DOCUSATE SODIUM- docusate sodium capsule
Contract Pharmacy Services-PA

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

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener

Uses

- prevents/relieves dry hard stool
- results usually occurs 1 to 3 days after the first dose

Warnings

Do not use

- when abdominal pain, nausea, or vomiting are present
- for more than one week unless directed by a doctor

Ask a doctor before use if you

- are taking mineral oil
- have noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if

- you have no bowel movement after 3 days
- you have rectal bleeding

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

- do not exceed recommended dose

adults and children over 12	take 1-2 softgels daily until first bowel movement; 1 softgel

years	daily thereafter
children 6 to 12 years	take 1 softgel daily
children under 6 years	consult a doctor

Other information

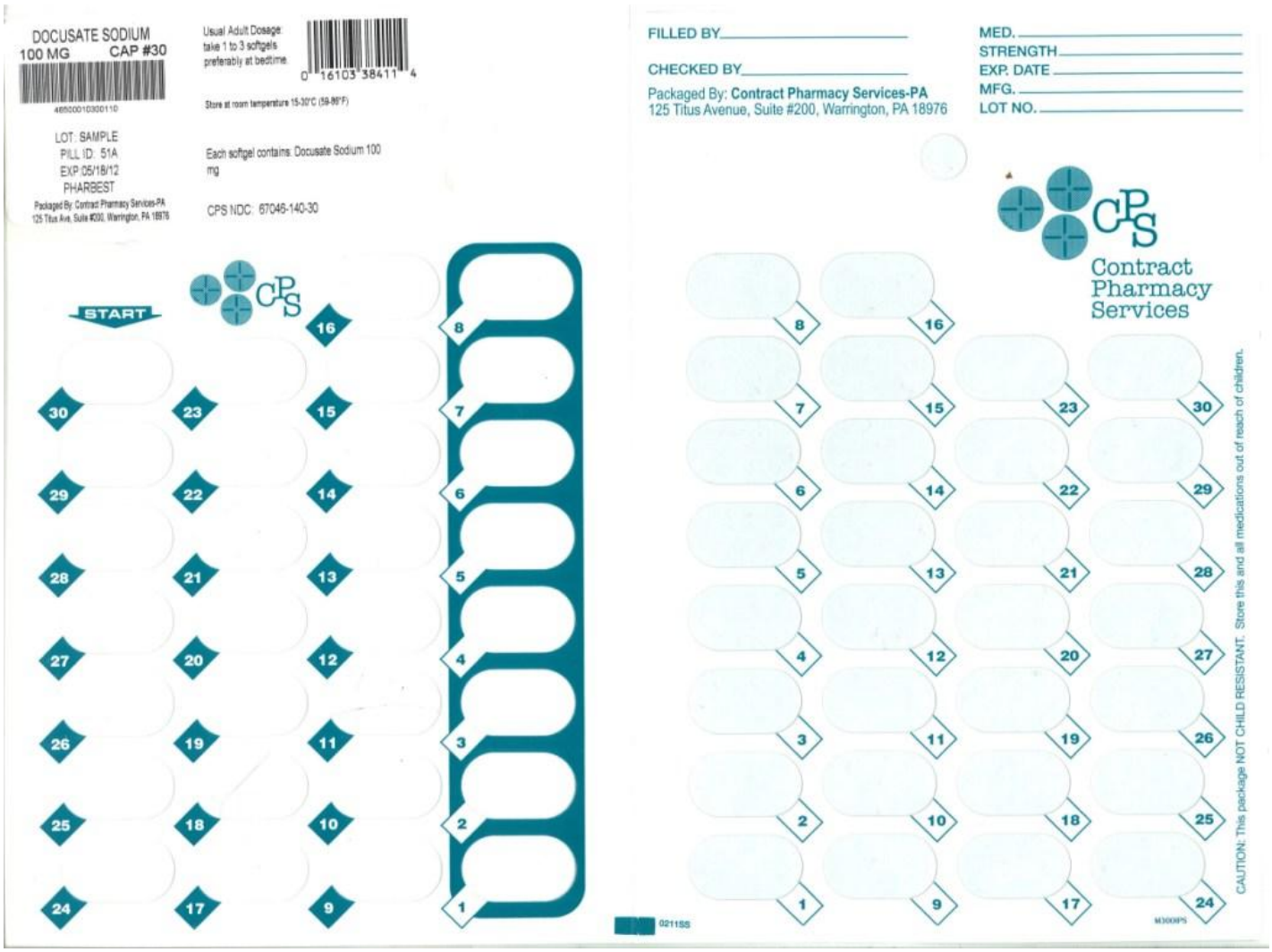
- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature 15 º to 30 ºC (59 º to 86 ºF)
- protect from moisture

Inactive ingredients: D&C yellow #10, FD&C red #40, gelatin, glycerin, ink white, polyethylene glycol, sorbitol, propylene glycol.

Questions?

Adverse drug event call: (866) 562-2756

Principal Display Panel



DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67046-140(NDC:16103-384)
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 YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red (Two-toned- white and clear red)	**Score**	no score
Shape	OVAL	**Size**	5mm
Flavor		**Imprint Code**	51A
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67046-140-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/15/2012	
2	NDC:67046-140-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/22/2007	

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises Inc.		945429777	repack(67046-140)