SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Docusate sodium 12.5mg/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of the solution contains docusate sodium 12.5mg

Excipient(s) with known effect:

Methyl parahydroxybenzoate (E218) 5.0mg per 5ml dose

Propyl parahydroxybenzoate (E216) 2.5mg per 5ml dose

Sorbitol 70% (E420) 840.0mg per 5ml dose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Clear, colorless liquid with strawberry odor.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

a) To prevent and treat chronic constipation

b) As an adjunct in abdominal radiological procedures

4.2 Posology and method of administration

For oral administration

Children: 12.5mg (5ml) to 25mg (10ml) three times daily. Dilute the medicine in a glass of flavoured drink eg fruit juice or milk. Drink the diluted medicine within 30 minutes of preparation.

Infants (Over six months): 12.5mg (5ml) three times daily. Dilute the medicine in a glass of flavoured drink eg fruit juice or milk. Drink the diluted medicine within 30 minutes of preparation.

Adults: not appropriate for adults or elderly. For administration to adults use Docusate Sodium 50mg/5ml or 100mg/5ml oral solution.

For barium meals: 75mg (30ml) to be taken with meal.

4.3 Contraindications

Docusate sodium solution should not be taken

• by patients with a known hypersensitivity to docusate sodium or to any of the excipients listed in section 6.1.

• in the presence of abdominal pain, intestinal obstruction, nausea or if vomiting occurs.

4.4 Special warnings and precautions for use

Docusate sodium oral solution should not be given to infants under six months. Prolonged use can precipitate the onset of an atonic nonfunctioning colon and hypokalaemia.

Docusate sodium oral solution contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

This medicine contains 840.0mg sorbitol in each 5ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not be given this medicinal product.

This medicinal product contains 29.7mg sodium per 30ml (maximum daily dose), equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Docusate sodium solution should not be taken concurrently with mineral oil. Anthraquinone derivatives should be taken in reduced doses, if administered with Docusate sodium as their absorption is increased.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety of the drug in human pregnancy, nor is there evidence from animal work that it is free from hazard, but it has been in wide use for many years without apparent ill consequence. Use in pregnancy only if the benefits outweigh the potential risks.

Lactation

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

Fertility

Animal studies did not show an effect of docusate sodium on fertility.

There are no clinical data available about the effect of docusate sodium on fertility.

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.

There have been spontaneous reports of burning sensation in mouth and throat following the use of Docusate sodium. Patients are advised to drink plenty of water or flavoured drink after taking the solution.

Reporting of suspected adverse reactions

Reporting suspected adverse reaction 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

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A06AA02 Laxatives, softeners, emollients

Docusate sodium acts as a faecal softener by increasing the penetration of water and fats.

5.2 Pharmacokinetic properties

Docusate sodium exerts its effects by means of its physical surfactant properties. However, there is some evidence that it is absorbed from the gastrointestinal tract and excreted in bile.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Sodium dihydrogen phosphate dihydrate (E339i)

Disodium hydrogen phosphate dihydrate (E339ii)

Glycerol (E422)

Kollidon 90F (E1201)

Sorbitol 70% (E420)

Sucralose (E955)

Citric acid (E330)

Strawberry flavor

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

Once opened use within one month

6.4 Special precautions for storage

None

6.5 Nature and contents of container

Docusate sodium 12.5mg/5ml oral solution is available in an amber glass bottle of 300ml with a plastic screw cap. It comes with a dosing cup with 2.5 / 5 / 10 / 15 ml graduations.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Lucis Pharma Ltd

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Gloucestershire GL56 9QQ

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 42176/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/12/2021

10 DATE OF REVISION OF THE TEXT

29/01/2024