

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Docusate sodium 100mg/5ml oral solution

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

5ml of the solution contains docusate sodium 100mg

Excipient(s) with known effect:

Methyl parahydroxybenzoate (E218) 5.0mg per 5ml dose

Propyl parahydroxybenzoate (E216) 2.5mg per 5ml dose

Sodium benzoate (E211) 5.0mg 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**

Posology

Adults: 100mg (5ml) to 150mg (7.5ml) three times a day. Take as a single dose followed by plenty of water or flavoured drink e.g. milk or orange juice. Maximum daily dose 500mg (25ml).

Treatment should be commenced with large doses, which should be decreased as the condition of the patient improves.

For barium meals: 400mg (20ml) to be taken with the meal.

Elderly: There is no evidence to suggest that an adjustment of the dosage is necessary in the elderly.

#### *Paediatric population*

Children: For administration to children and infants over 6 months use Docusate sodium 12.5mg/5ml.

## Method of administration

Oral use

### **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 100mg/5ml oral solution is not recommended for children aged 12 years and under.

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.

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 5.0mg sodium benzoate in each 5ml dose.

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 take/be given this medicinal product.

This medicinal product contains 28.8mg sodium per 25 ml dose (maximum daily dose), equivalent to 1.4% of the WHO recommended maximum daily intake of 2g 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.

##### Breast-feeding

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 ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  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](http://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**

Pharmacotherapeutic group: Softeners, emollients, ATC code: A06AA02

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 benzoate (E211)  
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 100mg/5ml oral solution is available in an amber glass bottle of 150ml or 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  
14 Aston Magna, Moreton in Marsh  
Gloucestershire GL56 9QQ  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 42176/0024

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

03/12/2021

**10 DATE OF REVISION OF THE TEXT**

04/07/2023