NEW ZEALAND DATA SHEET

Read the accompanying Data sheet template explanatory guide for guidance on how to compile each section.
{Required information is already in this template}

1 PRODUCT NAME

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

4.5 Interaction with other medicines and other forms of interaction

4.6 Fertility, pregnancy and lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

{Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/}

4.9 Overdose

{For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).}

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

6.3 Shelf life

6.4 Special precautions for storage

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

6.6 Special precautions for disposal <and other handling>

7 MEDICINE SCHEDULE

8 SPONSOR

9 DATE OF FIRST APPROVAL

10 DATE OF REVISION OF THE TEXT

SUMMARY TABLE OF CHANGES