

**PROLAXA- docusate sodium 250mg capsule, liquid filled**  
**Terrain Pharmaceuticals**

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**Prolaxa™**

**Active ingredient (in each softgel)**

**Docusate sodium 250 mg - Extra Strength**

**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**

- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

## **Inactive Ingredients**

GELATIN, GLYCERIN, POLYETHYLENE GLYCOL, PROPYLENE GLYCOL, SORBITAN

## **Questions or comments?**

Call toll free (877) 985-8377 or [info@terrainrx.com](mailto:info@terrainrx.com)

## **Prolaxa™**

### **PROLAXA™**

Stool Softener

DOCUSATE SODIUM, 250 mg

STOOL SOFTENER LAXATIVE - SOFTGELS

- MAXIMUM STRENGTH
- Easy to swallow
- Relieves constipation
- Gentle Relieve
- Dependable
- Stimulant Free

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

## **Package Label; Display Panel**

### **Prolaxa™ Drug Facts**

NDC 53225-2001-1

**Prolaxa**<sup>TM</sup>

Docusate Sodium, 250MG

**Stool Softener**Maximum strength • Gentle relief  
Dependable • Stimulant-Free**100 softgels**

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DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

**Drug Facts****Active ingredient**  
Docusate sodium 250mg.....Stool Softener Laxative**Uses**

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

**Warnings**

- Ask a doctor before use if you have** • stomach pain • nausea • vomiting • noticed a sudden change in bowel habits that lasts over 2 weeks

**Ask a doctor before use if** • you are presently taking mineral oil**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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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:** store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)**Inactive ingredients**

gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution

**Questions?** Call toll-free (877) 985-8377 or info@terrainrx.com

Manufactured for:

**Terrain  
Pharmaceuticals, Inc.**  
Reno, NV 89509

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**PROLAXA**

docusate sodium 250mg capsule, liquid filled

**Product Information****Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:53225-2001

**Route of Administration**

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

<b>Color</b>	yellow (NAT-00 - Clear/Yellow)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Oblong)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	C76
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53225-2001-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/2025	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	04/15/2025	

**Labeler** - Terrain Pharmaceuticals (078358750)

Revised: 4/2025

Terrain Pharmaceuticals