

IPNODIS MEDIS® 2mg/2ml, solution for injection
IPNODIS MEDIS® 5mg/ml, solution for injection
IPNODIS MEDIS® 25mg/5ml, solution for injection
IPNODIS® 50 mg/10ml, solution for injection
Midazolam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
 - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- Slowing or cessation of breathing or heartbeats and loss of consciousness (coma).
 - If you receive IPNODIS MEDIS in intensive care for sedation, for a long time.
 - If you receive IPNODIS MEDIS as a sedative, you may become drowsy or have less effective.
 - You may become addicted to this medication, and may experience withdrawal symptoms upon discontinuation of treatment (see section 4).
 - If you stop using IPNODIS MEDIS solution for injection (IM-IV or rectal).
 - If you forget to take IPNODIS MEDIS, solution for injection

What is in this leaflet?

1. What is IPNODIS MEDIS, solution for injection, and in which case is it used?
2. What you need to know before you take IPNODIS MEDIS, solution for injection?
3. How to take IPNODIS MEDIS, solution for injection?
4. Possible side effects?
5. How to store IPNODIS MEDIS, solution for injection?
6. Content of the packaging and other information.

If you stop taking IPNODIS MEDIS, solution for injection
 If you receive IPNODIS MEDIS for a long time, such as in the intensive care unit, you may experience withdrawal symptoms when the medication is stopped. These symptoms are as follows:
 - Mood changes.
 - Convulsions.
 - Headaches.
 - Muscle aches.
 - Sleep disorders (insomnia).
 - Onset of great worry (anxiety), tension, agitation, confusion or bad temper (irritability).
 - Impression of seeing and perhaps hearing things that do not really exist (hallucinations). Your doctor will gradually reduce the dose to avoid withdrawal symptoms.

1. **What is IPNODIS MEDIS, solution for injection AND in which case is it used?**
 Pharmacotherapeutic Class: HYPNOTICS AND SEDATIVES; derivatives of benzodiazepines, code ATC: N05CD08.
 IPNODIS MEDIS contains a medicine called midazolam. It belongs to a class of medicines called "benzodiazepines".
 IPNODIS MEDIS acts rapidly in order to make you feel sleepy or fall asleep. It also makes you calm and relaxes your muscles.
 IPNODIS MEDIS is a fast-acting hypnotic and sedative whose indications are:
 1/ In Adults:
 - Conscious sedation, before and during diagnostic or therapeutic procedures, with or without local anesthesia.
 - Premedication before induction of anesthesia.
 - Sedative agent in combination with other anesthetic/analgesic agents.
 - Sedation in intensive care units.
 2/ In children:
 - Conscious sedation, before and during diagnostic or therapeutic procedures, with or without local anesthesia.

4. POSSIBLE SIDE EFFECTS ?
 Like all medicines, this medicine can cause side effects, although not everybody gets them.
Description of side effects
 The following adverse effects can occur during the administration of midazolam (with an unknown frequency; can not be estimated from the available data):
Stop taking IPNODIS MEDIS and consult a doctor immediately if you experience any of the following side effects. These effects may be life-threatening and you may require urgent medical treatment:
 - Severe allergic reaction (anaphylactic shock) Signs may be rash of sudden onset, itching or urticaria (pimples) and swelling of the face, lips, tongue or other parts of the body.
 - You may also have shortness of breath, wheezing, or breathing difficulty.
 - Heart attack (cardiac arrest). Signs may include chest pain.
 - Respiratory disorders, sometimes responsible for a cessation of breathing.
 - Muscle spasms (contraction) around the throat, responsible for choking.
 - Life-threatening side effects may be more common in adults over 60 years of age and in people with pre-existing respiratory or cardiac disorders, especially when the injection is done too quickly or when a high dose is administered.

2. **What you need to know before you take IPNODIS MEDIS, solution for injection?**
 Do not take IPNODIS MEDIS, solution for injection:
 - if you are allergic to midazolam, or any other component contained in this medicine mentioned in section 6.
 - if you are allergic to other benzodiazepines, for example diazepam or nitrazepam.
 - if you experience breathing difficulties because of a lung disease (severe respiratory failure) and you are going to receive IPNODIS MEDIS for "conscious sedation".
 You should not receive IPNODIS MEDIS if you have any of the above situations. If you are unsure, seek the advice of your doctor or nurse before receiving this medicine.

