Australian Government
Department of Health
Therapeutic Goods Administration

OTC medicine monograph: Laxatives: Docusate sodium and/or sennosides

Version 1.0, September 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation /Complementary and OTC Medicines Branch	15/09/2015

Contents

Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral laxative medicines containing docusate sodium and/or sennosides, when applied for as an OTC New Medicine N2 application. Proposed medicines must comply with all aspects of the monograph relevant to their strength and dosage form to qualify for evaluation as an N2 application.

This monograph should be read in conjunction with the document Requirements for OTC new medicine N2 applications.

Active substance

This monograph only applies to medicines containing docusate sodium (CAS no. 577-11-7) and/or Sennosides USP* (a partially purified complex containing not less than 60% Sennosides A and B) as active ingredients and excludes preparations containing any other salts or derivatives of these substances.

* The application form should specify both the quantity of Sennosides USP and the 'component' (or equivalent) content of Sennosides A and B.

Dosage forms and strengths

Acceptable dosage forms and strengths are shown in the table below.

Active substance/strength	Dosage forms (excludes modified release dosage forms)
Docusate sodium (as single active) 50 mg or 120 mg	Tablet (uncoated, film-coated), capsule
Sennosides A and B (as single active) 8 mg or 12 mg	Tablet (uncoated, film coated or chewable), capsule
Docusate sodium 50 mg and Sennosides A and B 8 mg (as fixed combination)	Tablet (uncoated, film-coated), capsule

Indications

Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods

Docusate sodium

Faecal softener for relief of constipation.

Sennosides A and B

Stimulant laxative for relief of constipation.

Docusate sodium and sennosides

Faecal softener and stimulant laxative for relief of constipation.

Label indications

Docusate sodium

- Stool softener or softens the stools or stool softening laxative

Sennosides A and B

- For the relief (or treatment) of constipation (required)
- Laxative or stimulant laxative (also acceptable)

Docusate sodium and sennosides

- For the relief (or treatment) of constipation (required)
- References to stool softener and laxative or stimulant laxative as above (also acceptable)

Directions for use

Dosage

Dosage must be as shown in the table below.

Active ingredients and strength	Dosage
Docusate sodium 50mg	Adults and children 12 years and over: Two or three tablets/capsules twice daily, as necessary
Docusate sodium 120mg	Adults and children 12 years and over: Two tablets/capsules once daily, as necessary
Sennosides A and B 8 mg	Adults and children 12 years and over: Two to four tablets/capsules, as necessary
Sennosides A and B 12 mg	Adults and children 12 years and over: One to three tablets/capsules, as necessary
Docusate sodium 50 mg and sennosides A and B 8 mg	Adults and children over 12 years: One or two tablets/capsules, as necessary. Increase up to 4 tablets/capsules if necessary.

Reference to taking the dose at bedtime is acceptable.

Advisory statements

The following statements, or words to the effect, are required:

For docusate sodium:

- Not recommended for use in children under 12 years.
- Do not take with other medicines or liquid paraffin, unless advised by a doctor.
- Drink plenty of water.
- Increase fibre in diet except in cases of medication-induced constipation (e.g. with codeine);
- If symptoms persist, seek advice from a health care practitioner.
- Prolonged use is not recommended and may lead to dependence.

For sennosides:

- Not recommended for use in children under 12 years.

- Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea.
- If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.
- Drink plenty of water.
- Increase fibre in diet except in cases of medication-induced constipation (e.g. with codeine).
- If symptoms persist, seek advice from a health care practitioner.
- Prolonged use is not recommended and may lead to dependence or serious bowel problems.

For docusate sodium and sennosides:

Include all of the above statements for sennosides as well as the following, regarding docusate sodium:

- Do not take with other medicines or liquid paraffin, unless advised by a doctor.

Note: This monograph currently includes all required advisory statements for docusate sodium and sennosides, including those specified in the 'Australian regulatory guidelines for OTC medicines' (ARGOM) and the 'Required advisory statements for medicine labels' (RASML).

Labelling

Labelling must comply with all relevant Australian regulatory requirements, as detailed in the document Requirements for OTC new medicine N2 applications, including all required warning statements.

Sennosides content should be expressed on labelling as 'Sennosides A and B'.

Quality requirements

In addition to the quality requirements outlined in the document Requirements for OTC new medicine N2 applications, the specific requirements detailed below also apply.

Finished product specifications

In addition to other requirements specified in the document Requirements for OTC new medicine N2 applications, the finished product specifications must comply, at a minimum, with the relevant set of requirements below.

The requirements below include relevant BP general monograph/USP General Chapter requirements and TGO78 requirements. References to pharmacopoeial monographs below refer to the **current** monograph at time of application.

As for all N2 applications, tests for identification, assay and dissolution must use either the relevant pharmacopoeial method validated for specificity and accuracy or an alternative equivalent or superior method validated fully as described in the ICH guideline, CPMP/ICH/381/95 *Note for Guidance on Validation of Analytical Procedures: Text and Methodology.*

Docusate sodium

The tests and limits of the USP monograph *Docusate Sodium Tablets* or BP monograph *Docusate Capsules*, as relevant, with the addition of:

- tablet/capsule appearance
- uniformity of dosage units (BP)[1]
- microbiological quality, in compliance with TGO 77.

Sennosides

The tests and limits of the USP monograph *Sennosides Tablets*, with the addition of:

- tablet/capsule appearance
- microbiological quality, in compliance with TGO 77.

Docusate sodium and sennosides

The tests and limits of the USP monograph *Docusate Sodium Capsules* or BP monograph *Docusate Capsules*, as relevant, and the tests and limits of the USP monograph *Sennosides Tablets*, with the addition of:

- tablet/capsule appearance
- uniformity of dosage units (BP)[1]
- microbiological quality, in compliance with TGO 77.

[1] Already captured in USP monographs. Included with reference to *Docusate Capsules BP* only.

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