

Dozile®

DOZILE TABLETS

Each tablet contains 25 mg Doxylamine Succinate.

Consumer Medicine Information

PLEASE READ THIS INFORMATION CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE.

This information provides a summary of the information available. It does not take the place of talking to your doctor or pharmacist who have more detailed information. Keep this information with the medicine, as you may want to read it again.

1. PRODUCT DESCRIPTION

Dozile tablets are white tablets with a break bar on one side, each tablet containing 25 mg of Doxylamine Succinate.

The tablets also contain the following inactive ingredients: calcium hydrogen phosphate, povidone, starch pregelatinised maize, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and talc.

Free from fragrance, colour, preservatives, lactose, yeast, dairy products, gluten, and PABA (p-aminobenzoic acid).

2. WHAT IS DOZILE USED FOR?

Dozile provides effective temporary relief of insomnia or sleeplessness.

It contains an active ingredient called Doxylamine Succinate. Doxylamine Succinate is an

antihistamine which helps you sleep.

If you want more information ask your doctor or pharmacist.

3. BEFORE YOU USE DOZILE TABLETS

- You must tell your doctor or pharmacist if you have any of these conditions:
 - Digestive problems
 - Glaucoma
 - Prostate problems
 - Problems passing urine
 - Heart problems
- See a doctor if you are pregnant or think you may be.
- See a doctor if you are breast-feeding.

When you must not use it

- Do not use Dozile tablets if you have an allergy to Doxylamine Succinate or to any other ingredient in the tablet (see section 1 entitled Product Description).
- If you have narrow angle glaucoma.
- If you have epilepsy.
- Do not use this product after the expiry date printed on the pack.
- Do not use Dozile tablets if the packaging is torn or shows signs of tampering.

Taking other medicines

Some medicines should not be taken with Dozile tablets.

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

In particular, you should tell your doctor or pharmacist if you are using:

- Any other medications used to help you sleep
- Medication for psychiatric disorders
- Any medicine which contains antihistamine
- 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

There are many other medicines or foodstuffs which may make you drowsy such as alcohol, sleeping tablets, medicines to treat mental disorders, tablets to calm your nerves and some antihistamines.

These medicines may be affected by Dozile, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist will advise you.

Taking a skin test

Stop taking Dozile tablets 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 Dozile may interfere with the skin test results.

4. HOW TO USE DOZILE TABLETS

Directions for use:

Adults and children over 12 years: Take 1 to 2 tablets with water 20 minutes before retiring.

Do not exceed the recommended dose.

Not recommended for children under 12 years of age.

Please read this information carefully before you start to take your medicine.

If you are unsure of how to take this medication ask your pharmacist or doctor.

5. WHILE YOU ARE USING DOZILE TABLETS

Precautions while using this medicine:

- This medication is for the relief of minor and temporary ailments and should be used as directed.
- Prolonged use without medical supervision may be harmful.
- If symptoms persist consult your doctor.
- This preparation is to aid sleep. This medication may cause drowsiness, which may continue the following day. If affected do not drive or operate machinery.
- Avoid alcohol.

6. IF YOU TAKE TOO MUCH (OVERDOSE)

Immediately telephone the Poisons Information Centre (Tel 131 126), or your doctor, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken an overdose of Dozile tablets even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose of Dozile tablets (and antihistamines in general) include excessive drowsiness, dizziness, impaired consciousness, nervousness, irrational behaviour, convulsions, dilated pupils, excitation, fast or irregular heartbeat or pulse rate, tremor and nausea or vomiting.

These are not the only possible symptoms of overdose.

7. UNWANTED SIDE EFFECTS

Dozile tablets provide relief of insomnia or sleeplessness but you may experience some of the following symptoms: dizziness, stomach pain, vomiting, excessive drowsiness, dry mouth or inability to pass urine. You may experience other symptoms – these are not the only possible adverse effects.

If you are concerned by any of these reactions, discontinue use and consult your doctor.

8. AFTER USING DOZILE TABLETS

Storage

Dozile tablets should be stored below 30°C until the expiry date shown on the carton and blister pack. Keep your tablets in the blister pack until immediately before use.

Do not leave Dozile tablets in the car on hot days.

Keep out of reach of children.

Disposal

Return any unused medicine to your pharmacist.

9. WHERE TO GO FOR FURTHER INFORMATION

If you have any questions about this or any other medication, discuss with your doctor or pharmacist.

10. SUPPLIER

Dozile tablets are supplied by:

Key Pharmaceuticals Pty Ltd

12 Lyonpark Road

Macquarie Park NSW 2113

Telephone: (02) 8113 6200

E-mail: otc@keypharm.com.au

The Australian Registration

Number for Dozile tablets is AUST R 143861

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Principles of good sleep hygiene:

- Go to bed and arise at the same time daily;
- Engage in relaxing activities before bedtime;
- Exercise regularly but not in the late evening;
- Avoid eating meals or large snacks 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 (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.

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