



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
MIDAZOLAM INJECTION
Midazolam Hydrochloride 5mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Midazolam Injection is and what it is used for
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3. How to use Midazolam Injection
4. Possible side effects
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1. WHAT MIDAZOLAM INJECTION IS AND WHAT IT IS USED FOR

Midazolam Injection contains Midazolam Hydrochloride which belongs to a group of medicines known as benzodiazepines.

It is a short acting medicine that is used to induce sedation (a very relaxed state of calm, drowsiness or sleep) and relieves anxiety and muscle tension. This medicine is used for:

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MIDAZOLAM INJECTION

You must not be given Midazolam Hydrochloride

- If you are allergic (hypersensitive) to Midazolam Hydrochloride or any of the other ingredients of the medicine
- You are allergic to other benzodiazepine medicines, such as diazepam or nitrazepam.
- You have severe breathing problems and you are going to have Midazolam Hydrochloride for conscious sedation. You must not be given Midazolam Hydrochloride if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Take special care with Midazolam Injection

Talk to your doctor or nurse before you are given Midazolam Hydrochloride if:

- You are over 60 years of age.
- You have a long-term illness (such as breathing problems or kidney, liver or heart



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problems). You are debilitated (have an illness that makes you feel very weak, run down and short of energy).

- You have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep), so you may be closely monitored.
- You have myasthenia gravis (a neuromuscular disease-causing muscle weakness).
- You regularly drink large amounts of alcohol, or you have had problems with alcohol use in the past. Alcohol can increase the effects of Midazolam Hydrochloride, possibly leading to severe sedation that could result in coma or death.
- You regularly take recreational drugs (drugs taken for other than medical use) or you have had problems with drug use in the past. You are pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding').

Children

If your child is going to be given this medicine:

It is particularly important to tell your doctor or nurse if your child has cardiovascular disease (heart problems). Your child will be carefully monitored and the dose will be adjusted specially. Children must be carefully monitored. For infants and babies under 6 months this will include monitoring of breathing and oxygen levels.

Talk to the doctor or nurse if any of the above applies to your child.

Other medicines and Midazolam Hydrochloride

Please tell your doctor or nurse if you are taking, have recently taken or might start taking any other medicines. This includes medicines obtained without a prescription and herbal medicines.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

Tell your doctor or nurse if you are taking any of the following medicines:

- Tranquilisers (for anxiety or to help you sleep)
- Hypnotics (medicines to make you sleep)
- Sedatives (to make you feel calm or sleepy)
- Antidepressants (medicines for depression)
- Narcotic analgesics (very strong pain killers)
- Antihistamines (used to treat allergies)
- Medicines to treat fungal infections (ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole)
- Macrolide antibiotics (such as erythromycin or clarithromycin)
- Diltiazem (used to treat high blood pressure)
- Medicines for HIV (protease inhibitors such as saquinavir)
- Medicines for Hepatitis C (protease inhibitors such as boceprevir and telaprevir)
- Atorvastatin (used to treat high cholesterol)



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- Rifampicin (used to treat mycobacterial infections such as tuberculosis) ticagrelor (used to prevent heart Attack)
- The herbal medicine St. John's Wort.

If any of the above applies to you, or if you are not sure, talk to your doctor or nurse before you are given Midazolam Hydrochloride.

Operations

If you are going to have an anaesthetic for an operation or for dental treatment (including inhaled anaesthetics that you breathe in), it is important to tell your doctor or dentist that you have been given Midazolam Hydrochloride.

Midazolam Hydrochloride with alcohol

Do not drink alcohol if you have been given Midazolam Hydrochloride. This is because alcohol can increase the sedative effect of Midazolam Hydrochloride and may cause problems with your breathing.

Pregnancy and breast-feeding:

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Your doctor will decide if this medicine is suitable for you.
- Do not breast-feed for 24 hours after being given Midazolam Hydrochloride. This is because Midazolam Hydrochloride may pass into your breast milk.

Driving and using machines:

This medicine may make you sleepy, dizzy, forgetful or affect your concentration and co-ordination. This may affect your performance at skilled tasks such as driving or using machines. Do not drive or use machinery until completely recovered. Your doctor should advise you when you can start these again.

3. HOW TO TAKE MIDAZOLAM INJECTION

Midazolam Hydrochloride should be given only by experienced healthcare professionals (doctor or nurse). It should be given in a place (hospital, clinic or surgery) equipped to monitor and support the patient's breathing, heart and circulation (cardiovascular function) and recognise the signs of and manage the expected side effects of anaesthesia.

How much Midazolam Hydrochloride is given

Your doctor will decide on a suitable dose for you. The dose you are given will depend on why you are being treated and the type of sedation needed. Your weight, age, your state of health, how you respond to Midazolam Hydrochloride and whether other medicines are needed at the same time will also influence the dose that you are given.

If you need strong painkillers, you will be given these first and then be given Midazolam Hydrochloride. Your doctor will decide on a suitable dose for you.



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How Midazolam Hydrochloride is given

Midazolam Hydrochloride may be given to you in one of four different ways:

- By slow injection into a vein (intravenous injection)
- Through a tube into one of your veins (intravenous infusion)
- By injection into a muscle (intramuscular injection)
- Into your back passage (rectum). You should always be taken home by a responsible adult after your treatment.