Other mental disorders and nervous system
 - Decreased alertness.
 - Confusion.
 - Excessive feeling of well-being or excitement (euphoria).
 - Feeling tired, somnolence or sedation for a long time.
 - Physical expense or perhaps hearing things that do not really exist (hallucinations).
 - Impaired dependence on the medicine.
 - Headaches.
 - Dizziness.
 - Difficulty in movements' coordination.
 - Seizures in preterm infants and newborns.
 - Temporary loss of memory. The duration of this effect depends on the dose of IPNODIS MEDIS administered to you. Occasionally, this effect has been prolonged.
 - Sensation of agitation, anger or aggressiveness. You may also have muscle spasms or uncontrolled muscle twitches (tremors). These reactions have been more often observed when a high dose of IPNODIS MEDIS is administered or when administration is too rapid. Children and the elderly are more exposed to these reactions.

- Warning and precautions**
 - Do not use or misuse this medicine if you take IPNODIS MEDIS if:
 - You are over 60 years old.
 - You have a chronic (long-term) illness, such as breathing problem or kidney, liver or heart disorders.
 - You have an illness that makes you feel very weak, depressed and without energy.
 - You suffer from "myasthenia" (a disease characterized by muscle weakness).
 - You have already had problems with alcohol.
 - You have already had any drug problem.
 - If you have any of the above situations (or if you are not sure), seek the advice of your doctor or nurse before receiving IPNODIS MEDIS.
 If your child must receive this medicine:
 - Tell your doctor or nurse if your child has any of the above situations.
 - In particular, tell your doctor or nurse if your child has had or is having breathing disorders.

Head circulation
 - Fainting.
 - Slow heart rate.
 - Redness of the face and neck (hot flashes).
 - Low blood pressure. You may have dizziness or vertigo.
Breathing
 - Hiccups.
 - Shortness of breath.
Mouth, stomach and intestine
 - Dry mouth.
 - Constipation.
 - Nausea or vomiting.
Skin
 - Itching.
 - Rash, including urticaria (pimples).
 - Redness, pain, blood clots or swelling of the skin at the injection site.
General disorders
 - Allergic reactions including rash and wheezing.
 - Withdrawal symptoms (see paragraph 4). If you stop using IPNODIS MEDIS, solution for injection (in section 2 above).
 - Falls and fractures. The risk increases if you take other medications known to make you sleepy (for example, sedatives or sleeping pills), or alcohol.
Special populations
 - The use of IPNODIS MEDIS may increase the risk of falls and fractures in the elderly.
 - Life-threatening side effects may be more common in adults over 60 years of age.

Other medicines and IPNODIS MEDIS, solution for injection
 Tell your doctor, pharmacist or nurse if you take, have recently taken or may take any other medicine.
 In fact, IPNODIS MEDIS may change the effects of other medicines and some other medicines may change the effects of IPNODIS MEDIS.

Reporting of side effects
 You may also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of the medicine.

In particular, tell your doctor or nurse if you take one of the following medicines
 - Medicines for treating depression.
 - Medicines to make you calm or sleepy.
 - Tranquilizers (to treat anxiety or to help falling asleep).
 - Carbamazepine or phenytoin (which can be used for convulsions).
 - Rifampicin (against tuberculosis).
 - Medicines for treating HIV called "protease inhibitors" (e.g. saquinavir).
 - Antibiotics called "macrolides" (against bacterial infections) (erythromycin or clarithromycin).
 - Medicines to treat fungal infections (e.g. ketoconazole, voriconazole, fluconazole, Itraconazole, posaconazole).
 - powerful analgesics (to relieve pain).
 - Aurostatin (to treat hypercholesterolemia).
 - Antiulceratives (to treat allergic reactions).
 - St. John's Wort extract (herbal medicine against depression).
 - Medicines to treat high blood pressure called calcium channel blockers (e.g. diltiazem).

