if you have kidney or liver problems
- if you suffer from anxiety (nervousness) accompanied by an underlying depressive disorder (feelings of deep sadness and unworthiness)
- if you are taking barbiturates (medicines used to treat epilepsy) or other depressants (medicines for depression)
- if you are drinking alcohol, as it has an additive effect
- if you suffer from a psychotic illness (a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly). DORMONOCT should not be used alone to treat depression or anxiety with depression, as suicide may be precipitated in such patients
- if you have a history of alcohol or drug abuse.

Dependence:

DORMONOCT can be addictive, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once dependence has developed, abrupt termination of treatment is accompanied by withdrawal symptoms (headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability).

Rebound effects:

A temporary syndrome may occur when treatment is withdrawn, whereby the symptoms that led to treatment with DORMONOCT recur in an enhanced form. It may be accompanied by other reactions including mood changes, anxiety and restlessness. Since the risk of withdrawal or rebound effects is greater after abrupt discontinuation of treatment, the dose is decreased gradually.

Tolerance:

Some loss of hypnotic effects may develop after repeated use for a few weeks.

Amnesia:

You may experience anterograde amnesia (loss of memory for events following some trauma). To reduce this risk, ensure that you are able to have an uninterrupted sleep of 7 – 8 hours.

Paradoxical reactions:

You may experience psychiatric and paradoxical reactions (such as restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, inappropriate behaviour). If these occur, DORMONOCT should be discontinued. They are more likely to occur in children and the elderly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist.

Taking DORMONOCT with food and drink:

Do not drink alcohol or take medicines that contain alcohol while being treated with DORMONOCT. This is because alcohol can increase the effects of DORMONOCT.

Pregnancy and Breastfeeding:

DORMONOCT should not be used during pregnancy. During labour it crosses the placenta and may cause the "floppy-infant" syndrome characterised by shallow breathing, low body temperature and poor sucking. It should not be given to breastfeeding mothers.

If you use this class of medicine (benzodiazepines) continuously during the later stages of your pregnancy, your baby may become addicted to the medicine and have withdrawal symptoms after birth.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DORMONOCT.

Driving and using machinery:

Do not drive a motor vehicle, operate dangerous machinery or perform potentially hazardous tasks where impaired decision making could lead to accidents, particularly at the start of therapy.

Important information about some of the ingredients of DORMONOCT:

DORMONOCT tablets contain lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DORMONOCT.

Taking other medicines with DORMONOCT:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

This is because DORMONOCT can affect the way some other medicines work. Also some medicines can affect the way DORMONOCT works.

In particular, tell your doctor if you are taking any of the following:

- alcohol, as the sedative effect may be enhanced when the medicine is used in combination with alcohol. This affects the ability to drive or use machines (see Driving and using machinery)
- medicines used to treat certain mental and emotional conditions (antipsychotics or neuroleptics)
- medicines used to induce sleep (hypnotics)
- medicines used to help relieve anxiety symptoms (anxiolytics) and produce calmness or help you sleep (sedatives)
- medicines for depression (antidepressants)
- medicines used to relieve pain (called narcotic analgesics)
- medicines for epilepsy
- medicines used to put you to sleep during an operation or procedure (anaesthetics)
- antihistamines that make you sleepy (sedative antihistamines)
- medicines used to relax muscles (neuromuscular depressants and muscle relaxants).

HOW TO TAKE DORMONOCT:

Do not share medicines prescribed for you with any other person.

Always take DORMONOCT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage:

The usual adult dose is 1 – 2 mg at bedtime, the higher dose being recommended for patients who have been previously treated with benzodiazepines for severe persistent insomnia (inability to sleep). An initial dose of 0,5 mg – 1,0 mg is recommended in elderly and debilitated patients. The 2 mg tablet may not be suitable for use as initiation, in elderly patients and patients with kidney, liver or lung problems.

Duration of treatment:

Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded.

Treatment should be as short as possible. Generally the duration of treatment varies from a few days to two weeks, with a maximum of four weeks including the tapering-off process. After that, your doctor will decide whether you should keep taking it.

Taking DORMONOCT:

- DORMONOCT should be taken half an hour before bedtime.
- Tablets should be swallowed without chewing, with sufficient amount of liquids.
- If you have the impression that the effect of DORMONOCT is too weak or too strong, talk to your doctor or pharmacist.

If you take more DORMONOCT than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdosage include: somnolence (sleepiness, drowsiness), confusion, coma, shallow breathing and low blood pressure.

If you forget to take/missed a dose of DORMONOCT:

If you forget to take a dose of DORMONOCT, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

Effects when treatment with DORMONOCT is stopped:

Keep taking DORMONOCT until your doctor tells you to stop. Do not stop taking DORMONOCT just because you feel better. When your doctor says that you can stop taking DORMONOCT, you need to do this gradually. Your doctor will help you to do this. Stopping DORMONOCT suddenly can lead to withdrawal symptoms (including convulsions). Your doctor will gradually lower your dose until you stop your medicine, to prevent these effects happening.

POSSIBLE SIDE EFFECTS:

DORMONOCT can have side effects.

Not all side effects reported for DORMONOCT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking DORMONOCT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DORMONOCT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- drowsiness (more common in elderly and debilitated patients, and in those receiving high doses)
- over-sedation
- depression of mood and affect
- disorientation or confusion
- lethargy (feeling of tiredness, drowsiness or lack of energy)
- ataxia (clumsiness and lack of co-ordination, affecting balance and manner of walking, limb or eye movements and/or speech)
- constipation, nausea and diarrhoea
- changes in libido (sexual drive).
- paradoxical reactions such as acute hyper-excitability with rage (see Take special care with DORMONOCT).

There is a potential for abuse. Withdrawal symptoms (including convulsions) have occurred following abrupt cessation, especially in patients who have received large doses for prolonged periods.

Anterograde amnesia (loss of memory for events following some trauma) may occur using therapeutic dosages, the risk increasing at higher dosages.

Pre-existing depression may be unmasked by benzodiazepine use.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF DORMONOCT:

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light, heat and humidity.

Keep tablets in the blister pack until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister/carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DORMONOCT:

2 mg tablets packed in blister packs of 30's and 100's.

IDENTIFICATION OF DORMONOCT:

Light yellow, biconvex round tablets. "B" and "026" are engraved and separated by a score line on one side. The other side is neutral.

REGISTRATION NUMBER:

Q/2.2/355

NAME AND ADDRESS OF REGISTRATION HOLDER:

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2 Bond Street

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South Africa

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