

HYPNODORM™

Consumer Medicine Information (CMI) summary

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

1. Why am I taking HYPNODORM?

HYPNODORM contains the active ingredient flunitrazepam. HYPNODORM is used to treat severe cases of insomnia (trouble sleeping).

For more information, see Section [1. Why am I taking HYPNODORM?](#) in the full CMI.

2. What should I know before I take HYPNODORM?

Do not take HYPNODORM if you have ever had an allergic reaction to flunitrazepam, any other benzodiazepine, 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 take HYPNODORM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYPNODORM 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 take HYPNODORM?

- The dose varies from patient to patient. Your doctor will decide the right dose for you.
- HYPNODORM should only be taken when you go to bed.

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

5. What should I know while taking HYPNODORM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking HYPNODORM.• Use HYPNODORM exactly as prescribed by your doctor.
-----------------------------	---

	<ul style="list-style-type: none"> • Call your doctor straight away if you become pregnant while taking HYPNODORM.
Things you should not do	<ul style="list-style-type: none"> • Do not take HYPNODORM for a longer time than your doctor has prescribed. • Do not stop taking HYPNODORM, or change the dose, without checking with your doctor. • Do not take HYPNODORM to treat any other conditions unless your doctor tells you to. • Do not give HYPNODORM to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or operate machinery until you know how HYPNODORM affects you. HYPNODORM may cause drowsiness, dizziness or

	lightheadedness in some people
Drinking alcohol	<ul style="list-style-type: none"> • Alcohol may increase the effects of HYPNODORM and should be avoided while you are being treated with HYPNODORM.
Looking after your medicine	<ul style="list-style-type: none"> • Store it in a cool dry place away below 30°C. • Keep your tablets in the bottle until it is time to take them.

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

6. Are there any side effects?

Less serious side effects: tiredness or drowsiness, hangover feeling in the morning, headache, confusion, dizziness, unsteadiness when walking, stomach upsets, dry mouth, slurred speech. **Serious side effects:** skin rash, fast heartbeat, muscle weakness, aggressive behaviour, delusions, hallucinations, sudden excitation or anxiety, severe sleep disturbances, nightmares, loss of memory, swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

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.

HYPNODORM™

Active ingredient: *flunitrazepam*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking HYPNODORM?

HYPNODORM contains the active ingredient flunitrazepam. HYPNODORM belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

HYPNODORM is used to treat severe cases of insomnia (trouble sleeping).

In general, benzodiazepines such as HYPNODORM need only be taken for a few nights and then discontinued by gradually decreasing the dosage. Continuous long term use of HYPNODORM is not recommended. The use of benzodiazepines may lead to dependence on the medicine.

HYPNODORM is not recommended as a first choice of treatment in patients with depression and/or psychosis as it can increase your risk of suicide.

Your doctor may have prescribed HYPNODORM for another reason. Ask your doctor if you have any questions about why HYPNODORM has been prescribed for you.

2. What should I know before I take HYPNODORM?

Warnings

Do not take HYPNODORM if:

- you are allergic to flunitrazepam, any other benzodiazepine, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- wheezing or shortness of breath.

Always check the ingredients to make sure you can take this medicine.

- you have severe and chronic lung disease
- you have myasthenia gravis, condition where there is severe muscle weakness
- you have sleep apnoea, condition where you temporarily stop breathing while you are asleep
- you have severe liver disease.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- have, or have had, any medical conditions, especially the following:
 - hypotension (low blood pressure)
 - myasthenia gravis (severe muscle weakness)
 - liver or kidney problems
 - lung problems
 - a blood disorder
 - glaucoma (increased pressure in the eye)
 - depression, psychosis or schizophrenia
 - epilepsy (convulsions).

Your doctor may want to take special care if you have any of these conditions.

- take any medicines for any other condition
- drink alcohol regularly

- need to drive, operate dangerous machinery, or are involved in activities requiring concentration.
- plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking HYPNODORM.

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

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking HYPNODORM during pregnancy.

HYPNODORM crosses the placenta and may cause poor muscle tone, slowed breathing, feeding problems and low body temperature in the newborn infant if used in high doses during labour. Withdrawal symptoms in newborn infants have been reported with long term use of this class of drugs.

Do not take HYPNODORM if you are breastfeeding.

Tell your doctor if you are breastfeeding or plan to breastfeed.

HYPNODORM passes into breast milk and may affect your baby. It is not recommended for use when breastfeeding.

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 may be affected by HYPNODORM or may affect how well it works. These include:

- other sleeping tablets, sedatives or tranquilisers
- medicines for depression
- medicines used to treat mental illness
- medicines to treat epilepsy
- antihistamines, medicines for allergies or colds
- muscle relaxants
- cimetidine, medicine used to treat stomach ulcers
- cisapride, medicine used to treat reflux
- strong pain relievers
- disulfiram, medicine used in the treatment of alcohol dependence
- anticholinergics, medicines for travel sickness, stomach cramps or Parkinson's Disease.

Your doctor can tell you what to do if you are taking any of these medicines.

HYPNODORM may produce additive depressant effects when using together with other medications, such as alcohol, sedatives, antidepressants, antipsychotics drugs, epilepsy drugs, hypnotics, relaxants, antihistamines, severe pain relievers and

anaesthetics. This has the potential to significantly increase the effects on HYPNODORM and may lead to addiction or result in death from overdose.

