

FINAL PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS
S5
Midazolam 1 mg/ml Accord
Midazolam (as midazolam hydrochloride)
Sugar free
Read all of this leaflet carefully before you start using Midazolam 1 mg/ml Accord <ul style="list-style-type: none">• Keep this leaflet. You may need to read it again.• If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
What is in this leaflet <ol style="list-style-type: none">1. What Midazolam 1 mg/ml Accord is and what it is used for2. What you need to know before you take Midazolam 1 mg/ml Accord3. How to take Midazolam 1 mg/ml Accord4. Possible side effects5. How to store Midazolam 1 mg/ml Accord6. Contents of the pack and other information
1. What Midazolam 1 mg/ml Accord is and what it is used for <p>Midazolam 1 mg/ml Accord 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.</p> <p>Midazolam 1 mg/ml Accord is used for:</p> <ul style="list-style-type: none">• Conscious sedation (an awake but very relaxed state of calm or drowsiness during a medical test or procedure) in adults and children.

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<ul style="list-style-type: none">• 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 Midazolam 1 mg/ml Accord is administered to you
<p>Midazolam 1 mg/ml Accord should not be administered to you:</p> <ul style="list-style-type: none">• if you are hypersensitive (allergic) to midazolam or to any of the other ingredients of Midazolam 1 mg/ml Accord (listed in section 6 of this leaflet).• if you are allergic to other benzodiazepine medicines, such as diazepam or nitrazepam.• if you have severe breathing problems and you are going to have Midazolam 1 mg/ml Accord for conscious sedation.• if you are pregnant• if you are breastfeeding your baby <p>You must not be given Midazolam 1 mg/ml Accord if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given Midazolam 1 mg/ml Accord.</p>
Warnings and precautions
<p>Talk to your doctor or nurse before being given Midazolam 1 mg/ml Accord.</p> <p>Children</p> <p>If your child is going to be given this medicine:</p> <ul style="list-style-type: none">• 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. <p>Adults</p> <p>Talk to your doctor or nurse before you are given Midazolam 1 mg/ml Accord:</p> <ul style="list-style-type: none">• if you are over 60 years of age.

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- if you have a long-term illness (such as breathing problems or kidney, liver or heart problems).
- if you are debilitated (have an illness that makes you feel very weak, run down and short of energy).
- if you have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep), so you may be closely monitored.
- if you have myasthenia gravis (a neuromuscular disease-causing muscle weakness).
- if you regularly drink large amounts of alcohol or you have had problems with alcohol use in the past. Alcohol can increase the clinical effects of **Midazolam 1 mg/ml Accord**, possibly including severe sedation that could result in coma or death.
- if you regularly take recreational drugs or you have had problems with drug use in the past.
- if you are pregnant or think you may be pregnant (see **Pregnancy and breastfeeding**).
- during labour and delivery
- you may only be discharged at least four hours after being given **Midazolam 1 mg/ml Accord** or upon recommendation by your treating doctor and if you are accompanied by a responsible person

If any of the above apply to you, or if you are not sure, talk to your doctor or nurse before you are given **Midazolam 1 mg/ml Accord**.

Other medicines and Midazolam 1 mg/ml Accord

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may increase the effects of **Midazolam 1 mg/ml Accord** and some may decrease its effects. Your doctor will decide, if you should be treated with **Midazolam 1 mg/ml Accord** when taking these medicines and how closely you should be monitored.

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

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- tranquilisers (for anxiety or to help you sleep) hypnotics (medicines to make you sleep)
sedatives (to make you feel calm or sleepy)
- antidepressants or antipsychotics (medicines for depression or schizophrenia)
- narcotic analgesics (very strong pain killers)
- cough medicines (such as ones containing codeine)
- antihistamines (used to treat allergies)
- medicines to treat fungal infections (ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole)
- macrolide antibiotics (such as erythromycin, clarithromycin or roxithromycin)
- medicines used to treat high blood pressure and heart disease (such as diltiazem, verapamil and methyldopa)
- diltiazem (used to treat high blood pressure)
- medicines for HIV (efavirenz or protease inhibitors, such as saquinavir) medicines for Hepatitis C (protease inhibitors such as boceprevir and telaprevir)
- atorvastatin (used to treat high cholesterol)
- rifampicin (used to treat mycobacterial infections such as tuberculosis)
- ticagrelor (used to prevent heart attack)
- herbal medicine (St John's wort)
- carbamazepine (used to treat epilepsy and bi-polar disorder)
- phenytoin (used to treat epilepsy)
- aprepitant (used to stop you feeling or being sick).

