

**SENOKOT- s standardized senna concentrate tablet**  
**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.*

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**Senokot**  
**s standardized senna concentrate**

***Drug Facts***

***Active ingredient (in each tablet)***

Sennosides 8.6 mg

Laxative

***Uses***

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

***Warnings***

**Do not use**

- laxative products for longer than 1 week 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 continues over a period of 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 may indicate 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 preferably at bedtime or as directed by a doctor

<b>age</b>	<b>starting dosage</b>	<b>maximum dosage</b>
adults and children 12 years of age and	2 tablets once a day	4 tablets twice a day

over		
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

***Other Information***

- each tablet contains: **calcium 10 mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***Inactive ingredients***

dicalcium phosphate, magnesium stearate, microcrystalline cellulose, pregelatinized starch

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Avrio Health L.P.  
Stamford, CT 06901-3431  
305018-0A

100 Tablets



100 Tablets & 50 Tablets 2 pack



100 Tablets & 50 Tablets Dual pack



standardized senna concentrate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67618-300
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	BROWN	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	S
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-300-40	1 in 1 CARTON	06/01/1956	12/31/2016
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:67618-300-24	3 in 1 CARTON	06/01/1956	12/31/2016
2		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:67618-300-20	2 in 1 CARTON	06/01/1956	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:67618-300-50	1 in 1 CARTON	06/01/1956	
4		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:67618-300-10	1 in 1 CARTON	06/01/1956	
5		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:67618-300-04	4 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/01/1956	12/31/2016
7	NDC:67618-300-15	2 in 1 CARTON	06/01/1956	

7	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/01/1956	

## SENOKOT

standardized senna concentrate tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-371
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	5
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-371-00	2 in 1 CELLO PACK	06/01/1956	
1		100 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	06/01/1956	

**Labeler** - Avrio Health L.P. (141916531)

**Registrant** - Purdue Pharma LP (932323652)

### Establishment

Name	Address	ID/FEI	Business Operations
Purdue Pharma		250955291	MANUFACTURE(67618-371, 67618-300)

Revised: 12/2018

Avrio Health L.P.