

SCHEDULING STATUS: S5

DORMICUM® 5 mg/5 mL Ampoules

DORMICUM® 15 mg/3 mL Ampoules

DORMICUM® 50 mg/10 mL Ampoules

Midazolam

Read all of this leaflet carefully you are given DORMICUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- 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 is in this leaflet

1. What DORMICUM is and what it is used for
2. What you need to know before you are given DORMICUM
3. How DORMICUM will be given
4. Possible side effects
5. How to store DORMICUM
6. Contents of the pack and other information

1. What DORMICUM is and what it is used for

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

DORMICUM is used for:

- Anaesthesia in adults.

- Sedation of adults and children, in intensive care units.
- Conscious sedation (an awake but very relaxed state of calm or drowsiness during a medical test or procedure) in adults and children.
- Premedication (medicine used to cause relaxation, calm and drowsiness before an anaesthetic) in adults and children.

2. What you need to know before you are given DORMICUM

Do not receive DORMICUM:

- If you are allergic (hypersensitive) to midazolam or any medicine from the benzodiazepines group or to any ingredients within the medicine.
- 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 pregnant or breastfeeding.

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

Warnings and precautions

Check with your doctor or nurse before you are given DORMICUM 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,
- 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 are given DORMICUM.

If your child is going to be given DORMICUM:

- Talk to your doctor or nurse if any of the above applies to your child. In particular, tell your doctor or nurse if your child has heart or breathing problems, as your child will have to be monitored while DORMICUM is being administered.

Other medicines and 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 hepatitis C, such as boceprevir and telaprevir. You must not take these medicines with DORMICUM.
- 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, delavirdine).
- 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).
- Herbal medicines such as St John's Wort, berberine, goldenseal, Echinacea purpurea root, quercetin or Panax ginseng.
- Medicines for high blood pressure called "calcium channel blockers" (such as diltiazem, verapamil).
- Medicines used in the treatment of leukaemia and other cancers, such as imatinib, lapatinib, idelalisib, mitotane or enzalutamide.
- Oestrogen receptor modulators such as raloxifene.
- Oral contraceptive medicines such as ethinylestradiol combined with norgestrel or gestodene.
- Neurokinin-1 receptor antagonists such as aprepitant, netupitant, casopitant.

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

DORMICUM with food and drink

Drinking alcohol: Do not drink alcohol if you have been given 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. Receiving DORMICUM during the first three months of pregnancy and cause your baby to be born with birth defects. If your doctor decides you should be given DORMICUM during late pregnancy, labour or Caesarean section, your baby may have an irregular heartbeat, a low body temperature, floppiness, difficulty in sucking, or breathing difficulties and may have developed physical dependence and suffer withdrawal symptoms.

DORMICUM may pass into breast milk therefore you should not breastfeed your baby while receiving it. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given DORMICUM.

Important information about some of the ingredients of DORMICUM:

DORMICUM is essentially “sodium free” as it contains less than 1 mmol sodium (23 mg) per small glass bottle (ampoule).

Driving and using machines

After being given DORMICUM, do not drive or use tools or machines until your doctor says you can. This is because DORMICUM may make you sleepy, forgetful or affect your concentration and co-ordination, these effects can be worsened if you take alcohol at the same time. This may affect your performance at skilled tasks such as driving or operating machinery. Your doctor will let you know when it is safe for you to drive or use machines again.

3. How DORMICUM will be given

DORMICUM will be given to you by a doctor or nurse. It will be given to you in a place that has the equipment needed to monitor you and to treat any side effects. This might be a hospital, clinic or doctor’s surgery. In particular, your breathing, heart and circulation will be monitored.

DORMICUM is not recommended for use for infants and babies under 6 months of age. However, if the doctor feels that it is necessary, it can be given to an infant or baby under 6 months who is in intensive care.

You will be given DORMICUM in one of the following ways:

- By slow injection into a vein (intravenous injection).
- Through a drip into one of your veins (intravenous infusion).
- By injection into a muscle (intramuscular injection).

