DOCUSATE SODIUM- docusate sodium tablet
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.

Doc

OTC - ACTIVE INGREDIENT SECTION

Docusate sodium 100 mg

OTC - PURPOSE SECTION

Stool softener

INDICATIONS & USAGE SECTION

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

OTC - DO NOT USE SECTION

Do not use if you are presently taking mineral oil, unless told to do so by a doctor

OTC - ASK DOCTOR SECTION

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

OTC - STOP USE SECTION

you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
you need to use a laxative for more than 1 week

OTC - PREGNANCY OR BREAST FEEDING SECTION

If pregnant or breast-feeding, ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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

DOSAGE & ADMINISTRATION SECTION

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

OTHER SAFETY INFORMATION

each softgel contains: sodium 5 mg VERY LOW SODIUM
store at 15°-30°C (59°-86°F)
keep tightly closed

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

INACTIVE INGREDIENT SECTION

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol 400, purified water, sorbital special

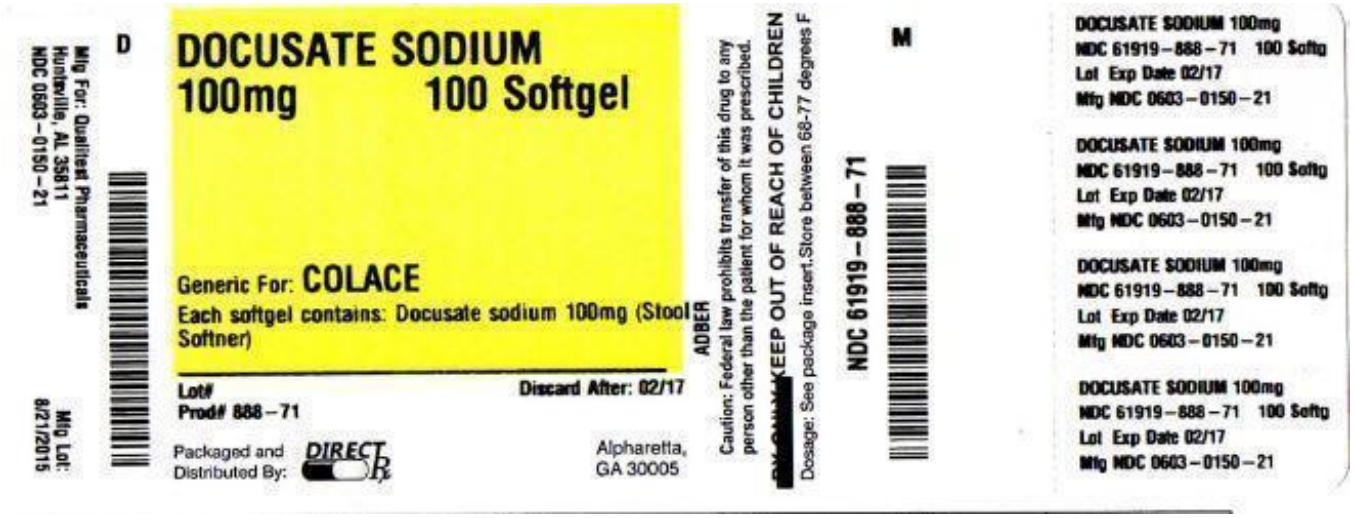
SPL UNCLASSIFIED SECTION

Manufactured for:
QUALITEST PHARMACEUTICALS
HUNTSVILLE, AL 35811

R0 07/2011
015021CPR

WARNINGS SECTION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



DOCUSATE SODIUM

docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-888(NDC:0603-0150)
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 GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red (Reddish)	**Score**	no score
Shape	capsule	**Size**	12mm
Flavor		**Imprint Code**	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-888-71	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61919-888-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	
3	NDC:61919-888-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2015	

Labeler - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	relabel(61919-888) , repack(61919-888)

Revised: 11/2015 Direct Rx