DOK EXTRA STRENGTH STOOL SOFTENER- docusate sodium capsule, liquid filled Liberty 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 250mg

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 taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for more 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 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 over 12 years of age and over: take 1 softgel daily or as directed by a doctor
- **children under 12 years of age**: take as directed by a doctor

Other information

- each softgel contains sodium 15mg
- store at controlled room temperature 15° 30° C (59°- 86° F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

edible white ink, FD&C Red No# 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified wter, sorbitol special.

Questions or comments?

Adverse Drug Event Call: (800) 616-2471

Product Labeling

MAJOR DOKTM

Docusate Sodium 250 mg

Extra Strength Stool Softener

For use as a Stool Softener in treating & Avoiding Constipation

Distributed by:

Major Pharmaceuticals

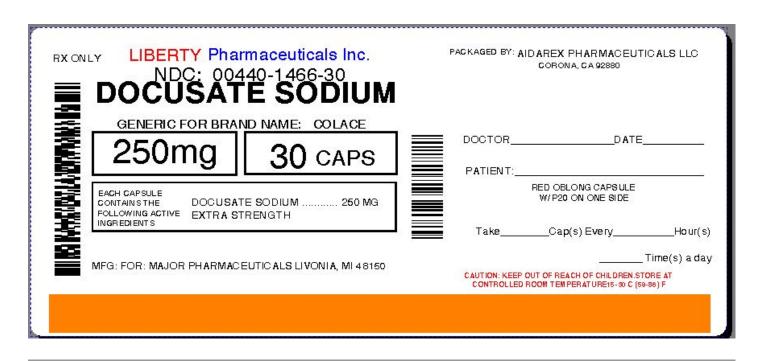
31778 Enterprise Drive

Livonia, MI 48150, USA

Repackaged By:

Aidarex Pharmaceuticals LLC,

Corona, CA 92880



DOK EXTRA STRENGTH STOOL SOFTENER docusate sodium capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0440-1466(NDC:0904-7891)

ORAL

Active Ingredient/Active Moiety

SORBITOL (UNII: 506T60A25R)

8 · · · · · · · · · · · · · · · · · · ·		
Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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)			

Product Character	Product Characteristics				
Color	ORANGE (orange)	Score	no score		
Shape	CAPSULE	Size	20 mm		
Flavor		Imprint Code	P20		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0440-1466-30	30 in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	08/27/2002		

Labeler - Liberty Pharmaceuticals, Inc. (012568840)

Revised: 9/2013 Liberty Pharmaceuticals, Inc.