



Consumer Medicine Information

HYPNOVEL[®] Solution

Midazolam

5mg/5mL, 15mg/3mL solution in ampoules

What is in this leaflet

This leaflet answers some common questions about HYPNOVEL solution.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your using HYPNOVEL solution against the benefits expected for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What HYPNOVEL solution is used for

HYPNOVEL solution contains the active ingredient midazolam, as midazolam hydrochloride.

HYPNOVEL solution may be given as a sedative during some short medical procedures.

HYPNOVEL solution may be given before an operation to produce sleepiness or drowsiness and to relieve anxiety. It may also be used in combination with other anaesthetic agents to keep you asleep during an operation.

If you are in an intensive care unit, you may receive HYPNOVEL solution as a sedative.

HYPNOVEL solution belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

HYPNOVEL solution can cause sedation (sleepiness), short term amnesia (no memory of events around the time you are given HYPNOVEL solution), and/or anaesthesia (heavy sleep for surgery) depending on the dose you are given.

Your doctor, however, may have prescribed HYPNOVEL solution for another purpose.

Ask your doctor if you have any questions about why HYPNOVEL solution has been prescribed for you.

This medicine is available only with a prescription.

Before you receive HYPNOVEL solution

When you must not have HYPNOVEL solution

Do not have HYPNOVEL solution if:

1. **you have had an allergic reaction to HYPNOVEL solution or tablets, any other benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet**

If you are not sure whether you should be given HYPNOVEL solution, talk to your doctor.

Before you receive it

Tell your doctor if:

1. **you are pregnant or plan to become pregnant**
HYPNOVEL solution is not recommended for use in pregnant women, especially in the third (last) trimester or during labour. If there is a need for HYPNOVEL solution when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
2. **you are breastfeeding or plan to breastfeed**
HYPNOVEL solution passes into breast milk. You should not breastfeed while receiving HYPNOVEL solution.
3. **you have any other health problems including:**
 - liver, kidney, heart or lung disease
 - breathing difficulties
 - any long term illness that is making you weak
 - history of alcohol or drug abuse
 - you have severe muscle weakness, known as myasthenia gravis
4. **you are a child**
5. **you are over 60 years of age**
6. **if you are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, do so before you receive HYPNOVEL solution.

Dependency

HYPNOVEL solution can cause physical dependency with long-term use (for example, when it is used in an intensive care unit for long periods of time). Your dose may be reduced gradually to overcome this effect.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with HYPNOVEL solution. These medicines include:

- erythromycin (Eromycin[®], E-Mycin[®], ERA[®]), an antibiotic
- sodium valproate (Epilim[®]), an epilepsy medicine
- fluconazole (Diflucan[®]) and itraconazole (Sporanox[®]), antifungal medicines
- saquinavir (Invirase[®], Fortovase[®]), an HIV/AIDS medicine

These medicines may be affected by HYPNOVEL solution or may affect how well it works. You may be given different amounts of your medicine, or you may need different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking HYPNOVEL solution.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How HYPNOVEL solution is given

How much is given

HYPNOVEL solution may be given to you as an injection into a vein or muscle, or as an infusion into a vein. Other medications may also be given at the same time.

In children HYPNOVEL solution can also be given as drops into the mouth or nose, or rectally (into the back passage) using a syringe without a needle.

Your doctor will adjust the dose necessary for you. This depends on which medical procedure you will be having, your age, weight, general health, and the way in which the medicine is being given to you. The usual dose is 0.025 to 0.50mg per kg bodyweight. Elderly or unwell patients may not need as much HYPNOVEL solution.

How long is it given

HYPNOVEL solution may be given before, during or after a medical procedure, or continuously for patients in an intensive care unit.

In case of an overdose

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much HYPNOVEL solution. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have received too much HYPNOVEL solution, you may feel drowsy, tired, confused, feel weak or become unconscious. A few people become over-excited and/or angry.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are having HYPNOVEL solution

Things you must do

Tell your doctor if you feel HYPNOVEL solution is not helping you.

Things you must not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how HYPNOVEL solution affects you.

HYPNOVEL solution may cause drowsiness, dizziness, fatigue, confusion, hallucinations and forgetfulness. Make sure you know how you react to HYPNOVEL solution before you drive a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Particular care should be taken if you are elderly or unwell.

If you drink alcohol these effects could be worse.

Drinking alcohol is not recommended after you have been given HYPNOVEL solution.

Ask your doctor or pharmacist how long you should avoid alcohol for.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received HYPNOVEL solution.

HYPNOVEL solution helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory
- confusion
- feelings of extreme happiness
- headache
- hiccups
- feeling sick with or without vomiting
- constipation
- dry mouth
- involuntary (uncontrollable) movements
- rash or itching
- redness or pain at the site of the injection

Tell your doctor immediately or go to your nearest Accident and Emergency centre if you notice any of the following:

- sudden anxiety or excitation
- feeling agitated, aggressive or angry
- hallucinations or delusions
- convulsions
- allergic reaction – sudden signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue and other parts of the body, wheezing or trouble breathing
- shortness of breath

These are serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.



Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking HYPNOVEL solution

Storage

HYPNOVEL solution will be stored in the pharmacy or on the ward out of reach of children. It is kept in a cool dry place where the temperature stays below 35°C. It should be protected from light.

Product Description

Availability

HYPNOVEL solution comes in ampoules in two strengths – 5mg in 5mL and 15mg in 3mL.

HYPNOVEL solution 5mg/5mL ampoules are supplied in packs of 10.

HYPNOVEL solution 15mg/3mL ampoules are supplied in packs of 5.

HYPNOVEL is also supplied as tablets – there is a separate Consumer Medicine Information leaflet for the tablets.

What HYPNOVEL solution looks like

HYPNOVEL solution is a clear to slightly yellow liquid, odourless and practically free from particles. It is packaged in colourless glass ampoules.

Ingredients

Active ingredient – midazolam, as midazolam hydrochloride

- each 5mg/5mL HYPNOVEL ampoule contains 5mg midazolam
- each 15mg/3mL HYPNOVEL ampoule contains 15mg midazolam

Inactive ingredients

- each ampoule also contains sodium chloride, hydrochloric acid, sodium hydroxide and water for injection

Distributor

Roche Products (New Zealand) Ltd
P O Box 12-492
Penrose
AUCKLAND

Telephone: (09) 633 0700
Toll Free: 0800 656 464

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