

ADCO MIDAZOLAM INJECTION 5 mg/5 ml
ADCO MIDAZOLAM INJECTION 15 mg/3 ml
ADCO MIDAZOLAM INJECTION 50 mg/10 ml

Adcock Ingram Critical Care (Pty) Ltd.
Email: Aicc.RegulatoryAffairs@adcock.com
17 June 2025

1.3.2.1 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

ADCO MIDAZOLAM INJECTION 5 mg/5 ml

Each ampoule contains midazolam 5 mg per 5 mL.

ADCO MIDAZOLAM INJECTION 15 mg/3 ml

Each ampoule contains midazolam 15 mg per 3 mL.

ADCO MIDAZOLAM INJECTION 50 mg/10 ml

Each ampoule contains midazolam 50 mg per 10 mL.

Sugar free

Read all of this leaflet carefully before you are given ADCO MIDAZOLAM INJECTION.

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

What is in this leaflet

1. What ADCO MIDAZOLAM INJECTION is and what it is used for
2. What you need to know before you are given ADCO MIDAZOLAM INJECTION

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3. How ADCO MIDAZOLAM INJECTION will be given
4. Possible side effects
5. How to store ADCO MIDAZOLAM INJECTION
6. Contents of the pack and other information

1. What ADCO MIDAZOLAM INJECTION is and what it is used for

ADCO MIDAZOLAM INJECTION contains a medicine called midazolam. This belongs to a group of medicines called “benzodiazepines” which can cause sedation (sleepiness) and anaesthesia (keeps you from feeling pain during surgery or other procedures).

ADCO MIDAZOLAM INJECTION is used for:

- Anaesthesia
- Pre-operative sedation (used to help you relax and feel calm before your surgery)
- 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)
- Premedication (medicine used to cause relaxation, calm and drowsiness before an anaesthetic).

2. What you need to know before you are given ADCO MIDAZOLAM INJECTION

ADCO MIDAZOLAM INJECTION should not be administered to you:

- If you are allergic (hypersensitive) to midazolam, any medicine from the benzodiazepine group or any of the other ingredients of ADCO MIDAZOLAM INJECTION (listed in section 6)
- If you have severe muscle weakness (myasthenia gravis)
- If you have difficulties breathing

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- If you suffer from sleep disorders, such as difficulty breathing while asleep (sleep apnoea syndrome)
- If you have severe liver disease
- If you are pregnant or breastfeeding.

Warnings and precautions

Special care should be taken with ADCO MIDAZOLAM INJECTION:

- If you are over 60 years
- If you have a long term illness that makes you feel very weak, run down and short of energy
- If you have any lung disorders or difficulty breathing
- If you have any heart condition or heart failure
- If you suffer from mental disorders including depression, psychosis or schizophrenia
- If you have impaired kidney function or kidney failure
- If you have impaired liver function
- As this medicine may lead to the development of physical and psychological dependence. There is an increased risk if you have a history of alcohol or drug abuse. Tolerance to ADCO MIDAZOLAM INJECTION may occur
- As withdrawal symptoms may occur. These may include headaches, diarrhoea, muscle pain, extreme anxiety, tension, sleep disturbances, restlessness, confusion, irritability, rebound insomnia, mood changes, hallucinations and convulsions.

Due to the possibility of amnesia, you will only be discharged after at least four hours and only with a responsible person.

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Children

- Talk to your doctor or nurse if any of the above applies to your child. Your child will need to be monitored and the dose adjusted.

Other medicines and ADCO MIDAZOLAM INJECTION

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines).

Tell your doctor or nurse if you have recently taken or are currently taking any of the following medicines:

- Medicines used to treat fungal infections such as ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole
- Medicines used to treat bacterial infections such as erythromycin, clarithromycin, rifampicin
- Medicines used to treat human immunodeficiency virus (HIV) such as saquinavir, ritonavir
- Medicines used to treat hepatitis C, such as boceprevir and telaprevir
- Medicines used to treat ulcers or gastroesophageal reflux disease (GERD) such as cimetidine
- Medicines used to treat angina, blood pressure or irregular heartbeats such as diltiazem
- Medicines used to treat high cholesterol such as atorvastatin
- Medicines used to treat epilepsy, bipolar disorder or migraines, such as valproic acid
- Alcohol, which can be found in some cough syrups
- Medicines used to treat severe pain such as fentanyl or opioids

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- Benzodiazepines which are used to relieve anxiety or aid sleep such as diazepam and lorazepam
- Medicines used to treat allergies (antihistamines) such as levocetirizine and desloratadine
- Medicines used to make your blood thinner such as ticagrelor
- Herbal medicines (herbs assisting with good health) such as *Echinacea purpurea* root extract, St. John's wort.

ADCO MIDAZOLAM INJECTION with alcohol

Do not drink alcohol or alcohol containing products (e.g. cough syrups) after receiving ADCO MIDAZOLAM INJECTION. The combination of ADCO MIDAZOLAM INJECTION and alcohol can increase the side effects of ADCO MIDAZOLAM INJECTION and also make you very sleepy or cause problems with your breathing and heart.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning on having a baby, please consult your doctor, pharmacist or other healthcare provider for advice before ADCO MIDAZOLAM INJECTION is given to you.

You should not be given ADCO MIDAZOLAM INJECTION if you are pregnant or breastfeeding.

Receiving midazolam during the first three months of pregnancy can cause your baby to be born with birth defects. If your doctor decides you should be given midazolam during late pregnancy, labour or caesarean section, your baby may have an irregular heartbeat, a low body temperature, decreased muscle tone, difficulty in sucking, or breathing difficulties and may have developed physical

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dependence and suffer withdrawal symptoms.

