For reference only – do not use this table in the template

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| **Changes to the Data Sheet Template** |
| September 2023 v1.2 | * Section 4.8 Reporting of suspected adverse reactions: changed reporting URL to: <https://pophealth.my.site.com/carmreportnz/s/>
 |
| November 2023: v1.3 | * Addition of new section: Changes to the Data Sheet Template
* Corrected hyperlink to the Data sheet template explanatory guide
* Section 4.8 Reporting of suspected adverse reactions: corrected formatting of reporting URL to remove final bracket
 |
| January 2025: v1.4 | * Added risk assessment wording in section 4.9
 |

Read the accompanying [Data sheet template explanatory guide](https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Data%20sheet%20template%20explanatory%20guide%20rev%201.pdf) for guidance on how to compile each section.

{Required information is already in this template}

## NEW ZEALAND DATA SHEET

## 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://pophealth.my.site.com/carmreportnz/s/>}

### 4.9 Overdose

{For risk assessment and 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