

Consumer Medicine Information

HYPNOVEL[®]

midazolam tablets 7.5 mg

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 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 HYPNOVEL is used for

HYPNOVEL tablets are used for the short term treatment of insomnia (inability to sleep).

HYPNOVEL tablets may also be given to you before an operation to produce sleepiness or drowsiness and to relieve anxiety.

HYPNOVEL belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals. HYPNOVEL tablets will cause sedation and help you sleep.

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.**

If you will be receiving HYPNOVEL before minor 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 tablets 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 respiratory problems
- you have a condition called acute narrow angle glaucoma
- you have a condition called sleep apnea syndrome
- you have severe liver damage or liver disease
- you are suffering from shock, coma or acute alcoholic intoxication
- you are taking antifungal medicines such as ketoconazole (Nizoral[®]), itraconazole (Sporanox[®]) or voriconazole (Vfend[®])
- you are taking HIV protease inhibitors including ritonavir boosted protease inhibitors

- **you suffer from galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption**

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

Do not give HYPNOVEL tablets to children. An injection solution is available which may be given by mouth for children who need sedation for minor procedures.

Do not take Hypnovel if the expiry date printed on the pack has passed. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

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

It is not known whether HYPNOVEL tablets are harmful to an unborn baby when given to a pregnant woman. 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 tablets are not recommended for use while breastfeeding.

3. if you have any other health problems including:

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

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

Use of benzodiazepines may lead to the development of physical and psychological dependence and the risk is increased with a history of alcohol or drug abuse. Tolerance to HYPNOVEL tablets may occur.

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 healthfood shop.

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

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines to control epileptic fits (convulsions) (Dilantin[®], Epilim[®], Tegretol[®], Teril[®])
- medicines for allergies or colds eg. antihistamines
- pain relievers (narcotics)
- cimetidine (Cytine[®], Apo-cimetidine[®], Duomet[®], Tagamet[®]) and ranitidine (Zantac[®], Apo-ranitidine[®]), medicines used to treat ulcers and indigestion
- disulfiram (Antabuse[®]), a medicine used in alcohol abuse
- erythromycin (ERYC[®], ERA EMU-V[®], EES[®], E-Mycin[®]), a common antibiotic
- rifampicin, a treatment for tuberculosis (TB)
- diltiazem (Cardizem[®], Apo-diltiazem[®], Dilzem[®], Dilacor[®], Dilcard[®])
- verapamil (Isoptin[®], Civicor[®]), medicines used for heart conditions
- ketoconazole (Nizoral[®]), itraconazole (Sporanox[®]) and fluconazole (Diflucan[®]), medicines used to treat fungal infections



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.

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

How to take HYPNOVEL

How much to take

Take HYPNOVEL tablets exactly as your doctor has prescribed. Your doctor will tell you how many tablets to take each evening.

If you are having HYPNOVEL tablets before a minor surgical procedure this will be administered by a doctor or nurse.

The normal dosage for insomnia is 7.5 to 15 mg (one to two tablets). The dose for sedation before procedures is normally 15 mg (two tablets).

How to take it

Swallow the tablets whole with a glass of water.

Take the tablets with or without food.

Do not break or crush tablets unless instructed to do so.

How long to take HYPNOVEL

HYPNOVEL is used for short term treatment of sleeping difficulty (insomnia) or as instructed by your doctor.

Continue take HYPNOVEL tablets until your doctor tells you to stop.

If you forget to take HYPNOVEL

If you forget to take your HYPNOVEL and your sleep is all right, do not take a dose until the next evening. If you miss a dose and wake up to have it, you require 7 or 8 uninterrupted sleeps for the effects to wear off.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much HYPNOVEL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

Symptoms of overdose may include feeling sick (nausea), vomiting, dizziness, slowing of breathing, drowsiness and coma.

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

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 tablets are 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, concentration impairment and memory loss 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 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 tablets.

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.

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:

- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams, tiredness
- blurred vision
- headache, hiccups
- feeling sick with or without vomiting
- worse sleep once you stop treatment
- depression
- agitation, aggression, irritability
- older patients may be more likely to fall and suffer fractures

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

- sudden anxiety or excitation, abnormal behaviour
- hallucinations or delusions, psychosis
- severe sleep disturbances



- an allergic reaction - symptoms may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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 tablets must be kept in a cool dry place where the temperature stays below 30°C. They should be protected from light.

Hypnovel tablets given before a procedure will be kept at the clinic and given by a nurse or doctor.

Product Description

What HYPNOVEL tablets look like

HYPNOVEL tablets are white oval with an imprint 'ROCHE 7.5' on one side.

Ingredients

Active ingredient – midazolam

Tablets containing midazolam maleate equivalent to 7.5 mg midazolam.

Inactive ingredients

- lactose
- microcrystalline cellulose
- pregelatinised starch
- magnesium stearate
- methyl hydroxypropyl cellulose
- talc
- colourant titanium dioxide (E171)

Distributor

HYPNOVEL is distributed by:

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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Reference: Hypnovel tablets Data Sheet dated 4 April 2008.