

Ipnodis[®] 5mg/1ml – Ipnodis[®] 2mg/2ml Ipnodis[®] 25mg/5ml – Ipnodis[®] 50mg/10ml

INN : Midazolam

Please read carefully the integrality of this notice before taking this drug.

- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

- In this notice:**
1. What is Ipnodis[®] and in which case is it used?
 2. What is necessary to be known before taking Ipnodis[®] ?
 3. How to use Ipnodis[®] ?
 4. What are the eventual undesirable effects?
 5. How to store Ipnodis[®] ?
 6. Further information

1. What is Ipnodis[®] and in which case is it used?
Ipnodis[®] contains a drug called midazolam. It belongs to a drugs class called « benzodiazepines ».

Therapeutic Indications:

- Anesthesia;
- Pre-medication before anesthesia in adults and children over 6 months.
- Induction of anesthesia in combination with other anesthetic and/or morphine agents in adults and children, including premature newborns
- Anesthesia maintaining in combination with other anesthetic and/or morphine agents in adults.
- Vigil Sedation in children over 6 months;
- For diagnosis or therapeutic procedures;
- During tracheal or loco-regional anesthesia.
- Sedation in intensive care units in premature newborn, neonates, infants and children up to 25kg, under assisted ventilation.

2. What is necessary to be known before taking Ipnodis[®] ?
Never use Ipnodis[®] in the following cases:

- If you are allergic (hypersensitive) to midazolam or to one of the components of this drug (see section 6: further information)
- If you are allergic to other benzodiazepines, for example, diazepam or nitrazepam.
- If you have severe respiratory difficulties due to lungs disease (severe respiratory insufficiency) and you are going to receive Ipnodis[®] in aim to obtain vigil sedation.
- You should not receive Ipnodis[®] if you are in one of the above situations

In case of doubt, do not hesitate to ask your doctor's or your nurse's advice before receiving this drug.

Be careful with Ipnodis[®]

Inform your doctor or your nurse before receiving Ipnodis[®] if:

- You are 60 years old or more;
- You have a chronic disease (long lasting), for example respiratory, kidney, hepatic or heart disorders;
- You have a disease provoking the feeling of being very weak, running down and without energy ;
- You suffer from "myasthenia" (a disease characterized by a muscular weakness) ;
- You have problems with alcohol.
- You have already experienced problems with drug.

Inform your doctor or your nurse before, if your child is in one of the above situations

In case of doubt, do not hesitate to ask your doctor's or your nurse's advice before receiving this drug.

If your child has to receive this drug:

- Especially, when your child presents cardiac or respiratory disorders, please inform your doctor or your nurse

Taking other drugs

If you take or you have recently taken other drugs, even those obtained without medical prescription, inform your doctor or your nurse.

It is important to know that Ipnodis[®] can modify the effects of some other drugs and that the effects of Ipnodis[®] can be modified by some other drugs.

Especially, inform your doctor or your nurse if you are taking one of the following drugs:

- Drugs against depression ;
- Hypnotic agents (to sleep) ;
- Sedatives (to make more calm or somnolent) ;
- Tranquillizing products (against anxiety or to sleep) ;
- Carbamazepin or phenytoin (which can be used for the convulsions) ;
- Rifampicin (against tuberculosis) ;
- Drugs against HIV called protease inhibitors (for example saquinavir) ;
- Antibiotics called Macrolides to treat infection by bacteria (for example erythromycin or clarithromycin) ;
- Drugs used to treat infections due to champignons (for example ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole) ;
- Potent analgesics (against pain) ;
- Atrovastatin (against hypercholesterolemia) ;
- Anti-histaminic agents (against allergic reactions) ;
- St. John's wort extract (herbal medicine against depression) ;
- Drugs against Hypertension called calcium channels blockers (for example diltiazem).

Inform your doctor or your nurse before, if you are in one of the above situations or in case of doubt, do not hesitate to ask your doctor's or your nurse's advice before receiving this drug.

Food and drinks

Alcohol consumption: do not drink alcohol while receiving Ipnodis[®], because this can make you very somnolent and can provoke respiratory disorders.

Interactions with herbal medicine or alternative therapy products

Not applicable.

Pregnancy and breastfeeding

Pregnancy

If you are or you think being pregnant you should inform your doctor before taking Ipnodis[®].

Your doctor will decide if this drug is adapted for you.

Ask your doctor's or your pharmacist's advice before taking any drug.

Breastfeeding

After receiving Ipnodis[®], you should not breastfeed during 24 hours because Midazolam can pass in the mother's milk.

