Hypnovel®
midazolam solution for injection 5mg/5mL and 15mg/3mL in ampoules

What is in this leaflet

This leaflet answers some common questions about Hypnovel solution for injection.
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 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 is Hypnovel used for

Hypnovel may be given as a sedative during some short medical procedures.
Hypnovel 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 as a sedative.
Hypnovel belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.
Hypnovel can cause sedation (sleepiness), short term amnesia (no memory of events around the time you are given Hypnovel, and/or anaesthesia (heavy sleep for surgery) depending on the dose you are given.
Your doctor, however, may have prescribed Hypnovel for another purpose.
Ask your doctor if you have any questions about why Hypnovel has been prescribed for you.
This medicine is available only with a prescription.

Before you receive Hypnovel

When you must not have Hypnovel solution for injection
Do not have Hypnovel if:
1. you have had an allergic reaction to Hypnovel solution for injection 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, talk to your doctor.

Before you receive it

Tell your doctor if:

1. you are pregnant or plan to become pregnant
   Hypnovel is not recommended for use in pregnant women or during labour. If there is a need for Hypnovel 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 passes into breast milk. You should not breastfeed while receiving Hypnovel.

3. you have any other health problems including:
   - liver, kidney, heart or lung disease
   - breathing difficulties including sleep apnoea
   - any long term illness that is making you weak
   - history of alcohol or drug abuse
   - you have severe muscle weakness, known as myasthenia gravis
   - mental disorders including; depression, psychosis or schizophrenia
   - epilepsy (fits or convulsions)

4. you are over 60 years of age

5. if you are allergic to any other medicines, foods, dyes or preservatives.

6. you are taking opioids, a class of medicines used to treat pain. Opioids include medicines such as oxycodone, fentanyl, hydromorphone, tramadol and taking them at the same time as Hypnovel has the potential to cause very serious side effects.

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

Dependency

Hypnovel can cause physical dependency, especially if you have a history of alcohol or drug abuse, when used long-term (for example, when 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 and Hypnovel may interfere with each other. These medicines include:

- erythromycin, clarithromycin and rifampicin which are antibiotics
- sodium valproate, an epilepsy medicine
- ketoconazole, voriconazole, fluconazole and itraconazole, antifungal medicines
- saquinavir and other HIV/AIDS medicines
- boceprevir and telaprevir, Hepatitis C medicines
- cimetidine and ranitidine, medicines used to treat ulcers and indigestion
- opioids
- ticagrelor, a medicine used to lower your risk of stroke
These medicines may be affected by Hypnovel 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.

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

If you have not told your doctor about any of the above medicines, tell them before you receive Hypnovel.

How Hypnovel is given

How much is given

Hypnovel solution for injection 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 for injection 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 are 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 0.50 mg per kg bodyweight. Elderly or unwell patients may not need as much Hypnovel.

How long is it given

Hypnovel 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 received too much Hypnovel solution for injection. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers for these places handy.

You may need urgent medical attention.

Symptoms of overdose may include feeling sick (nausea), vomiting, dizziness, slowing of breathing, slowing of heart rate, drowsiness, confusion, loss of muscle tone and coordination, tiredness, loss of muscle tone and coordination, difficulty in speaking, uncontrollable eye movements, loss of normal reflexes and coma. A few people may become over-excited and/or angry.

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

While you are having Hypnovel

Things you must do

Do not take any other medicines whether they require a prescription or not without first telling your doctor.
Tell your doctor if you feel Hypnovel is not helping you.

**Things you must not do**

_Do not drive or operate machinery until you know how Hypnovel affects you._

Hypnovel may cause drowsiness, dizziness, fatigue, confusion, hallucinations and forgetfulness and therefore may affect alertness. Make sure you know how you react to Hypnovel before you drive a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert. If you have not had enough sleep or have been drinking alcohol, you are likely to be less alert.

**Things to be careful of**

_Particular care should be taken if you are elderly, unwell or taking other medicines._

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

If you drink alcohol these effects could be worse.

**Drinking alcohol is not recommended after you have been given Hypnovel.**

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 for injection._

Hypnovel 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.

All medical procedures which involve the use of an anaesthetic have a very small risk which your doctor will discuss with you.

Rarely, in elderly or high risk patients, death has occurred due to a slowdown of the heart and lungs.

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness
- confusion, lack of concentration, feeling disorientated, restless or irritable
- mood changes
- anxiety, nightmares, hallucinations, inappropriate behaviour
- 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
- older patients, and those taking other sedatives or alcohol may be more likely to fall and suffer fractures
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 which may cause difficulty in swallowing or breathing and other parts of the body
- shortness of breath, wheezing or trouble breathing

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**

**Storage**

Hypnovel solution for injection 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 30°C. It should be protected from light.

**Product Description**

**Availability**

Hypnovel solution for injection 5mg/5mL ampoules are supplied in packs of 10.

Hypnovel solution for injection 15mg/3mL ampoules are supplied in packs of 5.

Hypnovel is also supplied as 7.5 mg tablets – there is a separate Consumer Medicine Information leaflet for the tablets.

**What Hypnovel looks like**

Hypnovel solution for injection is an odourless, clear to slightly yellow liquid. 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

Sponsor Details

Hypnovel is supplied in New Zealand by:

Roche Products (New Zealand) Ltd
PO Box 109113
Newmarket, Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 656 464

This leaflet was prepared on 18 September 2017.