STOOL SOFTENER- docusate sodium capsule
Valu Merchandisers Company (Best Choice)

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 capsule)

Docusate Sodium 100 mg

Purpose

Stool softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation. This product generally produces a bowel movement within 12 to 72 hours.

Warnings - 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

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

If pregnant or breastfeeding

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.

Directions

- **adults and children 12 years of age and over:** take 1- 3 capsules, preferably at bedtime
- **children 6 to 12 years of age:** take 1 capsule at bedtime

Other information

- **each capsule contains:** sodium 6 mg
- store at controlled room temperature 15º - 30º C (59º- 86º F)
- do not use if imprinted safety seal under cap is broken or missing.
- *This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered trademark Colace®

Inactive Ingredients

D&C Red #33, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special and titanium dioxide. May also contain: FD&C blue #1 and purified water.

Questions or Comments?

Call toll free: **1-877-753-3935**

Principal Display Panel

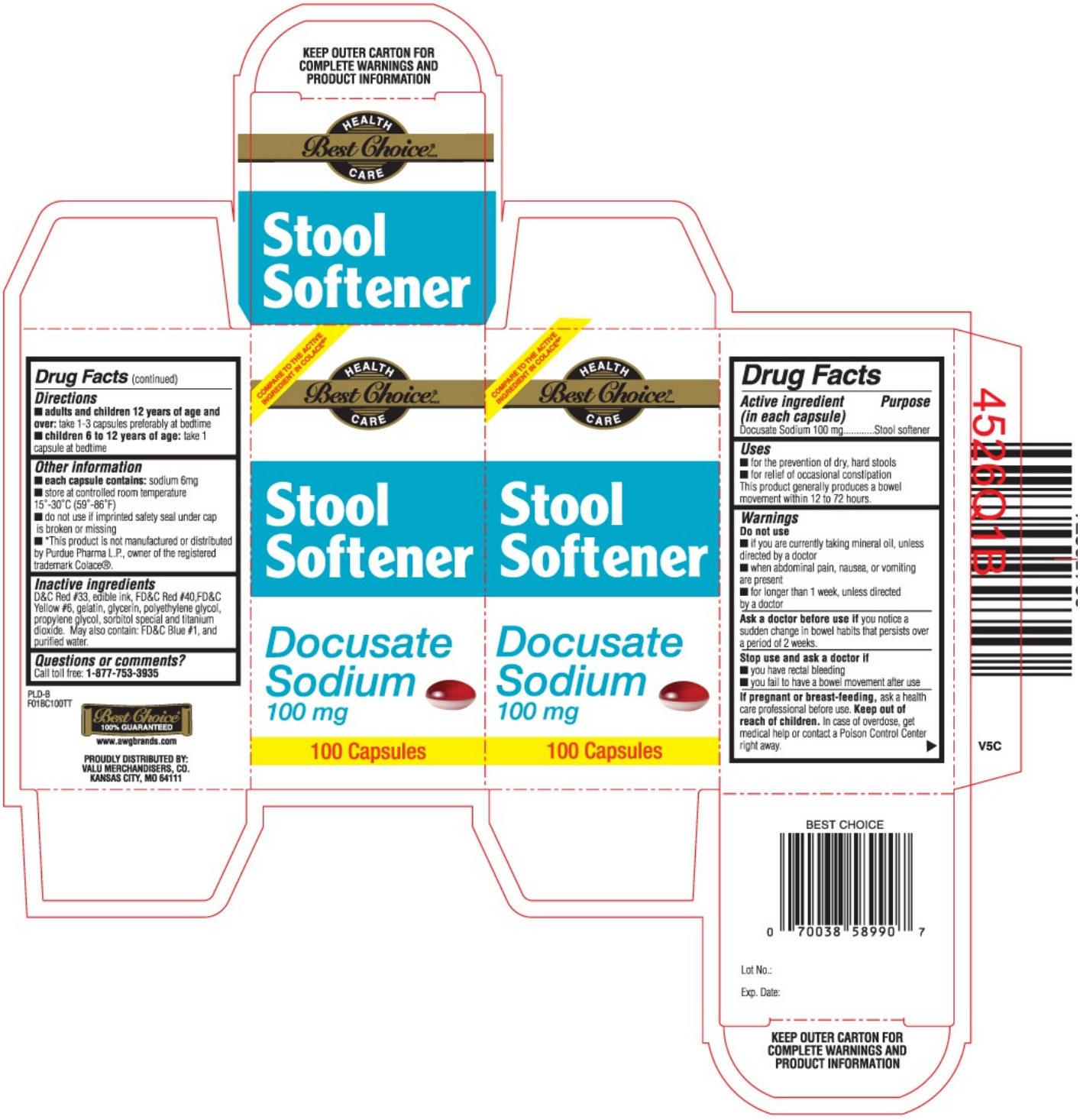
Compare to active ingredient in COLACE®*

stool softener

Docusate sodium 100 mg

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Docusate Sodium 100 mg

STOOL SOFTENER

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63941-146
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)	
SORBITOL (UNII: 506T60A25R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	RED, WHITE	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	P10;51A
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63941-146-01	1 in 1 BOX		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	08/24/2010	

Labeler - Valu Merchandisers Company (Best Choice) (868703513)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 11/2012 Valu Merchandisers Company (Best Choice)