COLACE KIT- docusate sodium
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.

Colace 2-in-1

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- 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.

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, preferably in the evening, or in divided doses

adults and children 12 years and over	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily

children under 2	ask a doctor

Other information

- each tablet contains: **calcium 7 mg, sodium 4 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Inactive ingredients

Croscarmellose sodium, dicalcium phosphate, FD&C Blue #1 Lake, FD&C Red #40 Lake, FD&C Yellow #6 Lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin

Avrio Health L.P.

305608-0A

Colace

Drug Facts

Active ingredient (in each capsule)

Docusate sodium 100 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 1-3 capsules daily
children 2 to under 12 years of age	take 1 capsule daily
children under 2 years	ask a doctor

Other information

- each capsule contains: **sodium 5 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Keep tightly closed.

Inactive ingredients

D&C Red No. 33, FD&C Blue #1, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, PEG 400, propylene glycol, sorbitol, titanium dioxide

Avrio Health L.P.

304996-0A

COLACE KIT

docusate sodium kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67618-372

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67618-372-60	1 in 1 KIT; Type 0: Not a Combination Product	05/01/2020	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PLASTIC	30
Part 2	1 BOTTLE, PLASTIC	60

Part 1 of 2

COLACE

docusate sodium - sennosides tablet, film coated

Product Information	
Item Code (Source)	NDC:67618-110
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
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	RED (burgundy)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	P;054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-110-30	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC; 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	02/08/1957	

Part 2 of 2

COLACE

docusate sodium capsule

Product Information

Item Code (Source)	NDC:67618-101
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED, WHITE	**Score**	no score

Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	RPC;053
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-101-60	1 in 1 CARTON		
1		60 in 1 BOTTLE, PLASTIC; 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	01/30/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/01/2020	

Labeler - Avrio Health L.P. (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		968334974	MANUFACTURE(67618-110)

Establishment

Name	Address	ID/FEI	Business Operations
P&L Development, LLC		079765031	PACK(67618-101)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	MANUFACTURE(67618-101)

Establishment

Name	Address	ID/FEI	Business Operations
Geodis		116937615	PACK(67618-372)