

AUSTRALIAN PRODUCT INFORMATION – TRADENAME (ACTIVE INGREDIENT) DOSE FORM

1 NAME OF THE MEDICINE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3 PHARMACEUTICAL FORM

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

4.2 DOSE AND METHOD OF ADMINISTRATION

4.3 CONTRAINDICATIONS

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions [if required]

Use in hepatic impairment [if required]

Use in renal impairment [if required]

Use in the elderly

Paediatric use

Effects on laboratory tests

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

Use in pregnancy – Pregnancy Category A/B1/B2/B3/C/D/X

Use in lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration. [optional]

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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

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

Clinical trials

5.2 PHARMACOKINETIC PROPERTIES

Absorption [if relevant]

Distribution [if relevant]

Metabolism [if relevant]

Excretion [if relevant]

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Carcinogenicity

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 - Qualitative and quantitative composition. [optional]

6.2 INCOMPATIBILITIES

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

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. [optional]

6.4 SPECIAL PRECAUTIONS FOR STORAGE

6.5 NATURE AND CONTENTS OF CONTAINER

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy. [optional – use one of these statements only]

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements. [optional – use one of these statements only]

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

CAS number

7 MEDICINE SCHEDULE (POISONS STANDARD)

8 SPONSOR

9 DATE OF FIRST APPROVAL

10 DATE OF REVISION

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information