DOCUSATE SODIUM- docusate sodium capsule, liquid filled
NuCare 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 250 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless directed by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last 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

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- **each softgel contains:** sodium 15 mg
- store between 20-25ºC(68-77ºF); excursions permitted between 15-30ºC (59-86ºF)

Inactive Ingredients

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan sorbitol

Questions or comments?

Call **1-800-616-2471**

Principal Display Panel

Extra Strength

Docusate Sodium

250 mg

Stool Softener

Laxative

Softgels

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

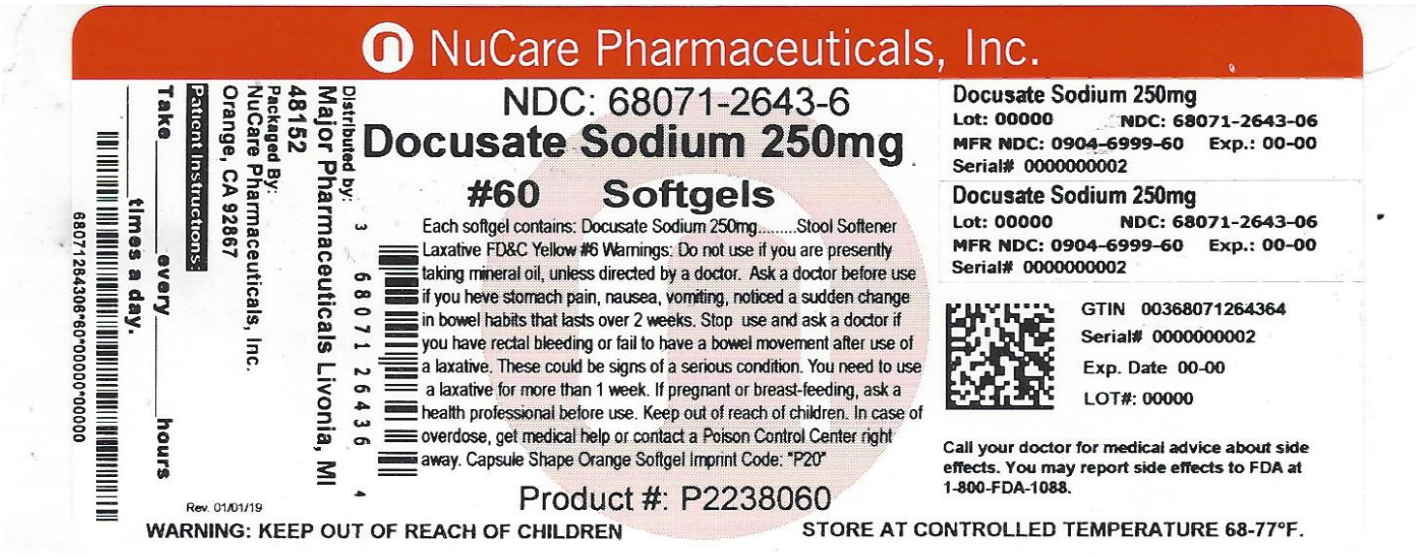
Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label



DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-2643(NDC:0904-6999)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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 GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 3OWL53L36A)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	20mm

Flavor		**Imprint Code**	P20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2643-6	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/30/2019	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-2643)

Revised: 2/2022 NuCare Pharmaceuticals,Inc.