DQZATE STOOL SOFTENER- docusate sodium capsule, gelatin coated
All Pharma LLC

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.

DQZATE Stool Softner

Warnings

Do Not use if you are presently taking mineral oils unless told to do so by a doctor.

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

relief of occasional constipation (irregularity)

generally produces bowel movement in 12 to 72 hours

If pregnant or breast-feeding

ask a doctor before use.

Keep out of reach of children.

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

Stop use and ask a doctor

If you have rectal bleeding

If you fail to have bowel movement after use of a laxative

If you need to use a stool softner laxative for more than a week

Directions

Adults and children 12 years and over:Take 1-3 Capsules once daily or in divided doses.

Children 6 years to under 12:Take one capsule once a day.

Children under 6 years: Ask your Doctor.

Other information

each softgel contains: sodium 7 mg

keep tightlyl closed

store at room temperature 15°-30°C (59°-86°F) in a dry place

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, sorbitol,purified water

DQZate

Label

DQZATE STOOL SOFTENER

docusate sodium capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53149-1001
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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red	**Score**	no score

Shape	capsule	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53149-1001-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/2019	

Labeler - All Pharma LLC (078572520)

Establishment

Name	Address	ID/FEI	Business Operations
All Pharma LLC		078572520	label(53149-1001)

Revised: 10/2020 All Pharma LLC