Read this leaflet carefully before taking the medicine.
- Keep this leaflet. You may need to read it again.
- If you have any question, consult yur doctor or pharmacist.
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.

This leaflet contains:

1. WHAT IS MIDAZOLAM NORMON INJECTABLE SOLUTION AND WHEN IT IS USED FOR.
2. BEFORE TAKING MIDAZOLAM NORMON INJECTABLE SOLUTION.
3. HOW TO TAKE MIDAZOLAM NORMON INJECTABLE SOLUTION.
4. POSSIBLE SIDE EFFECTS.
5. STORAGE OF MIDAZOLAM NORMON INJECTABLE SOLUTION.
6. INSTRUCTIONS FOR HEALTH PROFESSIONALS.

MIDAZOLAM NORMON 15 mg/3 ml INJECTABLE *SOLUTION*
MIDAZOLAM NORMON 5 mg/5 ml INJECTABLE SOLUTION

The active ingredient is midazolam. Each ampoule of MIDAZOLAM NORMON 15 mg/3 ml INJECTABLE SOLUTION contains 15 mg midazolam (I.N.N.) and each ampoule of MIDAZOLAM NORMON 5 mg/5 ml INJECTABLE SOLUTION contains 5 mg midazolam (I.N.N.). Excipients q.s.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER
LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 - 28760 Tres Cantos - Madrid (SPAIN)

1. WHAT IS MIDAZOLAM NORMON INJECTABLE SOLUTION AND WHAT IS IT USED FOR

MIDAZOLAM NORMON is an injectable solution for intramuscular, intravenous or rectal administration, contained in 5 ml ampoules (MIDAZOLAM NORMON 15 mg/3 ml INJECTABLE SOLUTION) and 10 ampoules (MIDAZOLAM NORMON 5 mg/5 ml INJECTABLE SOLUTION).

Midazolam belongs to the group of drugs called sedative agents and benzodiazepinic hypnotic agents.

MIDAZOLAM NORMON injectable solution is a sleep inductor short-acting drug indicated for:
- conscious sedation,
- premedication before an intervention
- anaesthesia induction and maintenance
- prolonged sedation in intensive care units (ICU)
- ataralgesia (treatment combining sedation and analgesia in children).

2. BEFORE TAKING MIDAZOLAM NORMON INJECTABLE SOLUTION

• Do not take MIDAZOLAM NORMON INJECTABLE SOLUTION:
- If you are allergic to midazolam or other drugs of the same group (benzodiazepines)
- If you have angle-closure glaucoma (increase of the intraocular pressure), since it may aggravate the disease (it may be used in patients with open-angle glaucoma only if they receive suitable therapy).
- If you have severe respiratory insufficiency.
- If you have sleep apnoea syndrome (temporary loss of respiration).
- If you have severe hepatic insufficiency.
- Do not administer to patients in shock or coma if they have consumed an excessive amount of alcohol.
- It should not be taken if suffering myasthenia gravis (a form of muscular weakness) or an important liver disease.

• Take special care with MIDAZOLAM NORMON INJECTABLE SOLUTION:
- The elderly and the weak must initially receive a lower dose. A reduction of the dose is also recommended in patients with renal and/or hepatic insufficiency.
- Special care should be taken when administering midazolan to patients with altered cardiac or respiratory functions.
- Patients treated by parenteral route with midazolam must not leave the hospital or surgery until three hours after the injection and always accompanied by a responsible person.

Consult your doctor, even if any of the aforementioned circumstances had occurred on a previous occasion.

• Taking MIDAZOLAM NORMON INJECTABLE SOLUTION with food and drink: Avoid the simultaneous administration of midazolam and alcohol.

• Pregnancy: Consult your doctor or pharmacist before taking a medicine. If you are pregnant or planning your pregnancy, you must contact your doctor. This medicine must not be used during pregnancy unless the doctor considers it absolutely necessary.

• Lactancy: Consult your doctor or pharmacist before taking a medicine. As benzodiazepines are eliminated through maternal milk, their use is contraindicated in mothers in the lactancy period.

• Driving and use of machines: Do not drive vehicles, nor handle dangerous machinery after administrating midazolam, since they may prevent you from safely driving and handling machinery.

• Use of other medicines: Inform your doctor or pharmacist if you are taking or recently have taken any other drug, even those purchased without medical prescription. Some drugs may affect the action of others.

Medicines that may modify midazolam activity are indicated below:
- Drugs affecting the central nervous system (anti-psychotics, anxiolytics, antidepressants, hypnotics, analgesics, antiepileptic, anaesthetic, antihistamines with sedative effect and alcohol) may increase the sedative action. In the case of narcotic analgesics, an increase of a sense of euphoria may also occur, which may increase psychic dependence.
- If administered with midazolam, cimetidine, erythromycin, diltiazem, verapamil, ketoconazole, itraconazole, etc. prolong the sedation effect.

