

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 tightly 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

NDC: 53149-1001-1

Drug Facts

Active Ingredient (in each capsule) **Purpose**
Docusate Sodium 100 mg Stool Softener

Uses
• relieves occasional constipation (irregularity)
• generally produces a 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 two weeks

Stop use and ask a doctor if • you have rectal bleeding
• you fail to have a bowel movement after use of a laxative
These could be signs of a serious condition. • you need to use a stool softener laxative for more than one week

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.

Drug Facts (continued)

Directions • take only by mouth
Adults and children 12 years and over Take 1-3 capsule once daily or in divided doses
Children 6 years to under 12 years Take 1 capsule once daily
Children under 6 years Ask a doctor

Other Information
• Each capsule contains: sodium 7 mg
• keep tightly 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 400, purified water, sorbitol

Questions? If you have any questions or comments, or to report an adverse event, please contact 800-491-7908

LOT: EXP:
MADE IN THE USA
Manufactured by: **AB** Pharma, LLC, Hialeah, FL 33016
www.dqzate.com

dqzate
Stool Softener
Docusate Sodium
100 mg/Capsules
100 Soft Gelatin Capsules

05062020

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: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	Score	no score
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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