

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Hypnovel.

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 you using Hypnovel against the benefits they expect it will have 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 is used for

Hypnovel may be injected as a sedative during some short medical procedures.

Hypnovel may be given to you by injection before an operation to produce sleepiness or drowsiness and to relieve anxiety.

If you are in an intensive care unit, you may receive an infusion of Hypnovel over several hours or days 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, hypnosis, amnesia and/or anaesthesia, depending on the dose.

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.

Hypnovel is only given by a doctor trained to use this medicine. If you will be receiving Hypnovel during surgery, your doctor will give you the medicine and closely follow your progress.

This medicine is available only with a doctor's prescription.

Before you receive Hypnovel**Do not use Hypnovel if**

- **you have had an allergic reaction to Hypnovel, any other benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet**
- **you have severe muscle weakness, also known as myasthenia gravis**
- **you have a condition called acute narrow angle glaucoma**
- **you are suffering from shock, coma or acute alcoholic intoxication**

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

The safety and effectiveness of Hypnovel in children less than eight years of age has not been established.

Before you receive it

Your doctor must know about all the following before you receive Hypnovel.

1. **if you are pregnant or plan to become pregnant**
Hypnovel is not recommended for use in pregnant women, especially in the third

(last) trimester or during labour. If there is a need to use Hypnovel when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

2. **if you are breastfeeding or plan to breastfeed**

Hypnovel may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Hypnovel is not recommended for use while breastfeeding.

3. **if you have any other health problems including:**

- liver, kidney, heart or lung disease
- high or low blood pressure
- mental disorders including; depression, psychosis or schizophrenia
- epilepsy (fits or convulsions)
- history of alcohol or drug abuse

4. **if you drink alcohol or use illicit (illegal) drugs regularly**

Hypnovel can cause physical dependency, especially if you have a history of drug or alcohol abuse, when used long-term. Your dose may be reduced gradually to overcome this effect.

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

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Hypnovel may interfere with each other. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- anaesthetics
- fluvoxamine, nefazodone and other medicines for depression
- medicines to control fits such as sodium valproate
- medicines for allergies or colds such as antihistamines
- pain relievers
- chlorzoxazone and other muscle relaxants
- cimetidine, a medicine used to treat ulcers
- disulfiram a medicine used in alcohol abuse
- erythromycin and clarithromycin, common antibiotics
- diltiazem, verapamil and atorvastatin, medicines used to treat high blood pressure or heart conditions
- ketoconazole, fluconazole, posaconazole and itraconazole, medicines used to treat fungal infections
- ritonavir, saquinavir and other HIV protease inhibitors, medicines used to treat HIV
- bicalutamide, a medicine used in the treatment of prostate cancer and for excessive hair loss particularly in women

- aprepitant, a medicine used for treatment of nausea (feeling sick) and vomiting associated with chemotherapy
- goldenseal, a complementary medicine

These medicines may be affected by Hypnovel or may affect how well Hypnovel works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also know of other medicines to be careful with or avoid while using Hypnovel.

Tell your doctor about any medicines you are taking including those listed above before you receive Hypnovel.

How Hypnovel is given

Hypnovel may be given to you as an injection into a vein or muscle. It may also be given through an infusion set in an intensive care unit. Other medications may also be given at the same time.

Your doctor will adjust the dose necessary for you. This depends on which medical procedure you will be having, your age, weight and your general health. Elderly patients may need to receive less.

How long is Hypnovel given

Hypnovel may be given once before a medical procedure, or continuously by infusion for patients in an intensive care unit. Hypnovel will be stopped once there is no further need for sedation.

If you have been given too much (overdose)

If you have received too much Hypnovel, you may feel drowsy, tired, confused, dizzy, feel weak or become unconscious.

While you are taking 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 and forgetfulness in some people 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.

Do not have any alcohol for at least 12 hours after you have been given Hypnovel.

Things to be careful of

Be careful if you are elderly, unwell, drinking alcohol 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.

Side Effects

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

In addition to the beneficial effects of Hypnovel it is possible that unwanted effects will occur during treatment, even when it is used as intended. All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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.

In elderly, or high risk patients, death has resulted rarely 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, reduced alertness
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams
- blurred vision
- pain, redness or hardness at the injection site
- muscle stiffness or inflammation of the vein
- coughing, hiccups
- constipation
- feeling sick with or without vomiting

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- difficulty breathing or wheezing
- changes in pulse rate and blood pressure
- sudden anxiety or excitement
- hallucinations, unusual mood or delusions
- severe sleep disturbances
- 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

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

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 will be stored in the pharmacy or on the ward. It is kept in a cool dry place

where the temperature stays below 30°C. It should be protected from light.

Product Description

What Hypnovel looks like

Hypnovel is a clear colourless to yellowish solution.

Ingredients

Active ingredient - midazolam

- each ampoule of Hypnovel 5 mg/5 mL and 5 mg/1 mL contains 5 mg midazolam
- each ampoule of Hypnovel 15 mg/3 mL contains 15 mg midazolam

Hypnovel ampoules 5 mg/5 mL and 5 mg/1 mL come in packs of 10.

Hypnovel ampoules 15 mg/3 mL come in packs of 5.

Inactive ingredients

- sodium chloride
- hydrochloric acid
- sodium hydroxide
- water for injection.

Distributor

Hypnovel is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000

Medical enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

- Hypnovel Injection 5 mg in 5 mL - AUST R 13779
- Hypnovel Injection 5 mg in 1 mL - AUST R 13726
- Hypnovel Injection 15 mg in 3 mL - AUST R 13727

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