

Restavit Tablets®

Doxylamine Succinate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about RESTAVIT.

It does not contain all the available information.

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

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

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

What Restavit is used for

Restavit 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 does Restavit work?

Restavit 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 Restavit is addictive.

Establishing Regular Sleep Patterns

In addition to taking Restavit, 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 (eg. 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 Restavit

Do not take Restavit if you have ever had an allergic reaction to:

- Restavit or any of the ingredients listed at the end of this leaflet.
- Dimetapp night time capsules, Dramamine or similar medicines.

Do not take Restavit 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

Do not take Restavit if you are taking any of the following medicines as they may interfere with each other:

- 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(Tryptanol) imipramine(Melipramine), nortriptyline(Allegron) and doxepin(Depran)
- 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 take Restavit if you are pregnant or intend to become pregnant.

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

Do not take Restavit if you are breast feeding or plan to breast feed.

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

Do not give Restavit to a child under 12 years of age.

Do not take Restavit after the expiry date (EXP) printed on the pack.

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

Do not take Restavit if the packaging is torn or shows signs of tampering.

While you are using Restavit

Things to be careful of:

Drowsiness on the day following use 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 Restavit. The effects of alcohol can be increased by some antihistamine medicines including Restavit.

How to take Restavit

Restavit will cause drowsiness and should be used only at bedtime.

Adults

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

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

They may differ from the information contained in this leaflet.

How long to take it

Do not take Restavit 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.

Side Effects

Restavit helps most people with sleeplessness, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you are over 65 years of age you may have an increased chance of getting side effects.

These are the more common side effects of Restavit. Mostly these are mild and short lived.

- drowsiness on the day following use
- dizziness

- uncoordination
- dry mouth, nose and/or throat
- headache
- muscle weakness
- thicker nasal discharge

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

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 immediately if you notice any of the following:

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

Overdose

If you think that you or anyone else may have taken too much Restavit, 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 Restavit 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

After using Restavit

Storage

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

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

Keep it where children cannot reach it.

Disposal

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

Product Description

Restavit is a white convex tablet with a break bar on one side.

Active ingredients:

Doxylamine succinate : 25mg per tablet.

Other ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- magnesium stearate

Restavit does not contain gluten

Who makes Restavit?

Restavit is made for H.W.Woods Pty.Ltd.
8 Clifford Street
Huntingdale
VIC 3166

Australian Registration Number:

13336

This leaflet was approved in March 2003.