

## **STRATUSCARE GLYCERIN LAXATIVE PEDIATRIC- 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.*

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### **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  
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pediatrics

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**Drug Facts (continued)**

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**STRATUSCARE GLYCERIN LAXATIVE PEDIATRIC**

glycerin suppository

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Glycerin</b> (UNII: PDC6A3C00X) (Glycerin - UNII:PDC6A3C00X)	Glycerin	1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>SODIUM STEARATE</b> (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 NOT FINAL	part334	06/01/2014	

**Labeler** - Stratus Pharmaceuticals (789001641)

## Establishment

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

Revised: 11/2022

Stratus Pharmaceuticals