If any of the above apply to you, or if you are not sure, talk to your doctor or nurse before you are given **Midazolam 1 mg/ml Accord**.

Concomitant use of **Midazolam 1 mg/ml Accord** and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing

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(respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However, if your doctor does prescribe Midazolam 1 mg/ml Accord together with opioids the dose and duration of concomitant treatment will be limited by your doctor.
Please tell your doctor about all opioid medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
Operations If you are going to have an inhaled anaesthetic (one that you breathe in) for an operation or for dental treatment, it is important to tell your doctor or dentist that you have been given Midazolam 1 mg/ml Accord .
Midazolam 1 mg/ml Accord with alcohol Do not drink alcohol if you have been given Midazolam 1 mg/ml Accord . This is because alcohol can increase the sedative effect of Midazolam 1 mg/ml Accord and may cause problems with your breathing.
Pregnancy and breastfeeding If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being administered Midazolam 1 mg/ml Accord . If you are pregnant or breastfeeding your baby, you should not be given Midazolam 1 mg/ml Accord . Inform your doctor immediately if you are pregnant while being administered Midazolam 1 mg/ml Accord .

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<p>Driving and using machines</p> <p>Midazolam 1 mg/ml Accord may make you sleepy, dizzy, forgetful or affect your concentration and coordination. This may affect your performance at skilled tasks such as driving or using machines.</p> <ul style="list-style-type: none">• Do not drive or use machinery until you are completely recovered. Your doctor should advise you when you can start these activities again.• You should always be taken home by a responsible adult after your treatment.
<p>Midazolam 1 mg/ml Accord contains sodium</p> <p>Midazolam 1 mg/ml Accord is essentially 'sodium free' as it contains less than 1 mmol sodium (23 mg) per injection.</p>
<p>3. How Midazolam 1 mg/ml Accord will be administered</p>
<p>Midazolam 1 mg/ml Accord 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.</p>
<p>Normal adult dose</p> <p>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 1 mg/ml Accord and whether other medicines are needed at the same time will also influence the dose that you are given.</p> <p>If you need strong painkillers, you will be given these first and then be given Midazolam 1 mg/ml Accord. Your doctor will decide on a suitable dose for you.</p> <p>Midazolam 1 mg/ml Accord may be given to you in one of three different ways:</p> <ul style="list-style-type: none">• by slow injection into a vein (intravenous injection)

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<ul style="list-style-type: none">• through a tube into one of your veins (intravenous infusion)• by injection into a muscle (intramuscular injection)
Children
<ul style="list-style-type: none">• Children 12 years and under will usually be given Midazolam 1 mg/ml Accord into a vein.
If more Midazolam 1 mg/ml Accord is given to you than the normal dose Midazolam 1 mg/ml Accord will be given to you by a doctor or nurse. If you are accidentally given too much Midazolam 1 mg/ml Accord you may: <ul style="list-style-type: none">• Feel drowsy.• Lose your co-ordination (ataxia) and reflexes.• Have problems with your speech (dysarthria).• Have involuntary eye movements (nystagmus).• Develop low blood pressure (hypotension).
Stopping Midazolam 1 mg/ml Accord injection
If you receive long term treatment with Midazolam 1 mg/ml Accord (are given the medicine for a long time) you may: <ul style="list-style-type: none">• Become tolerant to Midazolam 1 mg/ml Accord. 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 1 mg/ml Accord use particularly in children and the elderly: restlessness, agitation, irritability, involuntary movements, hyperactivity, nervousness, hostility, delusion, anger, aggressiveness, anxiety, nightmares, hallucinations (seeing and possibly hearing things that are not really there), psychoses (losing contact with reality) and inappropriate behaviour (these reactions are also known as paradoxical reactions, which are outcomes that are opposite to the effects normally expected for the medicine). If you experience these, your doctor will

