DOCUSATE SODIUM- docusate sodium capsule, liquid filled
DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DOCUSATE SODIUM

OTC - ACTIVE INGREDIENT SECTION

Docusate Sodium 100 mg

OTC - PURPOSE SECTION

Stool softener

INDICATIONS & USAGE SECTION

- for prevention of dry, hard stools
- for relief of occasional constipation

This product generally produces a bowel movement within 12 to 72 hours.

WARNINGS SECTION

Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for longer than 1 week, unless directed by a doctor

Ask a doctor before use if

if you notice a sudden change in bowel habits that persists over a period of 2 weeks.

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

Directions

adults and children over 12 years of age	take 1 to 3 softgels preferably at bedtime
children 6-12 years of age	take 1 softgel at bedtime
children under 6 years	ask a doctor

Other information

- each softgel contains: sodium 6 mg
- store between 15°-30°C (59°-86°F)

Questions or comments?

1-800-645-2158

Principal Display Panel

COMPARE TO ACTIVE INGREDIENT IN COLACE®*

NON-HABIT FORMING

Stool Softener Laxative

Docusate Sodium USP, 100 mg

SOFTGEL CAPSULES

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

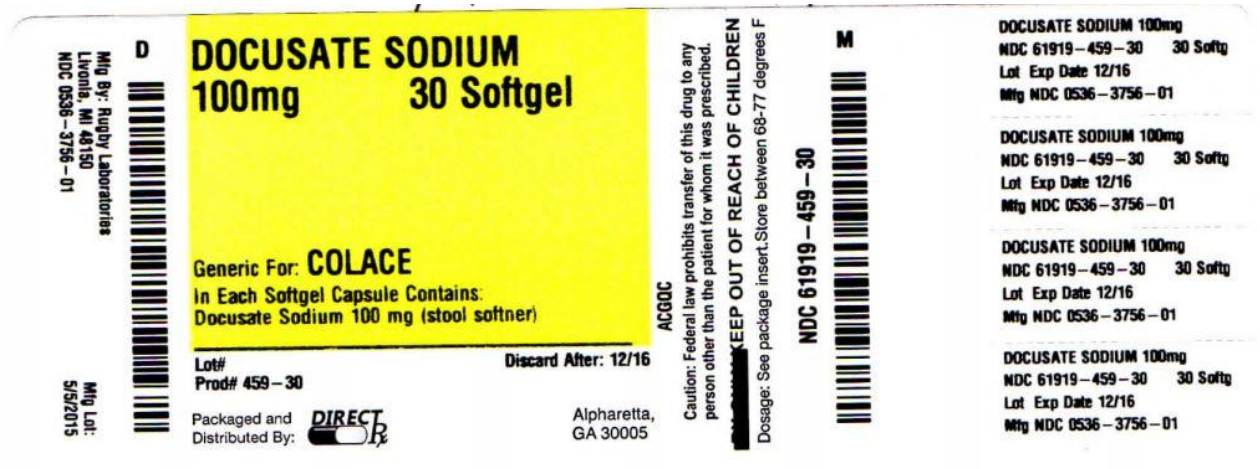
*Rugby Laboratories is not affiliated with the owner of the trademark Colace®.

Distributed by: Rugby Laboratories

31778 Enterprise Drive

Livonia, MI 48150

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



OTC - KEEP OUT OF REACH OF CHILDREN SECTION

In case of overdose, get medical help or contact a Poison Control Center right away.

INACTIVE INGREDIENT SECTION

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special.

DOCUSATE SODIUM
docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-459(NDC:0536-3756)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	P51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-459-71	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61919-459-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-459)