Ask your doctor's or your pharmacist's advice before taking any drug.

Sportmen and sportswomen

Not applicable.

Driving and machines use

After the administration of Ipnodis[®], you should not drive or use tools or machines. To drive again, please ask your doctor's advice.

Ipnodis[®] can make you somnolent, dizzy or can alter your concentration and coordination. These effects can affect your performances while driving or using tools or machines.

After finishing your treatment, you should always be accompanied home by an adult who can take care of you.

Important information concerning certain components of Ipnodis[®]

This drug contains sodium. The sodium content is equivalent to 9 mg per ml; this should be taken into the account in patients under sodium controlling diet.

3. How to use Ipnodis[®] ?

Ipnodis[®] will be administered by a doctor or by a nurse in a place adapted to monitor your condition and to treat the eventual undesirable effects. Your respiration, your heart and your circulation will be particularly monitored.

The use of Ipnodis[®] is not recommended in infants and children under 6 months.

However, when the doctor deems it necessary, Ipnodis[®] can be administered to infants less than 6 months who are hospitalized in an intensive care unit.

How will Ipnodis[®] be administered?

Ipnodis[®] will be administered as follows:

- By slow injection in a vein (intravenous injection) ;
- By drop-by-drop in one of your veins (intravenous infusion) ;
- By injection in a muscle (intra-muscular injection) ;
- By rectal route.

Which quantity of Ipnodis[®] will be administered?

The dose of Ipnodis[®] varies from one patient to another. The doctor will determine the dose to be administered to you. This will depend on your age, weight and general condition. It will also depend on:

- The receptor which you will receive this drug;
- Your response to the treatment;
- The other treatments you are receiving in the same time.

After receiving Ipnodis[®]

After receiving Ipnodis[®], you should always be accompanied home by an adult who will take care of you. In fact, Ipnodis[®] can make you somnolent, dizzy or will alter your concentration and your coordination.

If you receive Ipnodis[®] during a long time, for example in an intensive care unit, you can be used to this drug and its efficacy can be reduced over time.

If you have used Ipnodis[®] than you should

This drug will be administered by a doctor or a nurse. It is, thus, less probable that you receive more Ipnodis[®] than you should. However, if by mistake, you received more Ipnodis[®] than you should, you can experience the following

disorders:

- Somnolence and loss of coordination and reflexes.
- Speech disorders and abnormal movements of the eyes.
- Low arterial pressure. This can provoke dizziness.
- Slowdown or arrest of respiration or of heart beats (bradycardia) with unconsciousness (coma).
- If you receive Ipnodis[®] in an intensive care unit, for a long duration:
 - Ipnodis[®] can become less efficient.
 - You can develop a dependence to this drug, and experience the withdrawal symptoms at its discontinuation (see paragraph : when you stop using Ipnodis[®])
- If you forgot to use Ipnodis[®] ?

Not applicable.

When you stop using Ipnodis[®]

If you receive Ipnodis[®] for a long duration, in an intensive care unit, for example, you can present the withdrawal symptoms at its discontinuation. These symptoms are as follows:

- Mood changes.
- Convulsions.
- Headaches.
- Muscle pains.
- Sleep disorders (insomnia).
- Feeling of great concern (anxiety), tension, agitation, confusion or bad mood (irritability).
- Impression of seeing or hearing things which you do not actually see (hallucinations).

Your doctor will reduce progressively the dose in aim to avoid the withdrawal symptoms occurrence.

4. What are the eventual undesirable effects?

Like all drugs, Ipnodis[®] is susceptible to induce undesirable effects, but this does not concern everybody.

The following undesirable effects can occur during the midazolam administration (with an undetermined frequency; the frequency can't be estimated with the available data).

Stop using Ipnodis[®] and consult your doctor immediately if you present the following undesirable effects. These effects can threaten the vital prognosis and you may need an urgent medical treatment:

- Severe allergic reaction (anaphylactic shock). The signs can be a brutal cutaneous eruption, itching, or urticaria (pimples) and a swelling of the face, lips, tongue or other parts of the body. You can also present breathlessness, wheezing or difficulties to breathe.
- Heart attack (heart failure). The signs include thoracic pain.
- Respiratory disorders, sometimes responsible of a respiratory arrest.
- Muscular spasms (contraction) in the throat responsible of suffocation.

These undesirable effects which threaten life can be more common in adults of more than 60 years and in persons with preexisting respiratory or cardiac disorders, particularly when the injection is performed too rapidly or if the injected dose is too high.

