DULCOEASE PINK- docusate sodium capsule, liquid filled Boehringer Ingelheim 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.

DulcoEase *Pink*® Docus ate Sodium (USP) 100 mg/Stool Softener Laxative

Drug Facts

Active ingredient (in each capsule)	Purpose
Docusate sodium (USP) 100 mg	Stool softener laxative

Use

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. 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 take with a glass of water

adults and children 12 years of	1 to 3 capsules daily. This dose may be taken as a single daily dose
age and over	or in divided doses.
children 2 to under 12 years of age	1 capsule daily
children under 2 years of age	ask a doctor

Other information

- each capsule contains: sodium 6 mg
- store at 20–25°C (68-77°F)
- protect from excessive humidity
- do not use this product if the safety seal under the cap is torn or missing

Inactive ingredients black iron oxide, D&C Red #33, FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, high polychains, hypromellose, isopropyl alcohol, mannitol, polyethylene glycol 400, propylene glycol, sorbitan, sorbitol, titanium dioxide, water

Questions? call **1-888-285-9159** (English/Spanish) M – F, 8:30 – 5 EST, or visit **www.Dulcolax.com**

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 $DulcoEase^{\circledR} \ Pink^{\tiny{TM}} \ 25 \ Capsules$

NDC: 0597-0151-23





DULCOEASE PINK

docusate sodium capsule, liquid filled

D	ro	duct	Info	rma	tion
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0597-0151

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		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
MANNITOL (UNII: 3OWL53L36A)			
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			

Product Characteristics			
Color	RED (red on one side) , WHITE (white on the other)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	L486

Contains

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0597-0151-23	1 in 1 CARTON	02/01/2013	11/30/2021	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0597-0151-30	1 in 1 CARTON	02/01/2013	11/30/2021	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:0597-0151-64	1 in 1 CARTON	02/01/2013	11/30/2021	
3		38 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 2/0 1/20 13	11/30/2021

 $\pmb{Labeler - } \ \ \text{Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)}$

Registrant - Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

Revised: 11/2019 Boehringer Ingelheim Pharmaceuticals, Inc.