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

4. How do I take HYPNODORM?

How much to take

- The dose varies from patient to patient. Your doctor will decide the right dose for you.
- The usual dose is 1 mg to 2 mg (one to two tablets) at bedtime.
- The usual dose for elderly patients is 0.5 mg to 1 mg (half to one tablet) at bedtime.
- Follow all directions given to you by your doctor and pharmacist carefully.

How to take HYPNODORM

- Swallow the tablets with a glass of water.
- HYPNODORM tablets can be broken in half if your doctor has prescribed half a tablet.

When to take HYPNODORM

- HYPNODORM should be taken when you go to bed. Only take HYPNODORM if you feel you will need help sleeping.

- HYPNODORM can be taken with or without food.

Withdrawal

If you have taken HYPNODORM for a long period of time and suddenly stop taking it, you may experience withdrawal symptoms. Withdrawal symptoms may last for weeks or months and symptoms may include: extreme anxiety, shaking (tremor) including involuntary movements, difficulty sleeping (insomnia), depression, problems with your perception, confusion, fits (convulsions), muscle cramps, headaches, tension, restlessness, irritability, stomach problems, being sick (vomiting) and sweating. More severe withdrawal symptoms include: a feeling of loss of identity/ feeling detached from yourself (depersonalisation or derealisation), sensitivity to light, noise (including tinnitus) and physical contact, numbness or tingling in the hands or feet (paraesthesia), seeing or hearing things that are not real (hallucinations). HYPNODORM should be stopped gradually to reduce withdrawal symptoms.

If you forget to take HYPNODORM

If you forget to take HYPNODORM before you go to bed and you wake up late in the night or early in the morning, do not take HYPNODORM as you may have trouble waking in the morning.

Do not take a double dose to make up for the dose you missed.

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

How long to take HYPNODORM for

Take HYPNODORM only for as long as your doctor recommends.

Usually, HYPNODORM need only be taken for a few nights and then discontinued by gradually decreasing the dosage. Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

If you take too much HYPNODORM

If you think that you or anyone else has taken too much HYPNODORM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much HYPNODORM, you may feel drowsy, confused, tired, unsteady when walking, weak in muscle strength, dizzy, lightheaded, have trouble breathing or become unconscious.

5. What should I know while taking HYPNODORM?

Things you should do

- Take HYPNODORM exactly as prescribed by your doctor.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking HYPNODORM.
- Tell any doctors, dentists and pharmacists treating you that you are taking HYPNODORM.
- Tell your doctor immediately if you become pregnant while taking HYPNODORM.
- If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or ending your life. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.
- If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking HYPNODORM.
- If you have any clinical tests such as an EEG, tell your doctor that you are taking HYPNODORM.

HYPNODORM may affect the results of some tests.

- Visit your doctor regularly so they can check on your progress.

Your doctor needs to check your progress and see whether you need to continue taking HYPNODORM.

- Tell your doctor, if for any reason, you have not taken HYPNODORM exactly as prescribed.

Otherwise, your doctor may think that your medicine is not working properly and change your treatment unnecessarily.

Tell your doctor immediately if you:

- become pregnant while taking HYPNODORM.

Things you should not do

- Do not take HYPNODORM for a longer time than your doctor has prescribed.

HYPNODORM should be taken for short periods only unless advised otherwise by your doctor.

- Do not stop taking HYPNODORM, or change the dose, without checking with your doctor.

Stopping HYPNODORM suddenly may cause some unwanted effects. Your doctor will gradually reduce the amount of HYPNODORM you are taking before stopping completely.

- Do not suddenly stop taking HYPNODORM if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

- Do not take HYPNODORM to treat any other conditions unless your doctor tells you to.
- Do not give HYPNODORM to anyone else, even if they have the same condition as you.

Driving or using machines

Do not drive or use any machines or tools until you know how HYPNODORM affects you.

HYPNODORM may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous. This is very important if you are taking other drugs that also make you drowsy.

Even if you take HYPNODORM at night, you may still feel drowsy or dizzy the next day.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of HYPNODORM and should be avoided while you are being treated with HYPNODORM.

Combining HYPNODORM and alcohol can make you more sleepy, dizzy or lightheaded, or increase the risk of sleepwalking and some other related sleep behaviours, which may include sleep-driving, making phone calls or preparing and eating food whilst asleep.

This risk is also increased if you take more than the recommended dose.

Your doctor may suggest that you avoid alcohol while you are taking HYPNODORM.

Things to be careful of

Some sleep medicines may cause short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine. To reduce this risk, ensure that you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

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.

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking HYPNODORM or your tablets have passed their expiry date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking HYPNODORM.

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.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist if you have any further questions about the information below.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• tiredness or drowsiness• hangover feeling in the morning, headache, confusion• dizziness, unsteadiness when walking• stomach upsets• dry mouth• slurred speech	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin rash• fast heartbeat• muscle weakness• aggressive behaviour• delusions, hallucinations• sudden excitation or anxiety• severe sleep disturbances, nightmares• loss of memory	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.

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing 	

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. 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 HYPNODORM contains

Active ingredient (main ingredient)	flunitrazepam
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• maize starch• pregelatinised maize starch• magnesium stearate• Indigo carmine• Opadry Green OY-LS-21051 CHN (ID: 4346)
Potential allergens	sugars as lactose, and trace amounts of sulfites.

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

What HYPNODORM looks like

HYPNODORM is a 12.6 x 6 mm, oval, convex, green film-coated tablet. Debossed "FM/1" on one side and an alpha symbol on the other (AUST R 78344).

Who distributes HYPNODORM

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in January 2025.

HYPNODORM™ is a Viatris company trade mark.

HYPNODORM_cmi\Jan25/00