Midazolam also passes into your breastmilk, and you should not breastfeed your baby while receiving it.

Driving and using machines

After being given ADCO MIDAZOLAM INJECTION, do not drive or use tools or machines until your doctor says you can.

This is because ADCO MIDAZOLAM INJECTION 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.

ADCO MIDAZOLAM INJECTION contains sodium:

ADCO MIDAZOLAM INJECTION 5 mg/5 ml

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

ADCO MIDAZOLAM INJECTION 15 mg/3 ml

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

ADCO MIDAZOLAM INJECTION 50 mg/10 ml

This medicine contains 35,42 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 1,77 % of the recommended maximum daily dietary intake of sodium for an adult.

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3. How ADCO MIDAZOLAM INJECTION will be given

ADCO MIDAZOLAM INJECTION 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.

You will be given ADCO MIDAZOLAM INJECTION 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 ADCO MIDAZOLAM INJECTION 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 ADCO MIDAZOLAM INJECTION may make you sleepy or forgetful. It may also affect your concentration and co-ordination.

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

If you are administered too much ADCO MIDAZOLAM INJECTION

Since a healthcare professional will administer ADCO MIDAZOLAM INJECTION, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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If you are given ADCO MIDAZOLAM INJECTION for a long time:

- Your body may start to get used to the medicine (become tolerant). The medicine becomes less effective and does not work well for you.
- You may become dependent upon this medicine and get withdrawal symptoms when it is stopped.

Withdrawal symptoms

If ADCO MIDAZOLAM INJECTION was given to you over a long period, you may become dependent and if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms.

These symptoms can include headache, diarrhoea, muscle pain, feeling very worried (anxious), tense, restless, confused or bad-tempered (irritable), problems with sleeping (insomnia), mood changes, hallucinations (seeing and possibly hearing things that are not there) and fits (convulsions).

Your doctor will reduce your dose gradually to avoid these effects happening to you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

ADCO MIDAZOLAM INJECTION can have side effects.

Not all side effects reported for ADCO MIDAZOLAM INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO MIDAZOLAM INJECTION, please consult your healthcare provider for advice.

If any of the following happens, ADCO MIDAZOLAM INJECTION treatment should be stopped and you should tell your doctor or nurse immediately or go to the casualty department at your nearest hospital.

- Anaphylactic reaction (a life-threatening allergic reaction) or hypersensitivity. Signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You may have shortness of breath, wheezing or troubled breathing or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness. Additionally, you may experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Heart attack (cardiac arrest). Signs may include chest pain which may spread to your neck and shoulders and down your left arm
- Breathing problems or complications (sometimes causing the breathing to stop)
- Choking and sudden blockage of the airway (laryngospasm).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Feelings are depressed, disorientated and confused
- Paradoxical reactions: restlessness, agitation, hyperactivity, irritability, aggression, delusion, anger, nightmare
- Fits (convulsion) in premature infants and new-born babies
- Amnesia (the loss of memories, such as facts, information and experiences)
- Hallucination (seeing and possibly hearing things that are not really there)

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- Clotting in blood vessels (thrombosis)
 - Vasodilation (widening of blood vessels) causing low blood pressure (hypotension)
 - Dependence: drug dependence, withdrawal syndrome, substance abuse
 - Impaired balance or coordination
 - Thrombophlebitis (inflammation of a vein)
 - Rash, hives, itching
 - Falls and fractures

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pain and redness at the injection site
- Drowsiness (occurs more commonly in elderly and debilitated patients and in patients receiving high doses)
- Dizziness
- Oversedation.

Less frequent side effects:

- Headache
- Nausea (feeling sick)
- Vomiting (being sick).

Frequency not known

- Hiccups
- Fatigue

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- Dry mouth
- Constipation.

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO MIDAZOLAM INJECTION.

For reporting of side effects directly to the Holder of Certificate of Registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store ADCO MIDAZOLAM INJECTION

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

6. Contents of the pack and other information

What ADCO MIDAZOLAM INJECTION contains

The active substance is midazolam.

The other ingredients are: sodium chloride, water for injection, hydrochloric acid (for pH-adjustment) and sodium hydroxide (for pH-adjustment).

What ADCO MIDAZOLAM INJECTION looks like and contents of the pack

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ADCO MIDAZOLAM INJECTION 5 mg/5 ml: Clear, closed, easy break, 5 mL, Type 1 glass ampoule, 25 ampoules per carton. Transparent, low-density polyethylene (LDPE), 5 mL, plastic ampoule in strips of 10 plastic ampoules in an outer carton.

ADCO MIDAZOLAM INJECTION 15 mg/3 ml: Clear, closed, easy break, 3 mL, Type 1 glass ampoule, 50 ampoules per carton. Transparent, low-density polyethylene (LDPE), 5 mL, plastic ampoule in strips of 10 plastic ampoules in an outer carton.

ADCO MIDAZOLAM INJECTION 50 mg/10 ml: Clear, closed, easy break, 10 mL, Type 1 glass ampoule, 10 ampoules per carton. Transparent, low-density polyethylene (LDPE), 10 mL, plastic ampoule in strips of 10 plastic ampoules in an outer carton.

Not all pack sizes may be marketed

HOLDER OF CERTIFICATE OF REGISTRATION

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This leaflet was revised in

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REGISTRATION NUMBERS

ADCO MIDAZOLAM INJECTION 5 mg/5 ml: A40/2.2/0753

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ADCO MIDAZOLAM INJECTION 50 mg/10 ml: A40/2.2/0755

Namibia:

ADCO MIDAZOLAM INJECTION 5 mg/5 ml: NS3 10/2.2/0435