

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DORMICUM® 7,5 mg tablets

DORMICUM® 15 mg tablets

Read all of this leaflet carefully before you start taking DORMICUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- DORMICUM 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 DORMICUM CONTAINS

DORMICUM 7,5 mg tablets: Each tablet contains midazolam maleate equivalent to 7,5 mg midazolam.

Other ingredients: lactose anhydrous, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinised starch, talc and titanium dioxide (CI 77891).

DORMICUM 15 mg tablets: Each tablet contains midazolam maleate equivalent to 15 mg midazolam.

Other ingredients: carmellose sodium, lactose anhydrous, hypromellose, indigo carmine (CI 73015), macrogol, magnesium stearate, maize starch, microcrystalline cellulose, polyacrylate dispersion, talc and titanium dioxide (CI 77891).

WHAT DORMICUM IS USED FOR

DORMICUM contains a medicine called midazolam. This belongs to a group of medicines called “benzodiazepines”.

DORMICUM is used in adults:

- For the short-term to treatment of insomnia (inability to sleep).
- Before a medical test or operation to produce sleepiness or drowsiness and to relieve anxiety.

BEFORE YOU TAKE DORMICUM

Do not take DORMICUM:

- If you are allergic (hypersensitive) to benzodiazepines or to any other ingredients of the product.
- If you have severe muscle weakness, also known as myasthenia gravis.
- If you have severe liver disease.
- If you have difficulties with your breathing.
- If you suffer from sleeping disorders, such as difficulty breathing while asleep.
- If you are taking antifungal medicines including ketoconazole, itraconazole, voriconazole.
- If you are taking HIV protease inhibitors including ritonavir boosted protease inhibitors formulations.
- If you suffer from galactose intolerance.

DORMICUM tablets are not recommended for use in children.

You must not take DORMICUM if any of the above apply to you. If you are not sure, talk to your pharmacist, doctor or nurse before you take DORMICUM.

Take special care with DORMICUM:

Before you take DORMICUM tell your doctor or nurse if you:

- are over 60 years of age.
- take any benzodiazepine medicines, as these may lead to the development of physical and psychological dependence and the risk is increased with a history of alcohol or drug abuse.

Tolerance to DORMICUM may occur.

- If you regularly take recreational drugs or drink large amounts of alcohol or have had problems with alcohol or drug abuse in the past.
- have other health problems including breathing problems or kidney, liver, lung or heart problems.
- have high or low blood pressure, or heart disease.
- suffer from mental disorders including depression, psychosis or schizophrenia.
- are, or plan to become pregnant.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before you take DORMICUM.

Using DORMICUM with food and drink:

Drinking alcohol: Do not drink alcohol if you are taking DORMICUM. This is because alcohol may make you feel very sleepy and cause problems with your breathing.

Pregnancy and Breastfeeding

You must tell your doctor or dentist if you are pregnant, or if you think you are pregnant, they can then decide if DORMICUM is suitable for you.

If your doctor decides you should be given DORMICUM during late pregnancy, labour or Caesarean section, your baby may have an irregular heart beat, a low body temperature, floppiness or breathing difficulties and may have developed physical dependence and suffer withdrawal symptoms.

DORMICUM may pass into breast milk therefore you should not breast-feed your baby while taking it.

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

Driving and using machinery

DORMICUM may make you sleepy, forgetful or affect your concentration and co-ordination. This may affect your performance at skilled tasks e.g. driving or operating machinery.

Important information about some of the ingredients of DORMICUM:

DORMICUM contains lactose: If you suffer from galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you must not take DORMICUM.

Taking other medicines with DORMICUM:

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

DORMICUM can affect the way some other medicines work. Also some medicines can affect the way DORMICUM works.

In particular tell your doctor or nurse if you are taking any of the following medicines:

- Medicines for depression.
- Hypnotic medicines (to make you sleep).
- Sedatives (to make you feel calm or sleepy).
- Tranquilliser medicines (for anxiety or to help you sleep).
- Carbamazepine or phenytoin (these may be used for fits or seizures).
- Rifampicin (for tuberculosis).
- Medicines for HIV called “protease inhibitors” (such as saquinavir).
- Antibiotics called “macrolides” (such as erythromycin or clarithromycin).
- Medicines to treat fungal infections (such as ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole).
- Strong pain killers.
- Antihistamines (for allergic reactions).
- St John’s Wort (a herbal medicine for depression).
- Medicines for high blood pressure called “calcium channel blockers” (such as diltiazem).

