

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Hypnovel?

Hypnovel contains the active ingredient Midazolam. Hypnovel is used as a sedative during some short medical procedures. For more information, see Section [1. Why am I using Hypnovel?](#) in the full CMI.

### 2. What should I know before I use Hypnovel?

Do not use if you have ever had an allergic reaction to Hypnovel or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Hypnovel?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Hypnovel and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Hypnovel?

- 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.

More instructions can be found in Section [4. How do I use Hypnovel?](#) in the full CMI.

### 5. What should I know while using Hypnovel?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Hypnovel.</li><li>• Tell your doctor if you are taking any other medicines or have any conditions listed in section 2 of the full CMI prior to taking Hypnovel.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines whether they require a prescription or not without first telling your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machinery until you know how Hypnovel affects you.</li><li>• Hypnovel may cause drowsiness, dizziness, fatigue, confusion and affect alertness.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not have any alcohol for at least 12 hours after you have been given Hypnovel</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Hypnovel will be stored in the pharmacy or on the ward.</li><li>• It is kept in a cool dry place where the temperature stays below 30°C.</li><li>• It should be protected from light.</li></ul>

For more information, see Section [5. What should I know while using Hypnovel?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received Hypnovel, especially if you are over 60 years of age or have pre-existing heart and lung conditions. All medicines can have side effects. Sometimes they are serious, most of the time they are not. All medical procedures which involve the use of an anaesthetic have risk which your doctor will discuss with you. In elderly, or high-risk patients, death has resulted rarely due to heart attack or a slowdown of the heart and lungs. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

**Active ingredient(s):** *Midazolam*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Hypnovel. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hypnovel.**

**Where to find information in this leaflet:**

- [1. Why am I using Hypnovel?](#)
- [2. What should I know before I use Hypnovel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Hypnovel?](#)
- [5. What should I know while using Hypnovel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Hypnovel?

**Hypnovel contains the active ingredient Midazolam.**

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.

**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.**

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.

### 2. What should I know before I use Hypnovel?

#### Warnings

**Do not use Hypnovel if:**

- you are allergic to Midazolam, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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
- you are less than eight years of age.  
The safety and effectiveness of Hypnovel in children less than eight years of age has not been established.

**Check with your doctor if you:**

- have any other medical conditions 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
- are pregnant, intend to become pregnant or breastfeed
- if you are allergic to any other medicines, foods, dyes or preservatives

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Hypnovel is not recommended for use in pregnant women, especially in the third (last) trimester or during labour unless there is no safer alternative.

Hypnovel crosses the placenta and use in the third (last) trimester has resulted in serious and potentially fatal effects in newborns. These include irregular heart rates, muscle weakness, low body temperature, difficulty breathing, difficulty sucking. The newborn may also show signs of dependency and withdrawal after birth.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Hypnovel passes into the breast milk and may cause drowsiness, feeding difficulties and poor weight gain in the baby.

If you are breastfeeding while taking Hypnovel, monitor your baby for excessive sedation, poor feeding and poor weight gain, and seek medical attention if you notice these signs.

You should pump and discard breastmilk for at least 4 to 8 hours after receiving midazolam.

**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.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hypnovel.**

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.

### 4. How am I given 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.

#### When and how long Hypnovel is 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.

#### How much is given

- 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.

#### If you have been given too much Hypnovel

If you think that you have used too much Hypnovel, you may feel drowsy, tired, confused, dizzy, feel weak or become unconscious. If used in combination with other similar medicines, the effects of overdose may be serious and potentially fatal. You may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using Hypnovel?

#### Things you should do

#### Call your doctor straight away if you:

- feel Hypnovel is not helping you
- experience serious side effects listed in section 6

Remind any doctor, dentist or pharmacist you visit that you are using Hypnovel.

#### Things you should 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 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.

#### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Hypnovel affects you.

Hypnovel may cause dizziness, drowsiness, 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.

## Drinking alcohol

### Tell your doctor if you drink alcohol.

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

Alcohol may increase the risk of fall and fracture due to dizziness and unsteadiness, a possible side effect of Hypnovel.

### Looking after your medicine

- 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.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

In elderly, or high-risk patients, death has resulted on rare occasions, due to heart attack or a slowdown of the heart and lungs. These life-threatening diseases are more common in adults over 60 years of age and with pre-existing heart and lung conditions when a high dose of Hypnovel is administered or when the injection is given too rapidly. If you belong to these high-risk groups seek medical attention immediately if you notice heart or breathing issues.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• drowsiness, tiredness, reduced alertness</li><li>• dizziness, unsteadiness – there is a risk of fall and fracture which is increased in those taking sedatives, alcohol and in the elderly</li><li>• loss of memory, inattentiveness, confusion, lack of concentration, lethargy</li><li>• headache, hangover feeling in the morning</li><li>• slurred speech</li><li>• unpleasant dreams</li><li>• blurred vision</li><li>• pain, redness or hardness at the injection site</li><li>• muscle stiffness or inflammation of the vein</li><li>• coughing, hiccups</li><li>• constipation</li><li>• feeling sick with or without vomiting</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• difficulty breathing or wheezing</li><li>• changes in pulse rate and blood pressure</li><li>• sudden anxiety, excitation or agitation, involuntary movements such as muscle tremors</li><li>• hallucinations, unusual mood or delusions</li><li>• severe sleep disturbances</li><li>• 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</li><li>• withdrawal symptoms including withdrawal convulsions</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Hypnovel contains

<b>Active ingredient midazolam</b>	<ul style="list-style-type: none"><li>• each ampoule of Hypnovel 5 mg/5 mL and 5 mg/1 mL contains 5 mg midazolam</li><li>• each ampoule of Hypnovel 15 mg/3 mL contains 15mg midazolam</li></ul>
<b>Other ingredients (inactive ingredients)</b>	sodium chloride hydrochloric acid sodium hydroxide water for injection

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Hypnovel looks like

Hypnovel ampoules 5 mg/5 mL (AUST R 13779) and 5 mg/1 mL (AUST R 13726) come in packs of 10. Hypnovel ampoules 15 mg/3 mL come in packs of 5 (AUST R 13727).

### Who distributes Hypnovel

Hypnovel is distributed by:

Pharmaco (Australia) Ltd

Level 13

465 Victoria Avenue

Chatswood NSW 2067

AUSTRALIA

Phone: 1800 210 564

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

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