3. HOW TO TAKE MIDAZOLAM NORMON INJECTABLE SOLUTION

Follow these instructions unless otherwise indicated by your doctor.
This medicine will only be administered in the hospital by medical health personnel by means of an intramuscular or intravenous injection or by rectal administration.
Your doctor will indicate the dose amount and the most suitable administration method to achieve the sedation level you need, since the start of sedation varies in each person, according to his/her physical state and the specific treatment circumstances.
To achieve a conscious sedation level, the administered dose may vary from 3.5 to 7.5 mg, although if necessary, the dose may be repeated. In this case, the administration must be intravenous. To achieve a sedation level before an intervention, your doctor will exactly adjust the dose according to the duration of sedation, your physical state and your body weight. In both cases, your doctor must reduce and adjust the dose individually, especially if you are over the age of 60, weak or suffer a chronic illness.
In children, preoperatory rectal sedation may be used. In these patients, the doctor will adjust the dose individually according to his/her physical state and body weight.
When the administration of MIDAZOLAM NORMON INJECTABLE SOLUTION is required for the induction and maintenance of anaesthesia, your doctor must adjust the dose taking into account age, weight and previous medicine until reaching the desired effect, according to the patient's age and clinical state.
If you are a patient in the Intensive Care Unit, you doctor must individually adjust the posology of MIDAZOLAM NORMON INJECTABLE SOLUTION until reaching the desired sedation state depending on the clinical necessities, physical state, age and concomitant treatment.
Your doctor will recommend the duration of your treatment. Do not suspend the treatment before since the desired effect for which you are being treated may not be reached.
• **If you receive more MIDAZOLAM NORMON INJECTABLE SOLUTION than you should** immediately consult your doctor or pharmacist. Different reactions such as drowsiness, confusion or in more severe cases, muscular weakness, drop of blood pressure, respiratory depression and more rarely, coma, may occur. In the event of these circumstances occurring, a suitable treatment will be applied.
• **Effects occurring when the treatment with MIDAZOLAM NORMON INJECTABLE SOLUTION is interrupted:** The abrupt interruption of treatment with midazolam is accompanied by abstinence symptoms, such as headache, muscular pains, anxiety, stress, nervousness, confusion, irritability, secondary insomnia, mood changes, hallucinations and convulsions. In these cases, it is recommended to gradually reduce the dose and use the shortest treatment possible. The interruption process will be adjusted individually.

4. POSSIBLE SIDE EFFECTS

Like all drugs, MIDAZOLAM NORMON INJECTABLE SOLUTION may have side effects.
The most common side effects you may experience are:
Nervous system disorders, such as drowsiness, prolonged sedation, fatigue, reduction of the alertness state and headache. In some cases, confusion, hallucinations, memory loss and dizziness may also occur. Sometimes, reactions such as nervousness, agitation, irritability and other behaviour alterations may occur.
You may also have digestion problems (vomiting, nauseas, hiccups, constipation), skin disorders and changes in sexual behaviour.
Inform your doctor as soon as possible if you experience any of the effects described above.
If you observe any other reaction not described in this leaflet, consult your doctor of pharmacist.

5. STORAGE OF MIDAZOLAM NORMON INJECTABLE SOLUTION

Keep MIDAZOLAM NORMON INJECTABLE SOLUTION out of reach and sight of children.
MIDAZOLAM NORMON Injectable solution should not be frozen as they may burst. Moreover, a precipitate may be formed which dissolves on stirring the contents at room temperature.

6. INSTRUCTIONS FOR HEALTH PROFESSIONALS

Midazolam solution in ampoules may be diluted in 0.9% sodium chloride, 5% and 10% glucose, 5% levulose, Ringer and Hartmann solution in a mixture of 15 mg midazolam per 100-1000 ml infusion solution. These solutions are kept physically and chemically stable during 24 hours at room temperature (or three days in the refrigerator at 2-8°C). Absorption of midazolam in solutions containing 15 mg in 250 ml of 0.9% sodium chloride conserved during 24 hours at room temperature in PVC infusion bags and infused over 6 hours through a PVC infusion device half not been detected.
More concentrated solutions of midazolan for infusion may provoke a precipitation of midazolan, especially if the sample pH exceeds 4.5-5.
In the specific case of rectal administration, frequently used for the preoperatory sedation in children, the ampoule solution is administered with a plastic applicator fixed to the end of a syringe.