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before you take DORMICUM.

HOW TO TAKE DORMICUM

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

Do not share medicines prescribed for you with another person. DORMICUM must be taken for short-term treatment only.

Your doctor will tell you how many tablets to take before you go to bed.

If you are having DORMICUM tablets before a minor surgical procedure, this will be administered by a doctor, dentist or a nurse. The dose is normally 15 mg.

The normal dosage for insomnia is 7,5 mg to 15 mg.

Swallow the tablets whole with a glass of water. Do not break or crush tablets unless instructed to do so.

If you have the impression that the effect of DORMICUM is too strong or too weak, talk to your doctor, dentist, nurse or pharmacist.

If you take more DORMICUM than you should:

Symptoms of overdose may include feeling sick (nausea), vomiting, dizziness, slowing of breathing, drowsiness or coma, slurred speech, loss of balance, slow reactions.

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

If you forget to take DORMICUM:

If you forget to take your DORMICUM and your sleep is all right, do not take a dose until the next evening. If you miss a dose and wake up to have it, you require 7 to 8 hours uninterrupted sleep for the effects to wear off.

You should never make up for missing a dose by doubling it the next time. Instead, you should simply continue with the next dose when it is due.

Effects when treatment with DORMICUM is stopped:

If you take DORMICUM for a long time, you may:

- Become tolerant to DORMICUM. The medicine becomes less effective and does not work as well for you.

- Become dependent upon DORMICUM and get withdrawal symptoms (see below). Your doctor will reduce your dose gradually to avoid these effects happening to you.

Withdrawal symptoms: If you stop treatment with DORMICUM suddenly, or lower the dose too quickly, you may get withdrawal symptoms. These can include:

- Headache.
- Muscle pain.
- Feeling very worried (anxious), tense, restless, confused or bad tempered (irritable).
- Mood changes.
- Seeing and possible hearing things that are not really there (hallucinations).
- Sensitivity to light, noise or physical contact.
- Fits (convulsions).
- Problems with sleeping (insomnia).

POSSIBLE SIDE EFFECTS

DORMICUM can cause side effects.

Stop taking DORMICUM and see a doctor straight away if you notice any of the following side effects. They can be life-threatening and you may need urgent medical treatment:

- Heart attack. The signs may include chest pain.
- Breathing problems, sometimes causing the breathing to stop.

Other possible side effects:

- Hypersensitivity reactions.
- Feeling confused.
- Feeling very happy or excited (euphoria).
- Loss of libido.
- Feeling depressed.
- Other reactions such as restlessness, agitation, irritability, aggression, delusion, anger, nightmares, hallucinations, psychosis or inappropriate behaviour.

- Feeling tired or sleepy or being sedated for a long time.
- Headache.
- Feeling dizzy.
- Difficulty co-ordinating muscles.
- Temporary loss of memory.
- Seeing double.
- Stomach upsets.
- Skin reactions including rash.
- Muscle weakness.
- Fatigue.
- An increased risk of falling and fractures in the elderly.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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

STORING AND DISPOSING OF DORMICUM

Store at or below 30 °C, protect from light and moisture. Store in original pack until required for use.

DORMICUM should not be used after the expiry date shown on the container.

Store out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DORMICUM

DORMICUM 7,5 mg tablets: blister packs of 20's, 30's and 60's.

DORMICUM 15 mg tablets: blister packs of 20's, 30's and 60's.

Not all pack sizes may be marketed.

IDENTIFICATION OF DORMICUM

DORMICUM 7,5 mg tablets: white to almost white, oval, cylindrical, biconvex, film-coated tablets. Imprint: upper surface "ROCHE 7.5", lower surface scored.

DORMICUM 15 mg tablets: grey-blue, oval, cylindrical, biconvex, film-coated tablets. Imprint: upper surface "ROCHE 15", lower surface scored.

REGISTRATION NUMBERS

DORMICUM 7,5 mg tablets: 27/2.2/0078

DORMICUM 15 mg tablets: R/2.2/123

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Roche Products (Pty) Ltd

24 Fricker Road

Illovo

Gauteng

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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