Other eventual undesirable effects:

mental and nervous system disorders:

- vigilance diminution; Confusion : exaggerated sensation of feeling good or of excitation (euphoria) ; Sensation of fatigue or somnolence or loss of coordination for a long duration ; Impression of seeing or may be hearing things that don't actually exist (hallucinations) ; headaches ; dizziness ; Difficulties in the movements coordination ; convulsive seizures in premature and newborn ; transient loss of memory. The duration of this effect depends on the administered dose of Ipnodis[®].
- Occasionally, this effect was prolonged; Sensation of agitation, anger or aggressiveness. You can also present muscles spasms or no controlled muscles twitching (tremor). These reactions were more often observed when a high dose of Ipnodis[®] was administered or when the administration was performed too rapidly. Children and elderly are more exposed to these reactions.

Heart and circulation :

- Fainting; slow cardiac frequency; face and neck redness (hot flashes); low arterial pressure. You can also present dizziness.
- Respiration ;
- Hiccup; Shortness of breath
- Mouth, stomach and intestine :
- Dry mouth; Constipation; Nausea or vomiting.
- Skin :
- Itching; Eruption, including urticaria (pimples); Redness, pain, blood clots or swelling of the skin at the injection site.

General disorders

Allergic reactions including cutaneous eruption and wheezing respiration; withdrawal Symptoms (see section 3: how to use Ipnodis[®], paragraph: if you stop using Ipnodis[®]).

Elderly

The use of Midazolam can increase the risk of falls and fractures; the undesirable effects which can threaten life can be more common in adults of more than 60 years.

If you experience undesirable effects which are not mentioned in this notice, or if some undesirable effects become severe, please inform your doctor or your nurse.

5. How to store Ipnodis[®] ?

Store the ampoules in the original external packaging, away from light.

6. Further information

What does Ipnodis[®] contain ?

	Ipnodis [®] 5mg/1 ml	Ipnodis [®] 2 mg/2 ml	Ipnodis [®] 25 mg/5 ml	Ipnodis [®] 50 mg/10 ml
Active substance				
Midazolam	5.0 mg	2.0 mg	25 mg	50 mg
Excipients:				
Sodium Chloride	9.0 mg	18.0 mg	45 mg	90 mg
Water for injectable preparation	s.q.f. 1 ml	s.q.f. 2 ml	s.q.f. 5 ml	s.q.f. 10 ml

What is Ipnodis[®] and external packaging content?

- Ipnodis[®] 5 mg / 1 ml - Midazolam: injectable solution in ampoules of 1 ml conditioned in boxes of 10 ampoules.
- Ipnodis[®] 2 mg / 2 ml - Midazolam: injectable solution in ampoules of 2 ml conditioned in boxes of 10 ampoules.
- Ipnodis[®] 25 mg / 5 ml - Midazolam: injectable solution in ampoules of 5 ml conditioned in boxes of 05 ampoules.
- Ipnodis[®] 50 mg / 10 ml - Midazolam: injectable solution in ampoules of 10 ml conditioned in boxes of 06 ampoules.

Delivry conditions:

Ipnodis[®] 5 mg / 1 ml - Midazolam: injectable solution in ampoules of 1 ml conditioned in boxes of 05 ampoules.

Ipnodis[®] 2 mg / 2 ml - Midazolam: injectable solution in ampoules of 2 ml conditioned in boxes of 06 ampoules.

Ipnodis[®] 25 mg / 5 ml - Midazolam: injectable solution in ampoules of 5 ml conditioned in boxes of 05 ampoules.

Ipnodis[®] 50 mg / 10 ml - Midazolam: injectable solution in ampoules of 10 ml conditioned in boxes of 06 ampoules.

Liste 1, drug reserved to hospital use.

Presentations and M.A. numbers :

Specialities	M.A numbers	Presentations
Ipnodis [®] 5 mg/1ml	923 328 1H	Box of 10 ampoules de 1 ml
Ipnodis [®] 2 mg/2ml	923 328 2H	Box of 10 ampoules de 2 ml
Ipnodis [®] 25 mg/5ml	923 328 3H	Box of 5 ampoules de 5 ml
Ipnodis [®] 50 mg/10 ml	923 328 4H	Box of 6 ampoules de 10 ml

Number of registration Decision : 05/1608/13/31
Marketing authorization holder and manufacturer :
 Les Laboratoires Médis
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This leaflet was last approved in April 2018.

This is a Medicament

- Medicament is a product but not like the others.
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children