SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusate Sodium 100 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains Docusate sodium Ph. Eur. 100 mg.

Excipients with known effect: sorbitol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule.

Approximately 13mm long and 7mm wide yellow opaque, oval, soft gelatin capsule containing clear to pale yellow liquid fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

a) To prevent and treat chronic constipation.

(i) to soften hard, dry stools in order to ease defaecation and reduce straining at stool; and

(ii) in the presence of haemorrhoids and anal fissure, to prevent hard, dry stools and reduce straining

b) As an adjunct in abdominal radiological procedures

4.2 Posology and method of administration

Posology

Adults:

Up to 500 mg should be taken daily in divided doses. Treatment should be commenced with large doses, which should be decreased as the condition of the patient improves.

For use with barium meals:

400 mg to be taken with the meal.

Elderly:

As for adults.

Paediatric population:

The safety and efficacy of Docusate Sodium 100mg Capsules in children aged 0 to 11 years have not yet been established. No data is available.

Method of administration

For oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Docusate Sodium 100mg Capsules should not be administered when abdominal pain, nausea, vomiting or intestinal obstruction is present.

4.4 Special warnings and precautions for use

Organic disorders should be excluded prior to the administration of any laxative.

The treatment of constipation with any medicinal product is only adjuvant to a healthy lifestyle and diet, for example:

- increased intake of fluids and dietary fibre.
- advice on appropriate physical activity

If laxatives are needed every day, or if there is persistent abdominal pain, consult your doctor.

Excipients

Fructose intolerance:

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Docusate Sodium 100mg Capsules should not be taken concurrently with mineral oil.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of the drug in pregnant women. Animal studies are insufficient with respect to effects on pregnancy and embryonic foetal development. The potential risk for humans is unknown. During wide use, no adverse consequences have been reported.

Use in pregnancy only if the benefits outweigh the risks.

Breast-feeding

Docusate sodium is excreted in breast milk and should therefore, be used with caution in lactating mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Frequencies are defined as follows: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Gastrointestinal disorders:

Rare: diarrhoea, nausea, abdominal cramps

Skin and subcutaneous tissue disorders:

Not known: skin rash and pruritus.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Management

In rare cases of overdose, excessive loss of water and electrolytes should be treated by encouraging the patient to drink plenty of fluid. Electrolyte loss should be replenished where appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: softeners, emollients, ATC code: A06AA02 Mechanism of action

Docusate sodium is an anionic wetting agent, which acts as a faecal softener by lowering the surface tension and allowing penetration of accumulated hard dry faeces by water and salts.

Docusate Sodium also possesses stimulant activity.

5.2 Pharmacokinetic properties

Distribution

Docusate sodium exerts its clinical effect in the gastrointestinal tract.

Elimination

There is some evidence that docusate sodium is absorbed and is excreted in the bile.

There is also evidence that docusate sodium is capable of enhancing absorption of certain compounds administered concomitantly.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol

Macrogol 400

Shell Formulation

Gelatin 200 bloom Purified water Sorbitol

Glycerol

Titanium dioxide (E171) Quinoline yellow (E104)

6.2 Incompatibilities

None

6.3 Shelf life

2yrs

Expiry after first opening: 6 months

6.4 Special precautions for storage

Do not store above 30ºC. Store in the original package in order to protect from moisture

6.5 Nature and contents of container

90cc Multilayered HDPE Bottle with 38 mm – SP 400 Neck & 38 mm PPCR closure with liner containing 100 capsules.

40cc Multilayered HDPE Bottle with 33 mm – SP 400 Neck & 33 mm PPCR closure with liner containing 30 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Iilco (UK) Ltd
Unit 1b, 142 Johnson Street, London, UB2 5FD
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 58775/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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