

Unisom[®] SleepGels[®]

Diphenhydramine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Unisom SleepGels.

It does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits.

Your pharmacist or doctor has weighed the risks of you taking Unisom SleepGels against the benefits they expect it will have for you.

If you need further information or have any concerns about taking this medicine, ask your pharmacist or doctor.

Read this leaflet carefully before starting Unisom SleepGels and keep it with the medicine.

You may need to read it again.

What Unisom SleepGels are used for

Unisom SleepGels are used for the temporary relief of sleeplessness at night.

If you have trouble falling asleep Unisom SleepGels may help.

Diphenhydramine belongs to a group of medicines called antihistamines. It has sedative properties which help you to sleep.

Your pharmacist or doctor may have given you Unisom SleepGels for another reason. Ask your pharmacist or doctor if you have any questions about why Unisom SleepGels have been prescribed for you.

There are some simple things that you can do to help establish good sleep patterns.

These include:

- Go to bed and arise at the same time every day
- Engage in relaxing activities before bedtime
- Exercise regularly, but not in the late evening
- Avoid eating large meals just before bedtime
- Eliminate daytime naps
- Avoid caffeine-containing drinks after midday
- Avoid alcohol or the use of nicotine late in the evening
- Minimise external disruption, such as noise and light
- If you are unable to sleep, do not become anxious. Leave the bedroom and participate in relaxing activities such as reading or listening to music until you are tired.

Before you take Unisom SleepGels

When you must not take it

Do not take Unisom SleepGels if:

1. You have an allergy to:

- any medicines containing diphenhydramine or other antihistamines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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.

If you are not sure if you have an allergy to Unisom SleepGels, check with your doctor.

2. You have any of the following medical conditions:

- an asthma attack
- glaucoma (high pressure in the eyes)
- prostate problems
- difficulty passing urine
- a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food
- stomach or duodenal ulcer.

3. You are also taking a cough and cold product that may be incompatible with Unisom SleepGels.

Ask your pharmacist or doctor if you are unsure if the cough and cold product can be taken with Unisom SleepGels.

4. You are taking medicines used to treat depression, particularly tricyclic antidepressants or monoamine oxidase inhibitors.

5. You are breastfeeding or plan to breastfeed.

Like most antihistamine medicines, Unisom SleepGels are not recommended while you are breastfeeding.

6. The packaging is torn or shows signs of tampering, or the capsules do not look quite right.

7. The expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give Unisom SleepGels to children under the age of 12 years.

Before you start to take it

Tell your pharmacist or doctor if:

1. You have or have had any of the following medical conditions:

- asthma
- liver problems.

2. You take sedatives, tranquilisers or other antihistamines.

3. You are pregnant or intend becoming pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using Unisom SleepGels during pregnancy.

If you are not sure if you should start taking Unisom SleepGels, contact your pharmacist or doctor.

Taking other medicines

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

Some medicines and Unisom SleepGels may interfere with each other and should not be taken together.

These include:

- alcohol
- medicines used to treat depression, such as monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants
- medicines used for pain, such as codeine, morphine, and dextropropoxyphene
- some medicines used for sedation or to help you sleep
- some medicines used to treat anxiety
- other antihistamines used to treat allergies
- some cough and cold medicines.

These medicines may be affected by Unisom SleepGels or may affect how well it works. You may need

different amounts of your medicines, or you may need to take different medicines.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take Unisom SleepGels

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

How much to take

Adults and children over 12 years:

- One capsule at bedtime if needed,

Do not exceed the recommended dosage.

How to take it

Swallow the capsules whole with a glass of water.

Unisom SleepGels can be taken with or without food.

How long to take it

Unisom SleepGels can be used for up to one week.

If your sleeplessness lasts for more than 7 to 10 nights in a row, talk to your doctor.

This may be a sign of a more serious medical problem.

If you forget to take it

Skip the dose you missed and take your next dose the following evening at bedtime, if needed.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital.

Do this if you think that you or anyone else may have taken too much Unisom SleepGels, even if there are no signs of discomfort or poisoning.

If you take too much of this medicine, you may feel dizzy, light-headed, upset in the stomach or dry in the mouth.

Toxic doses of antihistamines may cause convulsions or death, especially in infants or children.

While you are using Unisom SleepGels

Things you must do

If you are about to start taking any new medicines, tell your doctor, dentist or pharmacist that you are taking Unisom SleepGels.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Unisom SleepGels.

Talk to your pharmacist or doctor if your symptoms do not improve.

Things you must not do

Do not drive, operate machinery or do anything else that could be dangerous if you have just taken a Unisom SleepGel capsule.

Do not drink alcohol while taking Unisom SleepGels.

The sedative effects of alcohol may be increased.

Do not take Unisom SleepGels to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give Unisom SleepGels to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Unisom SleepGels affect you. You may still be sleepy or drowsy the morning after taking this medicine.

Side effects

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

Like other medicines, Unisom SleepGels can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and require medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following:

- tiredness, dizziness, lack of coordination
- shortness of breath
- nausea or vomiting
- diarrhoea
- blurred vision
- dry mouth
- difficulty or pain in passing urine
- tightness in the chest
- low blood pressure
- muscle weakness
- ringing in the ears
- feeling "high"
- headache

Serious side effects are rare.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not get any of them.

After using Unisom SleepGels

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least 1 ½ metres above the ground is a good place to store medicines.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not store the capsules, or any other medicine in the bathroom or near a sink. Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your capsules in their pack until it is time to take them.

Disposal

If your doctor tells you to stop taking Unisom SleepGels, or the capsules have passed their expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Unisom SleepGels are blue, oval, soft gelatine capsules filled with a liquid and imprinted with 'UNISOM' in white.

Unisom SleepGels are available in blister packs of 10 capsules

Ingredients

Active ingredient

diphenhydramine hydrochloride
50mg

Other ingredients

- macrogol 400

- glycerol
- gelatin
- sorbitol
- water – purified
- Brilliant Blue FCF
- Opacode WB Monogramming Ink NSP-78-18022 White.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Unisom SleepGels are supplied in Australia by:

Petrus Pharmaceuticals Pty Ltd,
Level 3, 1060 Hay Street,
West Perth WA 6005 Australia.

® = Registered Trademark

This leaflet was revised in February 2009

AUST R number 55323