DOCUSATE SODIUM- docusate sodium capsule, liquid filled
PD-Rx Pharmaceuticals, Inc.

Docusate Sodium, USP
Stool Softener

Active Ingredient *(in each softgel)*

Docusate Sodium 250 mg

Purpose

Stool Softener

Uses

- For the relief of occasional constipation.
- Helps to prevent dry, hard stools.
- This product generally produces a bowel movement within 12 to 72 hours.

WARNINGS Do not use:

- If you are currently taking mineral oil, unless directed by a doctor.
- When abdominal pain, nausea, or vomiting are present.
- For longer than one week unless directed by a doctor.

Ask a doctor before use

if you notice a sudden change in bowel habits that persists over a period of two weeks.

Stop use and ask a doctor

if you have rectal bleeding or you fail to have a bowel movement after use.

If pregnant or breast-feeding,

ask a healthcare professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (800) 222-1222.

Directions

Adults and Children over 12 years of age	Take orally 1 softgel preferably at bedtime for 2-3 days or until bowel movements are normal, or as directed by a doctor.

Children under 12 years of age	Do not use this product for children under 12 years of age, unless directed by a doctor.

Other Information

- **Each softgel contains 13 mg of Sodium.**
- Store at room temperature between 15°C to 30°C (59°F to 86°F).
- Do not use if printed seal under cap is broken or missing.
- For identification purposes, each softgel will have an imprint that reads NV12.

Inactive Ingredients

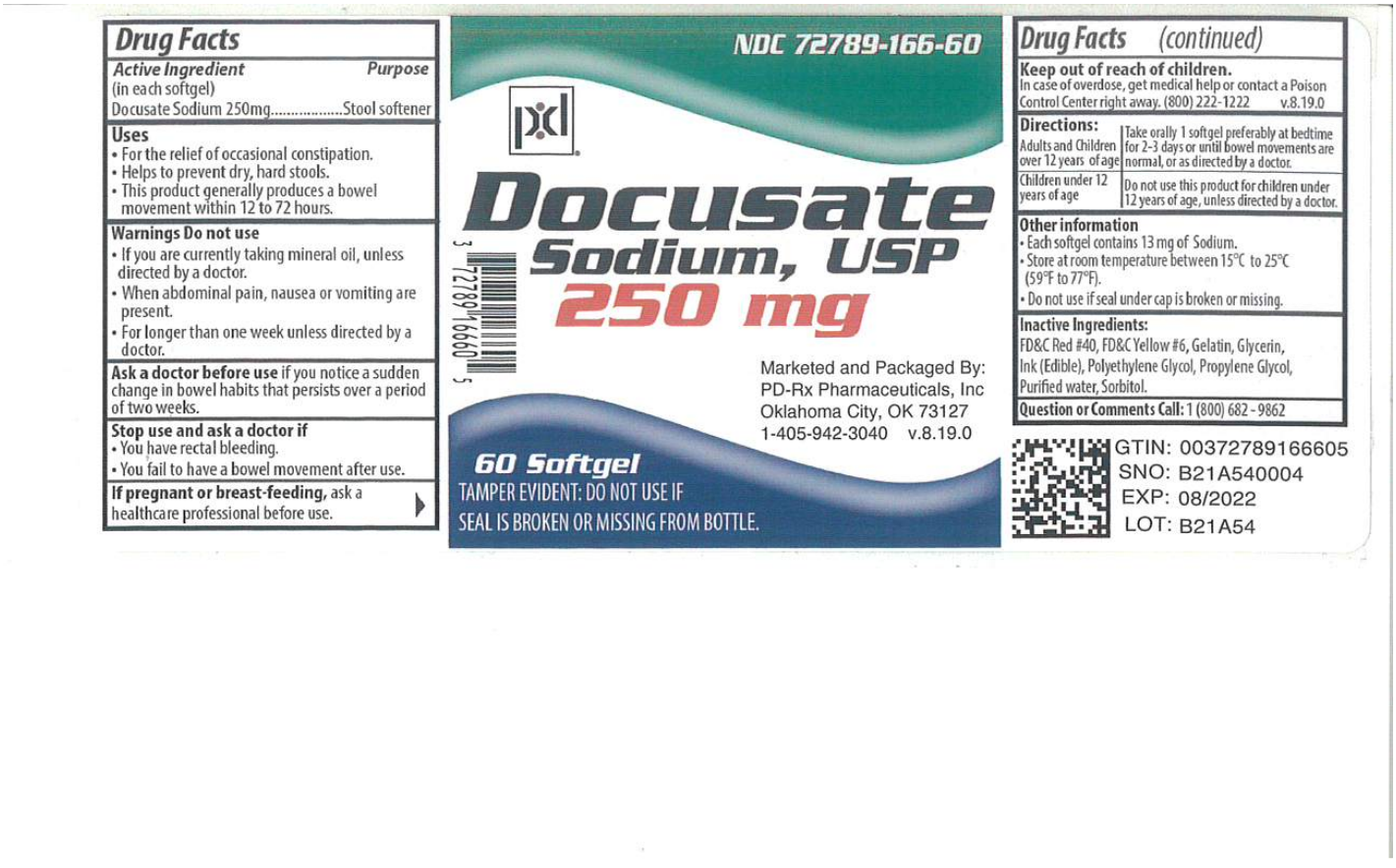
FD&C Red #40, FD&C Yellow #6, Gelatin, Glycerin, Ink (Edible), Polyethylene Glycol, Propylene Glycol, Purified Water, Sorbitol.

Questions

Call 1 (800) 682-9862

Package/Label Principal Display Panel

Docusate Sodium, USP
Stool Softener
250 mg Each



DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72789-166(NDC:54629-601)
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	NV12
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72789-166-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	05/01/2000	10/31/2027

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(72789-166)

Revised: 2/2025 PD-Rx Pharmaceuticals, Inc.