**STOOL SOFTENER DC LAXATIVE- docusate calcium capsule, liquid filled**
**ATLANTIC BIOLOGICALS CORP.**

*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 240 mg

**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

These could be signs of s serious condition.

**If pregnant or breast-feeding,**

ask a health care 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 between 15º-30ºC (59º-86ºF)

**Inactive ingredients**

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

**Questions or comments?**

**1-800-645-2158**

**Principal Display Panel**

Compare to active ingredient in SURFAK®*

Safe, Effective, Non-Habit Forming

Stool Softener Laxative DC

Docusate Calcium USP, 240 mg

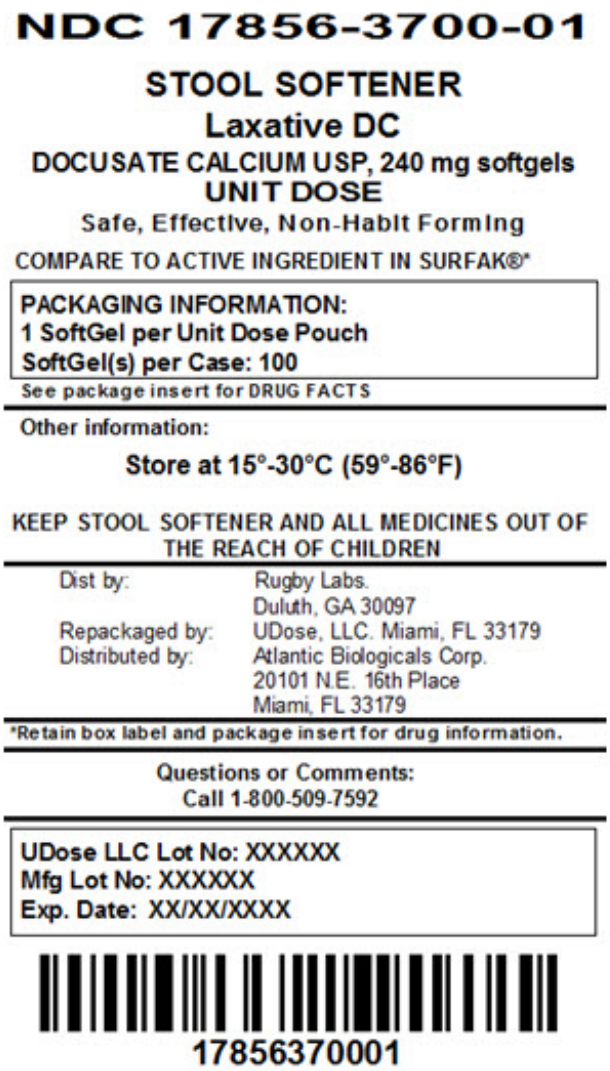
SOFTGEL CAPSULES

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

***Rugby Laboratories is not affiliated with the owner of the trademark Surfak®.**

**Distributed by: Atlantic Biologicals Corp**

**Miami, Fl 33179**




# STOOL SOFTENER DC LAXATIVE

docusate calcium capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:17856-3700(NDC:0536-3755) |
| **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: 059QF0KO0R) | |
| **SORBITOL** (UNII: 506T60A25R) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | RED (RED) | **Score** | no score |
| **Shape** | OVAL (OVAL) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | P58 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:17856-3700-1 | 1 in 1 POUCH; Type 0: Not a Combination Product | 09/02/2016 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH NOT FINAL | part334 | 09/04/2013 | |

## Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ATLANTIC BIOLOGICALS CORP. | | 047437707 | repack(17856-3700) |

Revised: 4/2013 ATLANTIC BIOLOGICALS CORP.