

## **PRESCRIBING INFORMATION**

### **ratio-DOCUSATE SODIUM**

**Docusate sodium USP**  
**20 mg / 5 mL syrup**  
**100 mg / 25 mL syrup unidose**

**Stool softener**

**Teva Canada Limited**  
**30 Novopharm Court**  
**Toronto, Ontario**  
**M1B 2K9, Canada**

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### **ACTIONS AND CLINICAL PHARMACOLOGY**

**ratio-DOCUSATE SODIUM** is an anionic surfactant with emulsifying, wetting and dispersing properties. In recommended oral doses, it lowers surface tension in the gastrointestinal tract, permitting water and fats to penetrate and soften fecal matter. It also appears to stimulate the secretion of water and electrolytes in the intestine.

The extent to which orally administered docusate salts are absorbed has not been determined, but these drugs appear to be absorbed to some extent in the duodenum and jejunum and subsequently excreted in bile.

Docusate agents do not interfere with the absorption of nutrients from gastrointestinal tract; however they increase the systemic absorption and the hepatic intake of lipids and other drugs administered concurrently, as well as increasing their toxicity.

By increasing intestinal motility, **ratio-DOCUSATE SODIUM** may potentially decrease transit time of concomitantly administered oral drugs and thereby decreasing their absorption.

### **INDICATIONS AND CLINICAL USE**

The management of constipation due to hard stools. In painful anorectal conditions, in cardiac and other conditions in which maximum ease of passage is desirable to avoid difficult or painful defecation and when peristaltic stimulants are contraindicated. Stool softening generally occurs within 1 to 3 days following initiation of therapy.

### **CONTRAINDICATIONS**

Presence of abdominal pain, nausea, fever or vomiting.

### **PRECAUTIONS**

Laxatives should not be given to children under 6 years of age unless prescribed by a physician. Since children are not usually able to describe their symptoms precisely, proper diagnosis should precede the use of a laxative. This will avoid the complication of a pre-existing condition (e.g., appendicitis) or the appearance of more severe side effects.

Do not take **ratio-DOCUSATE SODIUM** at the same time as other drugs without first consulting a physician. Do not administer **ratio-DOCUSATE SODIUM** within two hours of another medicine because the desired effect of the latter may be reduced. Do not administer concomitantly with mineral oil, increased absorption of the oil may result.

Overuse or extended use may cause dependence of bowel function. If a sudden change in bowel habits persists for two weeks or more, do not take any laxative without first seeking professional advice. Do not use any laxative for longer than one week unless the physician has ordered a special schedule. If a laxative produces no effect after it has been used as recommended for one week, or if rectal bleeding is observed, stop using the product and consult a physician.

Pregnancy and lactation:

Pregnant or nursing mothers should not take any drug, including **ratio-DOCUSATE SODIUM**, without consulting a health professional.

Drug Interactions:

Docusate agents do not interfere with the absorption of nutrients from the gastrointestinal tract; however they increase the systemic absorption and hepatic intake of lipids and other drugs administered concurrently.

**ADVERSE REACTIONS**

No serious effects have been reported, but excessive doses may cause anorexia, diarrhea and vomiting. Mild, transitory cramping pains may rarely occur. Skin rash is rare but has been observed.

**DOSAGE AND ADMINISTRATION**

Drink increased fluids (1 full glass (250 mL)) or more. To be taken with water or fruit juice. More rapid results are obtained when laxatives are taken on an empty stomach. Do not exceed the recommended dose.

**Orally-Suggested Daily Dosage:**

**ratio-DOCUSATE SODIUM Syrup:**

Adults and older children:	1 to 3 tablespoonfuls (15-45 mL) (Maximum of 8 tbsp.).
Children 6 to 12 years old:	2 teaspoonfuls (10 mL) two to three times daily.
Children 2 to 6 years old:	1/2 to 2 1/2 teaspoonfuls (2.5-12.5 mL).
Infants and children up to 2 years old:	As directed by physician.

**ratio-DOCUSATE SODIUM Unit dose:**

Adults and older children:	1 or 2 unit dose container(s) per day.
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Children 6 to 12 years old:

1 unit dose container per day.

### **AVAILABILITY OF DOSAGE FORMS**

#### **Syrup:**

Each teaspoonful (5 mL) of red mint flavoured syrup contains 20 mg docusate sodium USP. Non-medicinal ingredients in alphabetical order: Alcohol, artificial flavouring, citric acid, D&C red #33, FD&C red #40, menthol, methylparaben, peppermint oil, poloxamer, polyethylene glycol, propylparaben, purified water, sodium citrate and sucrose. Energy: 13.9 Kcal/5mL. Bottles of 500 mL.

#### **Unit dose:**

Each unit dose (25 mL) container contains 100 mg docusate sodium. Non-medicinal ingredients in alphabetical order: Alcohol, artificial flavouring, citric acid, D&C red #33, FD&C red #40, menthol, methylparaben, peppermint oil, poloxamer, polyethylene glycol, propylparaben, purified water, sodium citrate and sucrose

**ratio-DOCUSATE SODIUM should be stored in the container in which they were purchased. Do not expose container or contents to humidity, sources of heat or direct light.**

Store between 15 - 30°C.

**Additional Information: This leaflet was prepared by**

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