DOCUSATE SODIUM - docusate sodium capsule, liquid filled
Unit Dose Services

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.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are currently taking mineral oil, unless directed by a doctor

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- have noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use
- you need to use a stool softener laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- doses may be taken as a single daily dose or in divided doses

adults and children 12 years and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily

children under 2 years	ask a doctor

Other information

- each capsule contains sodium 6 mg
- store at room temperature 15º-30ºC (59º-86ºF)
- **Tamper Evident:** Do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients: D&C red #33,Edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special

Questions?

Adverse drug event call (800) 687-0176

HOW SUPPLIED

Product: 50436-1222

NDC: 50436-1222-1 30 CAPSULE, LIQUID FILLED in a BOTTLE

DOCUSATE SODIUM (DOCUSATE SODIUM) CAPSULE, LIQUID FILLED

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-1222(NDC:66424-030)
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
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)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red (Two toned- white and clear red)	**Score**	no score
Shape	OVAL	**Size**	5mm
Flavor		**Imprint Code**	51A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-1222-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/15/2010	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-1222) , RELABEL(50436-1222)

Revised: 12/2016 Unit Dose Services