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

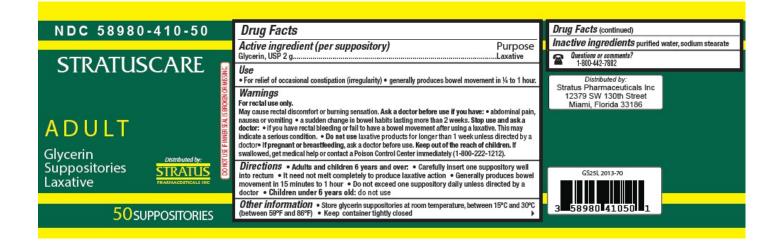
ADULT

Glycerin Suppositories Laxative

Distributed by: **STRATUS** PHARMACEUTICALS INC

DO NOT USE IF INNER SEAL IS BROKEN OR MISSING.

50 SUPPOSITORIES



STRATUSCARE ADULT GLYCERIN

glycerin suppository

Product Information HUMAN OTC DRUG Item Code (Source) NDC:5280-410 Route of Administration RECTAL NDC:5280-410 Active Ingredient/Active Woiety Stress Stress Active Ingredient/Active Ingredient Name Basis of Stress Stress Glycerin (UNII: PDC6A3C00X) (Glycerin - UNII: PDC6A3C00X) Glycerin 2 g Inactive Ingredients Stress Stress Water (UNII: 059QF0K00R) Stress Stress SODIUM STEARATE (UNII: QU7E2XA9TG) Stress Stress				
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Packaging				
# Item Code Package Description Marketing Start Marketing B Date Date				
NDC:58980-410- 12 in 1 JAR; Type 0: Not a Combination 05/30/2014				
2 NDC:58980-410- 25 Product 25 in 1 JAR; Type 0: Not a Combination 05/30/2014				
3 NDC:58980-410- 50 in 1 JAR; Type 0: Not a Combination Product 05/30/2014				
Marketing Information				
Marketing Category Application Number or Monograph Date Date Date				

Labeler - Stratus Pharmaceuticals (789001641)

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

Revised: 11/2022

Stratus Pharmaceuticals