

INFANT GLYCERIN LAXATIVE - glycerin suppository

Physicians Total Care, Inc.

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.

ACTIVE INGREDIENT

Glycerin, USP 80.7%

PURPOSE

Laxative

USE

For relief of occasional constipation

WARNINGS

For rectal use only. May cause rectal discomfort or a burning sensation.

Do not use

- more than one per day
- for a period of longer than one week unless directed by a doctor
- laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor
- if seal under product lid is damaged, missing or broken.

Ask a doctor

- before use if you have noticed a sudden change in bowel habits that persists over a period of two weeks
- if you are pregnant or nursing a baby

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.

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

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DIRECTIONS

- Children 2 - 6 years of age: carefully insert one suppository well into the rectum
- Do not use more than once per day
- Generally produces a bowel movement in 15 minutes to 1 hour
- Children under 2 years of age: ask a doctor.

OTHER INFORMATION

- Store container tightly closed
- Store at room temperature: 15° - 30° C (59° - 86° F). Do not exceed 30° C (86° F).

INACTIVE INGREDIENTS

sodium stearate, purified water

QUESTIONS

Adverse Drug Event Call: (800) 616-2471

PRINCIPAL DISPLAY PANEL

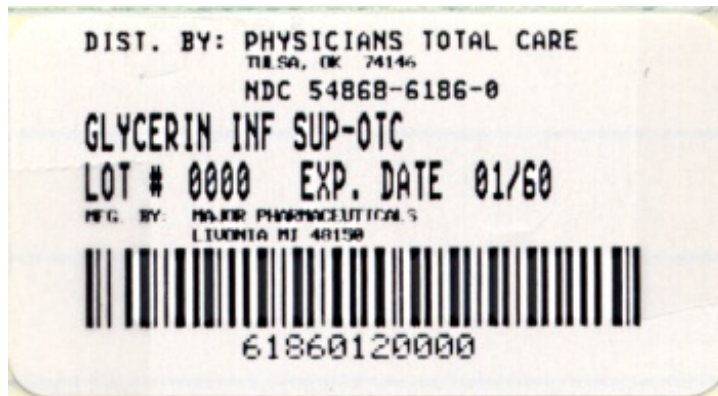
NDC 54868-6186-0

Infant

GLYCERIN SUPPOSITORIES

**Rectal evacuant
For relief of
temporary constipation**

12 Infant Suppositories



Compare to Fleet® Glycerin Suppositories*

*This product is not manufactured or distributed by C.B.Fleet co., owner of the registered trademark Fleet®.

Distributed by:
Major Pharmaceuticals
31778 Enterprise Drive
Livonia, MI 48150 USA

Reorder No. 233874
M-54 Rev 6/08

DO NOT USE IF PRINTED

INNER SEAL IS BROKEN
OR MISSING

Relabeling of "Additional Barcode Label" by:
Physicians Total Care, Inc.
Tulsa, OK 74146

INFANT GLYCERIN LAXATIVE

glycerin suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-6186(NDC:0904-2666)
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1.3 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6186-0	12 in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part334	10/27/2010	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel