

STRATUSCARE GLYCERIN LAXATIVE PEDIATRIC- glycerin suppository
Stratus Pharmaceuticals

Stratuscare Glycerin Suppositories Laxative Pediatric

Drug Facts

Active ingredient (per suppository)

Glycerin, USP 1g

Purpose

Laxative

Use

- For relief of occasional constipation (irregularity)
- generally produces bowel movement in ¼ to 1 hour.

Warnings

For rectal use only.

May cause rectal discomfort or burning sensation.

Ask a doctor before use if your child has:

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks.

Stop use and ask a doctor:

- if your child has rectal bleeding or fails to have a bowel movement after using a laxative. This may indicate a serious condition.
- **Do not use** laxative products for longer than 1 week unless directed by a doctor
- **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).

Directions

- **Children 2 to under 6 years of age:**
 - Carefully insert one suppository well into child's rectum
 - It need not melt completely to produce laxative action
 - Generally produces bowel movement in 15 minutes to 1 hour
 - Do not exceed one suppository daily unless directed by a doctor
- **Children under 2 years old:** Consult a doctor.

Other information

- Store glycerin suppositories at room temperature, between 15°C and 30°C (between 59°F and 86°F)

Inactive ingredients

purified water, sodium stearate

Questions or comments?

1-800-442-7882

Distributed by:

Stratus Pharmaceuticals Inc
12379 SW 130th Street
Miami, Florida 33186

PRINCIPAL DISPLAY PANEL - 25 Suppository Jar Label**NDC 58980-409-25****STRATUSCARE****INFANTS
& CHILDREN****pediatrics
Glycerin
Suppositories
Laxative**

Distributed by:

STRATUS
PHARMACEUTICALS INC**25 SUPPOSITORIES**

DO NOT USE IF INNER SEAL IS BROKEN OR MISSING.

NDC 58980-409-25

STRATUSCARE

**INFANTS
& CHILDREN**

pediatrics

Glycerin
Suppositories
Laxative



25 SUPPOSITORIES

DO NOT USE IF INNER SEAL IS BROKEN OR MISSING

Drug Facts

Active ingredient (per suppository) Glycerin, USP 1g.....	Purpose Laxative
---	----------------------------

Use
• For relief of occasional constipation (irregularity) • generally produces bowel movement in ¼ to 1 hour.

Warnings
For rectal use only.
May cause rectal discomfort or burning sensation. Ask a doctor before use if your child has: • abdominal pain, nausea or vomiting • a sudden change in bowel habits lasting more than 2 weeks. Stop use and ask a doctor: • if your child has rectal bleeding or fails to have a bowel movement after using a laxative. This may indicate a serious condition. • Do not use laxative products for longer than 1 week unless directed by a doctor • Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).

Directions • Children 2 to under 6 years of age: • Carefully insert one suppository well into child's rectum • It need not melt completely to produce laxative action • Generally produces bowel movement in 15 minutes to 1 hour • Do not exceed one suppository daily unless directed by a doctor • Children under 2 years old: Consult a doctor.

Drug Facts (continued)

Other information • Store glycerin suppositories at room temperature, between 15°C and 30°C (between 59°F and 86°F)

Inactive ingredients purified water, sodium stearate

Questions or comments?
1-800-442-7882

Distributed by:
Stratus Pharmaceuticals Inc
12379 SW 130th Street
Miami, Florida 33186



STRATUSCARE GLYCERIN LAXATIVE PEDIATRIC

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-409
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Glycerin (UNII: PDC6A3C00X) (Glycerin - UNII:PDC6A3C00X)	Glycerin	1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-409-12	12 in 1 JAR; Type 0: Not a Combination Product	06/01/2014	
2	NDC:58980-409-25	25 in 1 JAR; Type 0: Not a Combination Product	06/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M007	06/01/2014	

Labeler - Stratus Pharmaceuticals (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products		059890491	MANUFACTURE(58980-409)

Revised: 11/2024

Stratus Pharmaceuticals