How to take IPNODIS MEDIS, solution for injection
 The concomitant use of IPNODIS MEDIS with opioids (strong pain killers, medicines used for substitution treatment and certain analgesics) increases the risk of somnolence, breathing difficulty (respiratory depression), coma and can be life-threatening. For this reason, concomitant use should only be considered when other therapeutic options are not possible.
 However, if your doctor prescribes IPNODIS MEDIS at the same time as opioids, the posology and duration of concomitant treatment should be limited by your doctor.
 Tell your doctor about all the opioid medications you are taking and carefully follow your doctor's posology recommendations. It may be helpful to tell your friends or relatives to be attentive to the signs and symptoms mentioned above.
 Contact your doctor if you notice such symptoms.
 If you have one of the above situations (or if you are not sure), ask your doctor or nurse before receiving IPNODIS MEDIS.
IPNODIS MEDIS, solution for injection with food, drink and alcohol
 Consumption of alcohol
 - If you do not or have not received IPNODIS MEDIS it may make you very sleepy and cause breathing problems.
Pregnancy, breastfeeding and fertility
 This medicine is not recommended during pregnancy. If you find out that you are pregnant or you wish to get pregnant, consult your doctor. He may be able to help you with the use of this medicine.
 If you take IPNODIS MEDIS during the 1st trimester of pregnancy, numerous data have not shown a malformative effect of benzodiazepines. However, some studies have described a potentially increased risk of cleft lip and palate in newborns with the risk in the risk in the fetus (cleft lip and palate). Sometimes called "harelip" is a congenital malformation due to incomplete fusion of the palate and the upper lip. According to these data, the incidence of cleft lip and palate in newborns would be about 2/1000 after exposure to benzodiazepines during pregnancy while the expected rate in the general population is 1/1000.
 If you take IPNODIS MEDIS in the 2nd and/or 3rd trimester of pregnancy, a decrease of fetal active movements and a variability in the fetal heart rate may occur.
 If you take IPNODIS MEDIS at the end of pregnancy (during the medical team, monitoring of the newborn could be carried out: muscle weakness (axial hypotonia), feeding difficulties, sucking difficulties (newborns leading to low weight gain), hyper excitability, agitation or tremors may occur in the newborn, these disorders are reversible.
 In high doses, respiratory failure or apnea, a decrease in the body's core temperature (hypothermia); could also occur in the newborn.
 If your baby has one or more of these symptoms at birth or a while after birth, contact your doctor AND/or midwife.
 If you are breastfeeding, if you are planning a pregnancy, ask your doctor for advice before using this medicine. Your doctor will decide if this medicine is right for you.
 After receiving IPNODIS MEDIS, you should not be breastfed for 24 hours because IPNODIS MEDIS can pass into your breast milk.
Driving and using machines
 After administering IPNODIS MEDIS, you must not drive or use any tools or machines. To resume driving, seek the advice of your doctor. IPNODIS MEDIS may make you sleepy, dizzy or affect your concentration and coordination. These effects can affect your performance when driving vehicles and using tools or machines.
 After your treatment, you should always be accompanied to your home by an adult who can take care of you.
 This medicine contains sodium. The sodium level is equivalent to 9 mg per ml; this should be taken into consideration in patients on a sodium-restricted diet.

3. HOW TO TAKE IPNODIS MEDIS, solution for injection ?
 IPNODIS MEDIS should only be administered by an experienced physician in a place fully equipped for the monitoring and maintenance of respiratory and cardiovascular functions and by a person specifically trained in the recognition and management of expected adverse events.
Posology / Method of Administration / Frequency of Administration / Duration of Treatment
 IPNODIS MEDIS will be administered to you by a doctor or a nurse in a place equipped to monitor your condition and treat any possible side effects. Your breathing, your heart and your circulation will be monitored closely.
 Use IPNODIS MEDIS is not recommended in infants and children less than 6 months.
 However, if the doctor considers it necessary, IPNODIS MEDIS can be administered to an infant or a child of less than 6 months who is hospitalized in the intensive care unit.

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How will IPNODIS MEDIS be used?
 IPNODIS MEDIS will be administered in one of the following ways:
 - By injection into a vein (intravenous injection).
 - By drip into one of your veins (intravenous infusion).
 - By injection into a muscle (intramuscular injection).
 - By rectal route.

How much IPNODIS MEDIS will you be given ?
 The dose of IPNODIS MEDIS varies from patient to patient. The doctor will decide the dose to give you. This will depend on your weight and overall condition. It will also depend on:
 - The reason you are receiving this medicine.
 - Your response to treatment.
 - The other medicines you are receiving at the same time.

After receiving IPNODIS MEDIS
 After receiving IPNODIS MEDIS, you should always be accompanied to your home by an adult who can take care of you. Indeed, IPNODIS MEDIS can make you sleepy, dizzy or impair your concentration and coordination.
 If you receive IPNODIS MEDIS for a long time, for example in the intensive care unit, you may get used to the medicine and its effectiveness may decrease over time.

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 - The reason you are receiving this medicine.
 - Your response to treatment.
 - The other medicines you are receiving at the same time.

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THIS IS A MEDICINE.

- A medicine is a product but not like the others.
 - A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
 - Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
 - Your doctor and pharmacist are familiar with the medicine, its indications and contraindications.
 - Do not stop treatment on your own initiative during the prescribed period.
 - Do not take it again, do not increase the doses without consulting your doctor.

IPNODIS, 5mg/ml | **IPNODIS MEDIS, 5mg/ml** | **IPNODIS MEDIS, 2mg/2ml** | **IPNODIS MEDIS, 25mg/5ml**
 Excipients: Hydrochloric acid or sodium hydroxide, sodium chloride, water for injection
What is IPNODIS MEDIS, solution for injection and content of the outer packaging
 IPNODIS MEDIS, 2mg/2ml, is presented in the form of a