

NAME OF PRODUCT

Product description

This section should include:

- *a description of the dosage form;*
- *a list of the active ingredients expressed quantitatively; and*
- *a list of the excipients expressed qualitatively*

Pharmacology

Pharmacokinetics:

Active 1

Active 2

Active 3

Pharmacodynamics/Mechanism of action:

Active 1

Active 2

Active 3

Indications

This section must contain the indications of the product as specified in the ARTG. If the indications are not specified in the ARTG (e.g. for a non-validated grandfathered product), the indications must be as specified on the product label.

Contraindications

Active 1

Active 2

Active 3

Precautions

Active 1

Active 2

Active 3

Use in children and the elderly

Active 1

Active 2

Active 3

Use in pregnancy

Sponsors may include either:

a) a warning against use in pregnancy (e.g. “[Name of product] is not recommended for use in pregnancy)

OR

b) the relevant text from the Core PI relating to each active ingredient.

Active 1

Active 2

Active 3

Use in lactation

Sponsors may include either

a) a warning against use in lactation (“[Name of product] is not recommended for use in breast feeding mothers)

OR

b) the relevant text from the Core PI relating to each active ingredient.

Active 1

Active 2

Active 3

Interaction with other medicines

Active 1

Active 2

Active 3

Adverse reactions

Active 1

Active 2

Active 3

Dosage

This section must contain the current dosage instructions of the registered product, as specified on the product label.

Overdosage

In case of overdose, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice.

Presentation

Information should be included on:

- *the presentation, including dosage form and pack sizes;*
- *identifying details (eg. colour, shape, identifying markings);*
- *poisons schedule details; and*
- *name and address of the sponsor*

Include the date of approval as the date on which the notification application is lodged