

Data sheet template

Read the accompanying [Data sheet template explanatory guide](#) for guidance on how to compile each section.

1 PRODUCT NAME (strength pharmaceutical form)

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

4.9 Overdose

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

6.6 Special precautions for disposal

7 MEDICINE SCHEDULE

8 SPONSOR

9 DATE OF FIRST APPROVAL

10 DATE OF REVISION OF THE TEXT

SUMMARY TABLE OF CHANGES