DOCUSATE SODIUM - docusate sodium capsule
Pharbest Pharmaceuticals, Inc.

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
- prevents/relieves dry hard stool
- results usually occurs 1 to 3 days after the first dose

Warnings

Do not use
- when abdominal pain, nausea, or vomiting are present
- for more than one week unless directed by a doctor

Ask a doctor before use if you
- are taking mineral oil
- have noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if
- you have no bowel movement after 3 days
- you have rectal bleeding

These could be signs of a serious condition

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
- do not exceed recommended dose

adults and children over 12 years	take 1-2 softgels daily until first bowel movement; 1 softgel daily

12 years	thereafter
children 6 to 12 years	take 1 softgel daily
children under 6 years	consult a doctor

Other information

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature 15º to 30ºC (59º to 86ºF)
- protect from moisture

Inactive ingredients: D&C yellow #10, FD&C red #40, gelatin, glycerin, ink white, polyethylene glycol, sorbitol, propylene glycol.

Questions?

Adverse drug event call: (866) 562-2756

Principal Display Panel

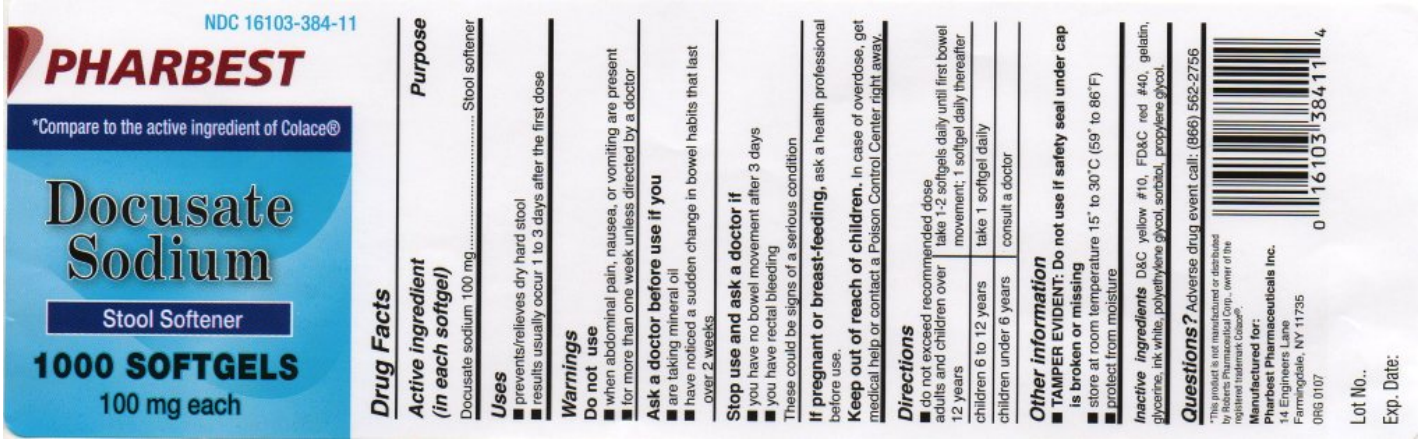
*Compare to the active ingredient of Colace®

Docusate Sodium

Stool Softener

1000 SOFTGELS

100 mg each



DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16103-384
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 Yellow No. 10 (UNII: 35SW5USQ3G)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Polyethylene Glycol (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:16103-384-08	100 in 1 BOTTLE		
2	NDC:16103-384-11	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/22/2007	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc		557054835	repack

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Ltd.		248441727	manufacture

Revised: 7/2010 Pharbest Pharmaceuticals, Inc.