COLACE- docusate sodium capsule, liquid filled
Avrio Health L.P.

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

Colace 50 mg

Active ingredients
(in each soft gel)

Docusate sodium 50 mg

Purpose

Stool softener

Uses

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

Warnings

Do not use

- if you are presently taking mineral oil, unless told to do so by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts 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 stool softener 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 only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1-6 soft gels daily
children 2 to under 12 years of age	take 1-3 soft gels daily
children under 2 years	ask a doctor

Other information

- each soft gel contains: **sodium 3 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Keep tightly closed.

Inactive ingredients

gelatin, glycerin, PEG 400, propylene glycol, sorbitol

Soft gels are imprinted with edible dye-free ink.

Dist. by: Avrio Health L.P.
Stamford, CT 06901-3431

304999-0A

Colace 50mg
28 Clear Soft Gels

COLACE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67618-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients	
Ingredient Name	Strength
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	BROWN (clear to light brown)	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	CLR;50
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-111-28	1 in 1 CARTON	01/07/1900	
1		28 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	01/07/1900	

Labeler - Avrio Health L.P. (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	MANUFACTURE(67618-111)

Establishment

Name	Address	ID/FEI	Business Operations
P&L Development, LLC		079765031	PACK(67618-111)

Revised: 1/2020 Avrio Health L.P.