

DOCUSOL KIDS- docusate sodium liquid
Enemeez LLC DBA Summit 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.

DocuSol® Kids

Drug Facts

Active Ingredient (per delivered dose)

Docusate Sodium USP 100 mg

Purpose

Stool Softener Laxative

Uses

- For relief of occasional constipation (irregularity).
- This product generally produces a bowel movement in 2 to 15 minutes.

Warnings

For rectal use only. Drug Interaction Precaution: Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

Do not use

- Laxative products when abdominal pain, nausea or vomiting are present.
- Laxative products for a period longer than 1 week unless directed by a doctor.

Stop use and ask a doctor if you have:

- Rectal bleeding.
- Noticed a sudden change in bowel habits that persists over a period of 2 weeks.
- Failed to have a bowel movement after use. This may indicate a serious condition.

Pregnant or Lactating Women

Ask a health professional before use.

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a Poison Control Center

immediately.

Directions

Children 2 years to under 12 years of age (with adult supervision) one unit daily. Children under 2 years of age, consult a doctor prior to use.

- Twist off and remove tip.
- Lubricate tip prior to insertion: Place a few drops of the tube's liquid content on the shaft prior to insertion. Also apply liquid content or lubricant to the anus before inserting the mini-enema.
- Positioning: For best results, lay on the left side with knees bent. Alternate Positions: Administer while seated on the toilet. Or, kneel, then lower head and chest forward until side of face is resting on the surface.
- With steady pressure, gently insert the tube into the rectum with care to prevent damage to the rectal wall. Insert up to shoulder of tube. Squeeze to empty the contents. Keep the tube squeezed until it is removed from the rectum. After the contents have been emptied, remove the disposable tube and discard. A small amount of liquid may remain in the unit after use.

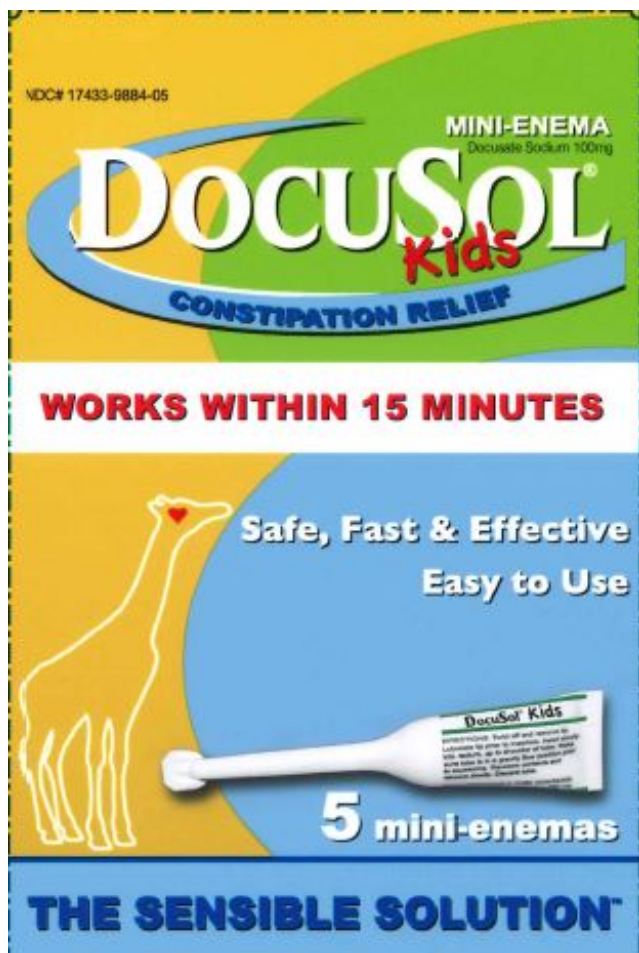
Other Information

Store at room temperature 15° - 30° C (59° - 86° F)

Inactive Ingredients

Glycerin USP and Polyethylene Glycol





DOCUSOL KIDS

docosate sodium liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:17433-9884 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 100 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|----------|------------------|---|------------|------------|
| 1 | NDC:17433-9884-5 | 5 in 1 BOX | 01/14/2014 | 11/30/2025 |
| 1 | NDC:17433-9884-1 | 5 mL in 1 TUBE; 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 | 01/14/2014 | 11/30/2025 |

Labeler - Enemeez LLC DBA Summit Pharmaceuticals (010717819)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|-------------------------|
| Enemeez LLC DBA Summit Pharmaceuticals | | 010717819 | manufacture(17433-9884) |

Revised: 1/2023

Enemeez LLC DBA Summit Pharmaceuticals