Information contained in the Australian Product Information (PI)

This is a graphical representation of the broad information contained in the current approved form for product information (PI) in relation to medicine under subsection 7D (1) of the *Therapeutic Goods Act 1989*. It is for illustrative purposes only.

For full text and approved form, see SCHEDULE 1 – Approved form for product information (tga.gov.au)

The Australian Product Information (PI) contains the following information:

Trade name (active ingredient)

1	Name of the medicine	The Australian Approved Name (AAN) of the therapeutically active ingredient or, in the case of a fixed-dose combination or composite pack containing multiple therapeutically active ingredients, the AAN of each therapeutically active ingredient
2	Qualitative and Quantitative Composition	Describes the formulation(s) including quantity, proportion or strength, clinically relevant physical and chemical characteristics, and list of excipients with known effect
3	Pharmaceutical form	States dosage form, together with the visual description of the appearance of the product (colour, markings, tablet scoring etc)
4	Clinical Particulars	
4.1	Therapeutic indications	States specific therapeutic uses clearly and concisely as well as mandatory conditions of product usage, where relevant, if not covered more appropriately in other parts of the PI
4.2	Dose and Method of Administration	Dose, interval, method of administration, dosage adjustment (if applicable), any monitoring advice, along with relevant information such as relationship to meals and compatibility with other medicines and fluids
4.3	Contraindications	Describes situations in which persons should never/generally should never be treated with the medicine
4.4	Special warnings and precautions for use	Describes circumstances where caution is required in relation to the medicine, includes identified precautions and special warnings specific to the use of the medicine under relevant subheadings including mandatory subheadings for use in the elderly, paediatric use, and effects on laboratory tests
4.5	Interactions with other medicines and other forms of interactions	Describes clinically relevant interactions or other forms of interaction (such as with food) and other potentially serious interactions. Where relevant, also cross-referenced to ‘Section 6.2- Incompatibilities’
4.6	Fertility, Pregnancy and Lactation	Mandatory information on effects on fertility, use in pregnancy, and use in lactation
4.7	Effects on ability to drive and use in machines	Describes extent to which the medicine influences the ability of persons to drive or use machines
4.8	Adverse effects (undesirable effects)	States severity, clinical importance and frequency of adverse effects as well as information on how to report adverse events
4.9	Overdose	States symptoms, signs and recommended treatment of overdose or accidental poisoning
5	Pharmacological properties	
5.1	Pharmacodynamic properties	Contains mandatory information on the pharmacology and pharmacological actions of the medicine (mechanism of action) and information on clinical trials related to the indications, both positive and negative
5.2	Pharmacokinetic properties	Contains pharmacokinetics information for absorption, distribution, metabolism and excretion
5.3	Preclinical safety data	Contains preclinical safety data on genotoxicity and carcinogenicity
6	Pharmaceutical particulars	
6.1	List of excipients	Contains complete list of excipients
6.2	Incompatibilities	Contains information on physical and chemical incompatibilities of the medicine with other products with which it is likely to be mixed or co-administered
6.3	Shelf life	Duration of approved shelf-life
6.4	Special precautions for storage	Storage conditions
6.5	Nature and contents of container	Information on container type (for example glass vials, PVC/aluminium blisters), any other components (for example needles, swabs, syringes), and pack sizes
6.6	Special precautions for disposal	Any special precautions that may be required for safe disposal
6.7	Physicochemical properties	Chemical structure and the Chemical Abstracts Service (CAS) Registry Number of the medicine
7	Medicine Schedule (Poisons Standards)	The schedule of the current Poisons Standard in which the medicine is included (if applicable)
8	Sponsor	Name, address and contact details of the sponsor (legal entity responsible for the product)
9	Date of first approval	Date of first inclusion in the Australian Register of Therapeutic Goods
10	Date of revision	Date of the most recent TGA approved changes to an approved PI (including changes to tradenames) along with a summary of changes