

Hypnodorm

contains the active ingredient flunitrazepam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Hypnodorm.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Hypnodorm against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Hypnodorm is used for

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

Hypnodorm belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

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.

Hypnodorm is available only with a doctor's prescription.

Before you take Hypnodorm

When you must not take it

Do not take Hypnodorm if you are allergic to medicines containing 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.

Do not take Hypnodorm if you have:

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

Do not take Hypnodorm if you are breastfeeding.

Hypnodorm passes into breast milk and may affect your baby.

Do not take Hypnodorm after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give Hypnodorm to children.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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.

Tell your doctor if you plan to breastfeed.

Hypnodorm passes into breast milk and is not recommended for use when breastfeeding.

Tell your doctor if you 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.

Tell your doctor if you drink alcohol regularly.

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

Tell your doctor if you need to drive, operate dangerous machinery, or are involved in activities requiring concentration.

Hypnodorm may cause drowsiness or dizziness up until the next day.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a 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 tranquillisers
- 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.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Hypnodorm.

How to 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 it

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 it

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 it

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 it

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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Hypnodorm. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are taking Hypnodorm

Things you must do

Use Hypnodorm exactly as prescribed by your doctor.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Hypnodorm.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Hypnodorm.

If you become pregnant while taking Hypnodorm, tell your doctor immediately.

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

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 to 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.

Things you must not do

Do not drive or operate machinery 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.

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 use 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.

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 when drinking alcohol while taking Hypnodorm.

Combining Hypnodorm and alcohol can make you more sleepy, dizzy or lightheaded, or increase the risk of sleep-walking 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.

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 while you are taking Hypnodorm.

Hypnodorm helps most people with insomnia, but it may have unwanted side effects in some people.

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.

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 to answer any questions you may have.

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

- tiredness or drowsiness
- hangover feeling in the morning, headache, confusion

- dizziness, unsteadiness when walking
- stomach upsets
- dry mouth
- slurred speech.

The above list includes the more common side effects.

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

- skin rash
- fast heart beat
- 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.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking Hypnodorm

Storage

Keep Hypnodorm where children cannot reach it.

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

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.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Hypnodorm or any other medicine in the bathroom or near a sink.

Do not leave Hypnodorm in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Hypnodorm, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Hypnodorm is a green, oval film-coated tablet with "FM|1" on one side and "a" on the other.

Each bottle contains 30 tablets.

Ingredients

The active ingredient in Hypnodorm is flunitrazepam.

Each Hypnodorm tablet contains 1 mg of flunitrazepam.

The tablets contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- pregelatinised maize starch
- magnesium stearate
- Indigo carmine CI73015
- Opadry Green OY-LS-21051.

Hypnodorm also contains sugars (as lactose and galactose) and trace amounts of sulfites. The tablets are gluten free.

Manufacturer

Hypnodorm is made in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

Hypnodorm 1 mg - AUST R 78344

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