The dose of DORMICUM varies from one patient to another. Your doctor will work out how much to give you. It depends on your age, weight, and general health. It also depends on what you need the medicine for, how you respond to treatment, and whether you are going to be given other medicines at the same time. After your treatment, you must be taken home by an adult who is able to look after you. This is because DORMICUM may make you sleepy or forgetful. It may also affect your concentration and co-ordination.

If you are given DORMICUM for a long time, such as in intensive care, your body may start to get used to the medicine. This means it may not work as well. If you have the impression that the effect of DORMICUM is too strong or too weak, talk to your doctor, nurse or pharmacist.

If you are given too much DORMICUM

Your medicine will be given to you by a doctor or a nurse. If you are given too much by mistake, you may notice the following:

- Feeling sleepy and losing your co-ordination and reflexes.
- Problems with speaking and unusual eye movements.
- Low blood pressure. This may make you feel dizzy or light-headed.
- Slow or stopping of your breathing and heart beat and being unconscious (coma).

Long term use of DORMICUM for sedation in intensive care

If you are given DORMICUM for a long time, the following may happen:

- It may start to work less well.
- You may become dependent on the medicine and get withdrawal symptoms when you stop having it. See “Effects when treatment with DORMICUM is stopped” below.

Effects when treatment with DORMICUM is stopped

If you receive 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.
- Diarrhoea.
- 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).

4. Possible side effects

DORMICUM can cause side effects.

Stop receiving DORMICUM and consult your 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 and an allergic skin disease characterised by patches of confined swelling involving the skin, the layers beneath the skin and/or the mucous membranes (angioedema).
- Feeling confused, disoriented, and emotional with mood swings.

- Feeling very happy or excited (euphoria).
- Loss of libido.
- Feeling depressed.
- Other reactions such as restlessness, agitation, hyperactivity, 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, the risk being increased when sedatives and/or alcohol are taken at the same time.

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 receiving DORMICUM, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DORMICUM.

5. How to store DORMICUM

Store at or below 30 °C.

Keep ampoule in outer carton in order to protect from light.

DORMICUM ampoules should not be frozen because they can burst. Furthermore, precipitation can occur which dissolves on shaking at room temperature.

Store out of reach of children.

This medicine should not be used after the expiry date (EXP) shown on the pack.

6. Contents of the pack and other information

What DORMICUM contains

DORMICUM contains 5 mg/5 mL, 15 mg/3 mL or 50 mg/10 mL midazolam active substance per ampoule, respectively.

The other ingredients are: sodium chloride, hydrochloric acid, sodium hydroxide and water for injection.

What DORMICUM looks like and contents of the pack

DORMICUM 5 mg/5 mL: clear, colourless to slightly yellow liquid in 5 mL colourless ampoules. Pack of 5 ampoules.

DORMICUM 15 mg/3 mL: clear, practically colourless liquid in 3 mL colourless ampoules. Pack of 5 ampoules.

DORMICUM 50 mg/10 mL: clear, colourless to slightly yellow liquid in 10 mL colourless ampoules. Pack of 1 ampoule.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pharmaco Distribution (Pty) Ltd.

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Ethical assistance Line: +27 (0) 11 784 00 77

This leaflet was last revised in

Registration: DORMICUM 5 mg/5 mL - Aug 1986; DORMICUM 15 mg/3 mL – Jul 1985; DORMICUM 50 mg/10 mL – Aug 1991.

Last revision: 2022-08-25

Registration numbers

DORMICUM 5 mg/5 mL ampoules: T/2.2/207

DORMICUM 15 mg/3 mL ampoules: Q/2.2/286

DORMICUM 50 mg/10 mL ampoules: Y/2.2/325

DORMICUM 15 mg/3 mL	
NAMIBIA Reg. No. 90/2.2/001404	NS3

DORMICUM 5 mg/5 mL	
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