

APOHEALTH Sleep Assist Tablets

Doxylamine succinate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet?

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOHEALTH Sleep Assist tablets. It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

APOHEALTH Sleep Assist tablets helps relieve insomnia. It is intended for short term use to re-establish regular sleep patterns. Do not use it for more than ten days consecutively.

What is insomnia?

Insomnia is having trouble getting to sleep or staying asleep. It may also be the feeling that you are not getting enough sleep.

What causes insomnia?

Insomnia may be caused by some or all of the following:

- stress
- noise
- late night eating
- late night exercise
- inactive lifestyle
- drinking too much tea, coffee or cola
- taking medicines containing stimulants such as cold or flu medicines

How it works

APOHEALTH Sleep Assist tablets belongs to a group of medicines called antihistamines. They block the action of histamine and other substances produced by the body to provide relief from allergic symptoms. Some antihistamines, including doxylamine cause the central nervous system to slow down

at the same time and this provides relief for insomnia.

There is no evidence that this medicine is addictive.

Establishing Regular Sleep Patterns

In addition to taking APOHEALTH Sleep Assist, the following good sleep habits must be established and maintained:

- go to bed and rise at the same time daily
- engage in relaxing activities before bedtime
- exercise regularly but not late in the evening
- avoid eating meals or large snacks just before bedtime
- eliminate day time naps
- avoid caffeine containing drinks after midday
- avoid alcohol or the use of nicotine late in the evening
- minimise external disruption (e.g. light and noise)
- 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 this medicine

When you must not take it

Do not take this medicine if you have, or have had any of the following medical conditions:

- asthma
- chronic bronchitis
- severe liver or kidney disease
- closed-angle glaucoma
- prostate problems
- difficulty passing urine
- a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food

- epilepsy

- **You are pregnant or intend to become pregnant.**

Like most antihistamine medicines APOHEALTH Sleep Assist tablets is not recommended for use during pregnancy. APOHEALTH Sleep Assist tablets is not known to cause birth defects but studies to prove it is safe for the developing baby have not been done.

- **You are breastfeeding or plan to breastfeed.**

Small amounts of APOHEALTH Sleep Assist tablets pass into breast milk. There is a possibility that the breastfed baby may become unusually excited or irritable. It is also possible that breast milk supply will be affected.

- **You are hypersensitive to, or have had an allergic reaction to, APOHEALTH Sleep Assist, Dimetapp night time capsules, Dramamine or similar medicines or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives

on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Some medicines may interact with APOHEALTH Sleep Assist These include:

- antidepressant medicines known as monoamine oxidase inhibitors (MAOI's). These include moclobemide (Arima, Aurorix), phenelzine (Nardil) and tranylcypromine (Parnate)
- tricyclic antidepressant medicines such as amitriptyline (Tryptan), imipramine (Melipramine), nortriptyline (Allegron) and doxepin (Deptran)
- strong pain killers such as codeine and morphine.
- other medicines used to help you sleep including temazepam (Temaze, Normison) triazolam (Halcion) or nitrazepam (Mogadon)
- medicines used to treat anxiety such as oxazepam (Serapax) or diazepam (Valium)
- antibiotics known as aminoglycosides such as tobramycin.

Do not give APOHEALTH Sleep Assist tablet to a child under 12 years of age.

How to take this medicine

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

Their instructions may be different to the information in this leaflet.

APOHEALTH Sleep Assist tablets will cause drowsiness and should be used only at bedtime.

How much to take

Adults:

Take one or two tablets 20 minutes before bed. Swallow APOHEALTH Sleep Assist tablets with a glass of water.

How long to take it for

Do not take APOHEALTH Sleep Assist tablets for more than ten days.

If sleeplessness persists continuously for longer than this tell your doctor. Insomnia might be a sign of another medical problem.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.

- Change the recommended dosage without first checking with your doctor or pharmacist.

Things to be careful of

Drowsiness on the following day may occur.

Use extreme care while doing anything that involves complete alertness such as driving a car, operating machinery, or piloting an aircraft.

Be careful drinking alcohol while taking this medicine. The effects of alcohol can be increased by some antihistamine medicines including APOHEALTH Sleep Assist tablets.

Possible side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking APOHEALTH Sleep Assist tablets or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

These are the more common side effects of APOHEALTH Sleep Assist tablets. Mostly these are mild and short lived.

Tell your doctor if you notice any of the following:

- drowsiness on the day following use
- dizziness
- incoordination
- dry mouth, nose and/or throat
- headache
- muscle weakness
- thicker nasal discharge

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

Serious side effects are rare.

Tell your doctor as soon as possible if you notice any of the following:

These may be serious side effects and you may need medical attention:

- fast, pounding or irregular heartbeats
- difficulty passing urine
- constipation
- tremors
- nervousness
- restlessness
- excitation
- faintness
- blurred vision
- increased gastric reflux

If you take too much (overdose)

If you think that you or anyone else may have taken too much APOHEALTH Sleep Assist Tablets, immediately contact your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26). Do this even if there are no signs of discomfort or poisoning.

If you have taken too much of this medicine, you may suffer:

- severe drowsiness
- severe dryness of the mouth, nose and throat
- flushing or redness in the face
- fast, pounding or irregular heartbeats
- shortness of breath
- hallucinations
- seizures
- convulsions
- insomnia
- dilated pupils
- delirium

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on the window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, ask your pharmacist what to do with any tablets that are left over.

Product Description

APOHEALTH Sleep Assist tablets are white to off white circular biconvex uncoated tablets, breakline on one side and plain on the other and in packs of 20.

Ingredients:

Each tablet contains 25 mg of Doxylamine succinate as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- magnesium stearate
- purified water

This medicine is gluten-free.

This medicine contains sugars as lactose.

*Australian Registration
Number*

APOHEALTH Sleep Assist
doxylamine succinate 25 mg tablet
(Blister pack): 254173

Sponsor

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