DOCQLACE- docusate sodium capsule
Qualitest Pharmaceuticals

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.

DocQLace

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 presently taking mineral oil, unless told to do so by a doctor

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- 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

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 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- each 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*.

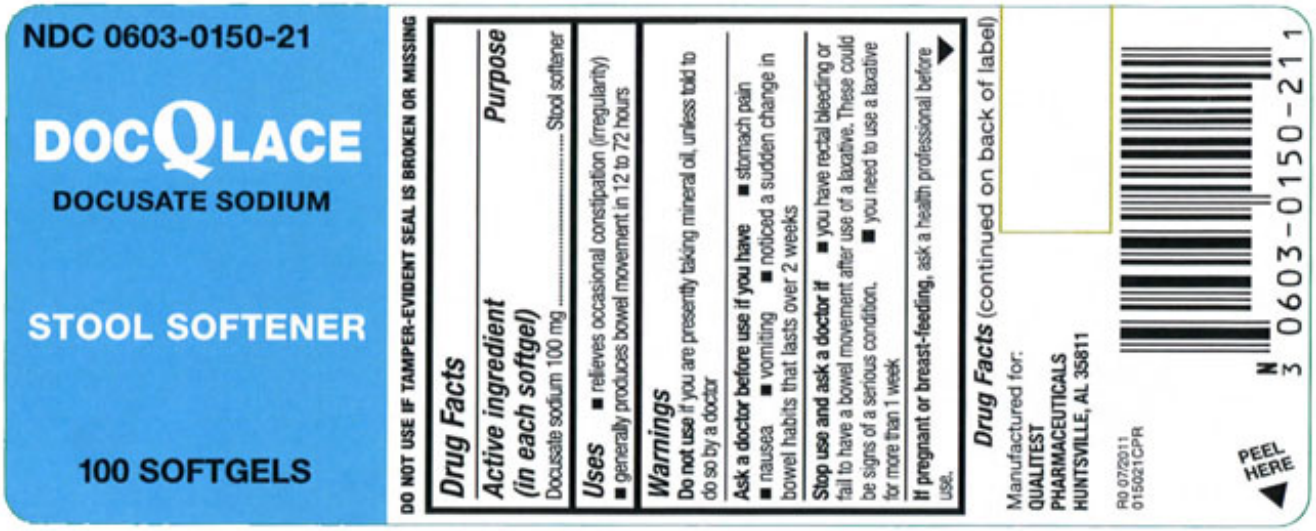
Inactive ingredients

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

Manufactured for:
QUALITEST PHARMACEUTICALS
HUNTSVILLE, AL 35811

R0 07/2011
015021CPR

PRINCIPAL DISPLAY PANEL



NDC 0603-0150-21

DOCQLACE

DOCUSATE SODIUM

STOOL SOFTENER

100 SOFTGELS

DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING

Drug Facts

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Drug Facts (continued on back of label)

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QUALITEST
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DOCQLACE

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0603-0150
Route of Administration	ORAL	**DEA Schedule**	

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:0603-0150-21	100 in 1 BOTTLE, PLASTIC		
2	NDC:0603-0150-32	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	08/01/2011	

Labeler - Qualitest Pharmaceuticals (011103059)

Revised: 10/2012 Qualitest Pharmaceuticals