

STRATUSCARE ADULT GLYCERIN- glycerin suppository

Stratus 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.

Stratuscare Adult Glycerin Suppositories

Drug Facts

Active ingredient (per suppository)

Glycerin, USP 2 g

Purpose

Laxative

Use

- For relief of occasional constipation (irregularity)
- generally produces bowel movement in $\frac{1}{4}$ to 1 hour.

Warnings

For rectal use only.

May cause rectal discomfort or burning sensation.

Ask a doctor before use if you have:

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

Stop use and ask a doctor:

- if you have rectal bleeding or fail 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
- **If pregnant or breastfeeding**, ask a doctor before use.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).

Directions

- **Adults and children 6 years and over:**
 - Carefully insert one suppository well into 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 6 years old:** do not use

Other information

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

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 - 50 Suppository Jar Label

NDC 58980-410-50

STRATUSCARE

ADULT

**Glycerin
Suppositories
Laxative**

Distributed by:

STRATUS
PHARMACEUTICALS INC

DO NOT USE IF INNER SEAL IS BROKEN OR MISSING.

50 SUPPOSITORIES

NDC 58980-410-50

STRATUSCARE

ADULT
Glycerin Suppositories Laxative

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PHARMACEUTICALS INC

50 SUPPOSITORIES

Drug Facts
Active ingredient (per suppository)
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Purpose
Laxative

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

Warnings
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May cause rectal discomfort or burning sensation. Ask a doctor before use if you have: • abdominal pain, nausea or vomiting • a sudden change in bowel habits lasting more than 2 weeks. Stop use and ask a doctor: • if you have rectal bleeding or fail 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 • If pregnant or breastfeeding, ask a doctor before use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1212).

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Drug Facts (continued)
Inactive ingredients purified water, sodium stearate

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STRATUSCARE ADULT GLYCERIN

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-410
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Glycerin (UNII: PDC6A3C00X) (Glycerin - UNII:PDC6A3C00X)	Glycerin	2 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-410-12	12 in 1 JAR; Type 0: Not a Combination Product	05/30/2014	
2	NDC:58980-410-25	25 in 1 JAR; Type 0: Not a Combination Product	05/30/2014	
3	NDC:58980-410-50	50 in 1 JAR; Type 0: Not a Combination Product	05/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT	part 234	05/30/2014	

FINAL	part 554	05/30/2014	
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Labeler - Stratus Pharmaceuticals (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products		059890491	MANUFACTURE(58980-410)

Revised: 11/2022

Stratus Pharmaceuticals