Use in children and adolescents.

- In infants and babies under 6 months of age Midazolam Hydrochloride is only recommended for sedation in intensive care units. The dose will be given gradually into a vein.
- Children 12 years and under will usually be given Midazolam Hydrochloride into a vein. When Midazolam Hydrochloride is used for premedication (to cause relaxation, calm and drowsiness before an anaesthetic), it may be given into the back passage (rectum).

If too much of Midazolam Hydrochloride is given

Your medicine will be given to you by a doctor or nurse.

If you are accidentally given too much Midazolam Hydrochloride you may:

- Lose your co-ordination (ataxia) and reflexes.
- Have problems with your speech (dysarthria).
- Have involuntary eye movements (nystagmus).
- Develop low blood pressure (hypotension).
- Stop breathing (apnoea) and suffer cardiorespiratory depression (slowed or stopped breathing and heart beat) and coma

Stopping treatment with Midazolam Hydrochloride

If you receive long term treatment with Midazolam Hydrochloride (are given the medicine for a long time) you may:

- Become tolerant to Midazolam Hydrochloride. The medicine becomes less effective and does not work as well for you.
- Become dependent upon this medicine and get withdrawal symptoms (see below).

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

The following effects have been seen with Midazolam Hydrochloride use, particularly in children and the elderly; restlessness, agitation, irritability, involuntary movements, hyperactivity, hostility, delusion, anger, aggressiveness, anxiety, nightmares, hallucinations. If you experience these, your doctor will consider stopping Midazolam Hydrochloride treatment.

Withdrawal symptoms: Benzodiazepine medicines, like Midazolam Hydrochloride,



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may make you dependent if used for a long time (for instance in intensive care). This means that if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms. The symptoms can include:

- Headache diarrhoea muscle pain
- Feeling very worried (anxious), tense, restless, confused or bad-tempered (irritable) problems with sleeping
- Mood changes
- Hallucinations (seeing and possibly hearing things that are not there) fits (convulsions).

In severe cases of withdrawal, the following can occur: a feeling of losing contact with reality, numbness and tingling of the extremities (e.g. hands and feet), feeling sensitive to light, noise and touch.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine (frequency not known).

Stop taking Midazolam Hydrochloride 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:

- Anaphylactic shock (a life-threatening allergic reaction). 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 also have shortness of breath, wheezing or trouble 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).
- Breathing problems or complications (sometimes causing the breathing to stop).
- Choking and sudden blockage of the airway (laryngospasm).

Life-threatening side effects are more likely to occur in adults over 60 years of age and those who already have breathing difficulties or heart problems, particularly if the injection is given too fast or at a high dose.

Other possible side effects:

Immune System problems:

- General allergic reactions (skin reactions, heart and blood system reactions, wheezing)

Effects on behavior:

- Restlessness, agitation, irritability nervousness, anxiety
- Hostility, anger or aggression



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- Hyperactivity, changes in libido
- Inappropriate behaviour

Mental and Nervous system problems:

- Confusion, disorientation, emotional and mood disturbances, involuntary movements, nightmares, abnormal dreams
- Hallucinations (seeing and possibly hearing things that are not really there), psychoses (losing contact with reality)
- Drowsiness and prolonged sedation, reduced alertness
- Headache, dizziness
- Difficulty in co-ordinating muscles
- Fits (convulsions) in premature infants and new-born babies
- Temporary memory loss. How long this lasts depends on how much Midazolam Hydrochloride you were given. You may experience this after your treatment. In isolated cases this could be prolonged (lasted for a long time)
- Drug dependence, abuse.

Heart and circulation problems:

- Low blood pressure
- Slow heart rate
- Redness of the face and neck (flushing), fainting or headache.

Breathing problems:

- Shortness of breath
- Hiccup.

Stomach, gut and mouth problems:

- Feeling sick or being sick
- Constipation
- Dry mouth.

Skin problems:

- Rash
- Hives (lumpy rash)
- Itchiness.

Muscle problems:

- Muscle spasms and muscle tremors (shaking of your muscles that you cannot control).

Injection site problems:

- Redness
- Swelling of the skin
- Blood clots or pain at the injection site.



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Injury:

- Patients taking benzodiazepines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).
- **General:** tiredness (fatigue).

Elderly patients:

- Life-threatening side effects are more likely to occur in adults over 60 years of age and those who already have breathing difficulties or heart problems, particularly when the injection is given too quickly or at a high dose.

Patients with severe kidney disease:

- Patients with severe kidney disease are more likely to experience side effects.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE MIDAZOLAM INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Midazolam Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What MIDAZOLAM INJECTION contains

Each ml of Midazolam 5mg Injection contains 5mg of Midazolam Hydrochloride.

What MIDAZOLAM INJECTION looks like and contents of the pack

Clear transparent liquid in 10x3ml Ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.
234-(0)8077008888
Customercare@fidson.com



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	Prepared by	Approved by	
Signature			
Date	26/08/2025	01-09-2025	12-09-2025
Designation	MRA	HoM	GM, QRA