Dozavit™

Active ingredient: doxylamine succinate

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- Why am I using Dozavit™?
- 2. What should I know before I use Dozavit™?
- 3. What if I am taking other medicines?
- 4. How do I use Dozavit™?
- 5. What should I know while using Dozavit™?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Dozavit™?

Dozavit™ contains the active ingredient doxylamine succinate. Dozavit™ is an antihistamine which helps you sleep.

Dozavit™ provides effective, temporary relief of insomnia or sleeplessness.

2. What should I know before I use Dozavit™?

Warnings

Do not use Dozavit™ if:

- you are allergic to doxylamine succinate or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can use this medicine.
- You have narrow angle glaucoma.
- You have epilepsy.

Check with your doctor or pharmacist if you have:

- any other medical conditions
- take any medicines for any other condition
- digestive problems
- glaucoma
- prostate problems
- problems passing urine
- heart problems
- take any medicines for any other condition

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

This product is not recommended for use by pregnant women.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

This product is not recommended for use by breastfeeding women.

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 interfere with Dozavit™ and affect how it works. These include:

- Any other medication used to help you sleep
- Medication for psychiatric disorders
- Any medicine which contains antihistamines
- Nasal decongestants and pain relief products from other cough, cold or allergy products
- Medicines used to treat depression
- Medicines used to treat anxiety
- Medicines used to treat high blood pressure
- Barbiturates
- Atropine
- Strong pain killers
- Medicines used to treat Parkinson's disease.

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

4. How do I use Dozavit™?

How much to take

Adults and children over 12 years: Take 1 to 2 tablets.

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take Dozavit™

Dozavit™ should be taken 20 minutes before going to bed.

How to take Dozavit™

Take with water.

If you use too much Dozavit™

If you think that you have used too much Dozavit™, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

5. What should I know while using Dozavit™?

Things you should do

This medication is for the relief of minor and temporary ailments and should be used as directed.

If symptoms persist, consult your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using $Dozavit^{TM}$.

Things you should not do

Do not exceed the recommended dose.

Do not take for more than a few days.

Prolonged use without medical supervision may be harmful

Not recommended for children under 12 years of age.

Taking a skin test

Stop taking Dozavit™ 48 hours before you have any skin tests. Skin tests are used to determine the reaction of the body to a substance by observing the results of injecting the substance within the tissue of the skin or applying it topically to the skin. Antihistamine in Dozavit™ may interfere with the skin test results.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dozavit™ affects you.

Dozavit[™] is to aid sleep. Drowsiness may continue the following day. If affected, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Avoid alcohol while taking this medicine.

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the blister pack until immediately before use.

Follow the instructions in 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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Principles of good sleep hygeine

- 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 daytime naps
- Avoid caffeine-containing drinks from midday
- Avoid alcohol or the use of nicotine late in the evening
- Minimize 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.

6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Side effects	What to do
 Dizziness Stomach pain Vomiting Excessive drowsiness Dry mouth Inability to pass urine. 	Discontinue use and speak to your doctor or pharmacist if you have any of these side effects and they worry you.

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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Dozavit™ contains

Active ingredient	Doxylamine succinate
(main ingredient)	
Other ingredients	Calcium hydrogen phosphate
(inactive ingredients)	Croscarmellose sodium
	Microcrystalline cellulose
	Magnesium stearate
	Povidone
	Pregelatinised maize starch
	Purified talc

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

What Dozavit™ looks like

Dozavit™ is a white tablet with a break-bar on one side. (AUST R 340137).

Who distributes Dozavit™

SANDOZ PTY LTD

North Sydney, NSW 2060, Australia

Telephone No: 1800 726 369

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