AUSTRALIAN PRODUCT INFORMATION – GOLD CROSS SLEEPWELL (DOXYLAMINE SUCCINATE) TABLETS

1 NAME OF THE MEDICINE

Doxylamine succinate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Gold Cross SleepWell tablet contains doxylamine succinate 25 mg.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

White concave tablet with break bar on one side.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Gold Cross SleepWell is indicated for the temporary relief of sleeplessness.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults and children over 12 years: 1 or 2 tablets with water 20 minutes before retiring. Do not exceed the recommended dose.

4.3 CONTRAINDICATIONS

Epilepsy, narrow angle glaucoma and known hypersensitivity to doxylamine succinate or to any other ingredients in the product.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Caution should be exercised with medical conditions such as prostatic enlargement, urinary retention, glaucoma, pyloroduodenal obstruction and cardiovascular disorders.

Use in the elderly

No data available.

Paediatric use

Not recommended for use in children under 12 years of age except on medical advice.

Effects on laboratory tests

Antihistamines should be discontinued approximately 48 hours prior to any skin tests since these drugs may suppress positive reactions to dermal reactivity indicators.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Doxylamine succinate may enhance the sedative effect of other CNS depressants such as opioid analgesics, neuroleptics, alcohol, hypnotics and psychotherapeutic drugs.

MAOIs may enhance doxylamine succinate's antimuscarinic effects.

An additive antimuscarinic action may be experienced with other antimuscarinic drugs such as atropine and tricyclic antidepressants.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

In the first trimester of pregnancy, Gold Cross SleepWell should be used only when the medical practitioner considers it essential for the welfare of the patient.

Use in lactation.

Gold Cross SleepWell should not be given to breast-feeding women, as it may inhibit lactation. Doxylamine succinate be excreted in human milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Doxylamine succinate may cause drowsiness in some patients. Such patients should avoid operating vehicles or machinery or engage in activities, which require them to be fully alert. Avoid alcohol.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Generally, antihistamines may cause dry mouth, dizziness, gastrointestinal disturbances blurred vision, urinary difficulty and retention, paradoxical CNS stimulation (insomnia, nervousness, euphoria, irritability, tremors, nightmares, hallucinations and convulsions) and tachycardia.

Epigastric distress, thickening of bronchial secretions and hypersensitivity reactions have also been reported.

Rarely - blood disorders, hypotension, tinnitus, headache and paraesthesia.

Doxylamine succinate may cause excessive drowsiness in some individuals.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Doxylamine succinate ingested in large amounts may cause impaired consciousness and less commonly cause psychotic behaviour, seizures, dilated pupils, tachycardia, and in one case, rhabdomyolysis had been reported.

Treatment: Supportive care, decontamination and enhancing elimination are useful in the treatment of overdose with doxylamine.

Supportive care - assessment of airway, breathing and circulation should be performed.

Decontamination - Administration of activated charcoal in a dose of 1-2 g/Kg of body weight for children and 50 -100 g for adults. Each gram of charcoal should be diluted with 6- 10 mL of water. Enhancing elimination - The clearance of the drug can be achieved by repeated doses of activated charcoal. Activated charcoal should not be used in patients in whom bowel sounds are absent.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Doxylamine succinate is an antihistamine of the ethanolamine class with pronounced sedative and antimuscarinic effects.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Doxylamine succinate has a peak plasma level 99 ng/mL, time of peak 2.4 hours, elimination half-life 10. 1 hours and apparent oral clearance 217 mL/min.
Elderly and young women did not differ significantly in peak plasma, time to Cmax, elimination half-life, volume of distribution or clearance. Cmax and tmax also did not differ between elderly and young men. However, elderly men had reduced doxylamine clearance and prolonged half-life in comparison to elderly women.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Gold Cross SleepWell tablets also contain: Calcium hydrogen phosphate, povidone, pre-gelatinised maize starch, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and talc.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30 °C

6.5 NATURE AND CONTENTS OF CONTAINER

Blister Pack.

Pack sizes: 10#, 12# and 20 tablets.

Not marketed.

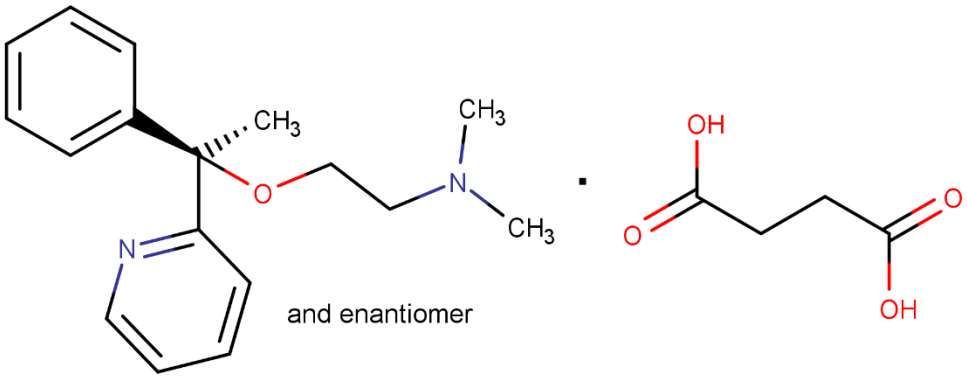
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Doxylamine succinate is a white or creamy white powder. Soluble in water (1 in 1), soluble in alcohol and in chloroform (1 in 2), slightly soluble in ether (1 in 370) (USP)

Chemical structure



Molecular formula: NN-Dimethyl-2-[a-methyl-a-(2-pyridyl)benzyloxy]ethyIamine hydrogen succinate

CAS number

562-10-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 (Pharmacist Only Medicine).

8 SPONSOR

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9 DATE OF FIRST APPROVAL

11 May 2010

10 DATE OF REVISION

10 November 2020

Summary table of changes

Section Changed	Summary of new information
All	Reformatted to current version