EXTRA STRENGTH STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Aidapak Services, 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.

Docusate Sodium 250mg - Relabeled Product

Active Ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool Softener

Uses:

•for the prevention of dry, hard stools

•for relief of occasional constipation

•this product generally produces a bowel movement within 12 to 72 hours.

Do not use

•if you are currently taking mineral oil, unless directed by a doctor

•when abdominal pain, nausea, or

vomiting are present

•for more than 1 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 2 weeks.

Stop use and ask a doctor if:

•you have rectal bleeding

•you fail to have a bowel movement after use. These could be signs of a serious condition.

•ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact 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: take as directed by doctor.

Other Information:

each softgel contains: sodium 15 mg.

Store between 15-30 C (59-86 F)

edible white ink, FD&C red 40, FD&C yellow 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water and sorbitol special.

DOCUSATE SODIUM
Stool Softener
250 mg SOFTGEL
Lot: xxxxxxxx
EXP:xx/xx/xxxx
52327001110

Pkg By: AIDAPAK SERVICES
VANCOUVER, WA 98684

Docusate Sodium 250 mg softgel capsules

100 UD BLISTERS
NDC 52327-0011-11

AIDAPAK

52327001111

Docusate Sodium 250 mg softgel cap

Drug Facts

Active Ingredient (in each softgel)	*Purpose*
Docusate Sodium 250 mg	Stool Softener

Uses •for the prevention of dry, hard stools -for relief of occasional constipation •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 more than 1 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 2 weeks.

Stop use and ask a doctor if •you have rectal bleeding •you fail to have a bowel movement after use. These could be signs of a serious condition.

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 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: take as directed by doctor.

Other Information *each softgel contains: sodium 15 mg. Store between 15-30 C (59-86 F)*

Inactive Ingredients: edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water and sorbitol special.

Packaged by Aidapak Services, LLC, 14301 SE 1st St., Vancouver, WA 98684
www.aidapak.com (360) 448-2090

EXTRA STRENGTH STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52327-011(NDC:0536-3757)
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 in 250 mg

Inactive Ingredients

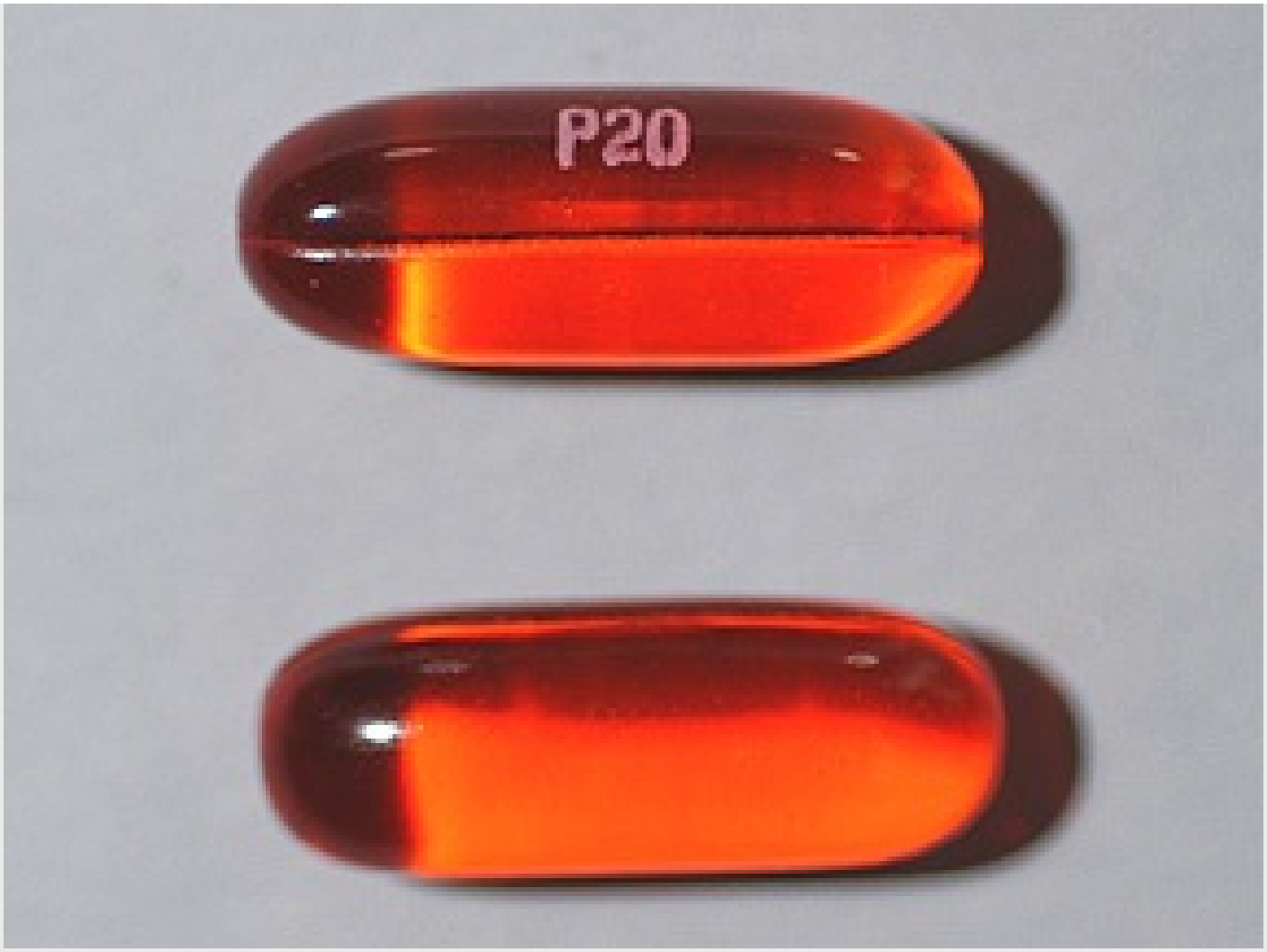
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	P20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52327-011-11	100 in 1 BLISTER PACK	10/20/2014	
1	NDC:52327-011-10	1 mg in 1 BLISTER PACK		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/20/2014	

Labeler - Aidapak Services, LLC (831612457)

Registrant - Aidapak Services, LLC (831612457)

Establishment

Name	Address	ID/FEI	Business Operations
Aidapak Services, LLC		831612457	relabel(52327-011)