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consider stopping Midazolam 1 mg/ml Accord treatment.
Withdrawal symptoms
Midazolam 1 mg/ml Accord 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:
<ul style="list-style-type: none">• 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)• fits (convulsions).
4. Possible side effects
Midazolam 1 mg/ml Accord can have side effects.
Not all side effects reported for Midazolam 1 mg/ml Accord are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Midazolam 1 mg/ml Accord , please consult your health care provider for advice.
<i>If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:</i>
<ul style="list-style-type: none">• 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.• Heart attack (cardiac arrest). Signs may include chest pain which may spread to your neck and

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shoulders and down your left arm. <ul style="list-style-type: none">• 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.
These are all very serious side effects. If you have them, you may have had a serious reaction to Midazolam 1 mg/ml Accord . You may need urgent medical attention or hospitalisation.
<i>Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:</i>
<ul style="list-style-type: none">• muscle spasms and muscle tremors (shaking of your muscles that you cannot control)
<ul style="list-style-type: none">• confusion, disorientation
<ul style="list-style-type: none">• involuntary movements
<i>Tell your doctor if you notice any of the following:</i>
<i>Frequent side effects:</i>
<ul style="list-style-type: none">• Drowsiness
<i>Less frequent side effects:</i>
<ul style="list-style-type: none">• emotional and mood disturbances• difficulty co-ordinating muscles• lack of energy (lethargy)
<i>Side effects with the frequency unknown:</i>
<ul style="list-style-type: none">• restlessness, agitation, irritability, nervousness, anxiety• hostility, anger, aggression• assault• excitement

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- hyperactivity
- euphoria (an excessive feeling of happiness or excitement)
- hallucinations (seeing and possibly hearing things that are not really there)
- prolonged sedation
- reduced alertness
- headache
- dizziness
- dependence, abuse
- low blood pressure
- slow heart rate
- redness of the face and neck (flushing), fainting or headache
- hiccups
- feeling sick or being sick (nausea or vomiting)
- constipation
- dry mouth
- rash
- hives (lumpy rash)
- itchiness and redness, swelling of the skin
- blood clots or pain at the injection site
- tiredness (fatigue)
- patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).
- temporary memory loss. How long this last depends on how much **Midazolam 1 mg/ml Accord** you were given.

Unexpected reactions:

Unexpected (paradoxical) reactions such as restlessness, agitation, irritability, involuntary movements (including muscle tremor), hyperactivity, nervousness, hostility, delusion, anger, aggressiveness, anxiety,

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nightmares, hallucinations (seeing and possibly hearing things that are not really there), psychoses (losing contact with reality) and inappropriate behaviour, excitement and assault have occurred with Midazolam 1 mg/ml Accord . These reactions may occur with high doses and/or when the injection is given rapidly. These reactions occur most commonly in children and the elderly.
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 or pharmacist. This includes any possible side effects not listed in this leaflet. 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 Midazolam 1 mg/ml Accord .
5. How to store Midazolam 1 mg/ml Accord <ul style="list-style-type: none">• Store at or below 25 °C.• Protect from light. Do not refrigerate.• Keep the syringe in the outer carton until required for use.• STORE ALL MEDICINES OUT OF REACH OF CHILDREN.• Do not use after the expiry date printed on the carton or container.• Return all unused medicine to your pharmacist.• Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
6. Contents of the pack and other information
What Midazolam 1 mg/ml Accord contains The active substance in Midazolam 1 mg/ml Accord is midazolam (as midazolam hydrochloride). Each ml of solution for injection or infusion contains 1 mg of midazolam (as midazolam hydrochloride).

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<p>The other ingredients are:</p> <p>Sodium chloride</p> <p>Concentrated hydrochloric acid (for pH-adjustment)</p> <p>Sodium hydroxide (for pH-adjustment)</p> <p>Water for Injections</p>
<p>What Midazolam 1 mg/ml Accord looks like and contents of the pack</p> <p>5 ml clear glass pre-filled syringe with plunger stopper and plunger rod.</p> <p>Pack sizes: 1 or 10 pre-filled syringes.</p> <p>Not all pack sizes may be marketed.</p>
<p>Holder of certificate of registration</p> <p>Accord Healthcare (Pty) Ltd</p> <p>Building 2, Tuscany Office Park,</p> <p>6 Coombe Place</p> <p>Rivonia</p> <p>Gauteng</p> <p>South Africa</p>
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