

## **KAO- TIN- docusate calcium capsule, liquid filled**

### **Major Pharmaceuticals**

*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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### **DRUG FACTS**

#### **Active Ingredient (in each softgel)**

Docusate Calcium 240mg

#### **Purpose**

Stool softener

#### **Uses**

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 longer 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

#### **If pregnant or breastfeeding**

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**

- **adults and children over 12 years of age:** take 1 softgel daily for several days, or until bowel movements are normal, or as directed by a doctor.
- **children under 12 years of age:** take as directed by a doctor.

#### **Other information**

- store at controlled room temperature 15° - 30° C (59°- 86° F)
- do not use if imprinted safety seal under cap is broken or missing.
- \*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Surfak® Stool Softener.

**Inactive Ingredients**

corn oil, DandC Red #33, edible white ink, FD&C Red #40, gelatin, glycerin, purified water and sorbitol special.

**Questions ?**

Adverse Drug Event Call: **(800) 616-2471**

NDC 0904-5779-60

**MAJOR KAO- TIN™**

Docusate Calcium 240 mg

Stool Softener

**For Mild, Dependable, More natural relief of constipation**

**Non- habit forming**

**NO SODIUM**

\*Compare to the active ingredient in Surfak® Stool Softener

Distributed by:

**Major Pharmaceuticals**

31778 Enterprise Drive

Livonia MI 48150 USA

**Product Label**



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**MAJOR**  
**KAO-TIN™**  
 240 mg  
 (Docusate Calcium)  
 STOOL SOFTENER  
 \*Compare to the active  
 ingredient in SURFAK®  
 STOOL SOFTENER

NDC 9904-5779-40

**MAJOR**  
**KAO-TIN™**  
 240 mg  
 (Docusate Calcium)  
 STOOL SOFTENER

For Mild, Dependable,  
 More Natural Relief  
 of Constipation  
 Non-habit forming  
 NO SODIUM

\*Compare to the active  
 ingredient in SURFAK®  
 STOOL SOFTENER

**100** Softgels

NDC 9904-5779-40

**MAJOR**  
**KAO-TIN™**  
 240 mg  
 (Docusate Calcium)  
 STOOL SOFTENER

For Mild, Dependable,  
 More Natural Relief  
 of Constipation  
 Non-habit forming  
 NO SODIUM

\*Compare to the active  
 ingredient in SURFAK®  
 STOOL SOFTENER

**100** Softgels

NDC 9904-5779-40

**MAJOR**  
**KAO-TIN™**  
 240 mg  
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 STOOL SOFTENER

For Mild, Dependable,  
 More Natural Relief  
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\*Compare to the active  
 ingredient in SURFAK®  
 STOOL SOFTENER

**100** Softgels

**Drug Facts**

**Active ingredient (in each softgel)** Purpose  
 Docusate Calcium 240 mg Stool softener

**Uses:** 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. If you have rectal bleeding, if you fail to have a bowel movement after use.

**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 are pregnant or breast-feeding, ask a health care professional before use, keep out of reach of children, in cases of overdose, get medical help or contact a Poison Control Center right away.

**Directions:** Adults and children over 12 years of age: take 1 softgel daily for several days, or until bowel movements are normal, or as directed by a doctor. Children under 12 years of age: take as directed by a doctor.

**Other information:** Store at controlled room temperature 15°-30°C (59°-86°F). Do not use if impunctured safety seal under cap is broken or missing. This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark SURFAK® Stool Softener.

**Inactive ingredients:** corn oil, D&C Red #33, white ink, FD&C Red #40, polyethylene glycol, purified water and sorbitol special.

**Questions?** Advise Drug Event Call (800) 618-6471

Distributed by:  
 Hebe Pharmaceuticals, Inc.  
 21778 Enterprise Drive, #40  
 Lowell, MA 01850, USA (800) 618-6471



LOT NO:

EXP. DATE:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Gradation goes from  
 100% PMS 2995 Blue  
 to 30% PMS 2995 Blue

1574Q1C

Docusate Calcium 240 mg

# KAO- TIN

docusate calcium capsule, liquid filled

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5779
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE CALCIUM	240 mg

## Inactive Ingredients

Ingredient Name	Strength
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	RED (RED)	Score	no score
Shape	CAPSULE (OVAL)	Size	21mm
Flavor		Imprint Code	P58
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5779-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2011	12/31/2020
2	NDC:0904-5779-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2011	12/31/2020

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/01/2011	12/31/2020

**Labeler** - Major Pharmaceuticals (191427277)