

**PROCTOZONE-G- glycerin suppository**  
**Rising Pharma Holdings, Inc.**

-----  
**Proctozone-G™ Glycerin Suppositories 1.2 g**

***Drug Facts***

***Active ingredient (in each suppository)***

Glycerin USP, 1.2 grams

***Purpose***

Laxative

***Uses***

- For relief of occasional constipation
- This product usually produces bowel movement in 1/4 to 1 hour

***Warnings***

**For rectal use only**

**Do not use** for longer than 1 week unless directed by a doctor.

***Ask a doctor before use if the child has***

- Stomach pain, nausea or vomiting
- A sudden change in bowel habits lasting more than 2 weeks

**When using this product** your child may have rectal discomfort or a burning sensation

**Stop use and ask a doctor if you have**

- Rectal bleeding
  - No bowel movement after using this product
- These may indicate a serious condition.

**Keep out of reach of children**

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

***Directions***

- Tear off one suppository from the strip
- If the suppository seems soft, place it in the refrigerator before use or run cold water over it before removing the foil wrapper
- Gently remove suppository by peeling apart the wrapper (**see illustration 1**)
- Rub a water-based lubricant over the tip or dip it in water. It will help you slide it in smoothly
- Lie on your side and insert 1 suppository, tapered end first, about the length of your finger into the rectum (**see illustration 2**)
- Hold the suppository for about 15-20 minutes to allow time for it to melt
- Children 2 to under 6 years of age ..... 1 suppository once daily
- Children under 2 years ..... ask a doctor

## Other Information

Keep away from excessive heat.

## Inactive ingredients

purified water, sodium stearate.

## Questions or Comments:

call 1-844-474-7464

TAMPER EVIDENT, INDIVIDUALLY SEALED FOR YOUR PROTECTION

## Distributed by:

Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816

## Made in India

Code No.: MH/DRUGS/25-KD/724

Issued: 05/2025

**NDC 57237-338-21 (2 blisters of 6 suppositories)**

**Proctozone-G™**

**GLYCERIN SUPPOSITORIES 1.2 g**

**RECTAL LAXATIVE**

GTIN No. 00357237338216  
SR. No.: XXXXXXXXXX  
LOT: XXXXXXXX  
EXP: YYYYMM



|   |   |   |   |   |
|---|---|---|---|---|
| <b>Drug Facts</b><br>Active ingredient (in each suppository)<br>Glycerin USP, 1.2 grams.<br>Purpose<br>Laxative         | <b>Drug Facts</b> (Continued)<br><b>Directions</b><br>Tear off one suppository from the strip.<br>If the suppository seems soft, place it in the refrigerator before use or run cold water over it.<br>Gently remove suppository by peeling apart the wrapper (see Illustration 1).<br>Rub a water-based lubricant over the tip or dip it in water. It will help you slide it in smoothly.<br>Use on your side and insert 1 suppository, tapered end first, about the length of your finger into the rectum (see Illustration 2).<br>Hold the suppository for about 15-20 minutes to allow time for it to melt.<br>Children 2 to under 6 years of age<br>1 suppository once daily.<br>Children under 2 years<br>ask a doctor. | <b>Other Information</b><br>Keep away from excessive heat.  | <b>Inactive ingredients</b><br>purified water, sodium stearate. | <b>Questions or Comments:</b> call 1-844-474-7464 |
| <b>Uses</b><br>For relief of occasional constipation.<br>This product usually produces bowel movement in 1/4 to 1 hour. | <b>Warnings</b> For rectal use only.<br>Do not use for longer than 1 week unless directed by a doctor.<br>Ask a doctor before use if the child has<br>Stomach pain, nausea or vomiting<br>A sudden change in bowel habits lasting more than 2 weeks<br>When using this product your child may have rectal discomfort or a burning sensation.<br>Stop use and ask a doctor if you have<br>Rectal bleeding<br>No bowel movement after using this product.<br>These may indicate a serious condition.  | <b>Keep out of reach of children</b><br>If swallowed, get medical help or contact a Poison Control Center right away. |   |   |

UNVARNISHED AREA FOR OPZ



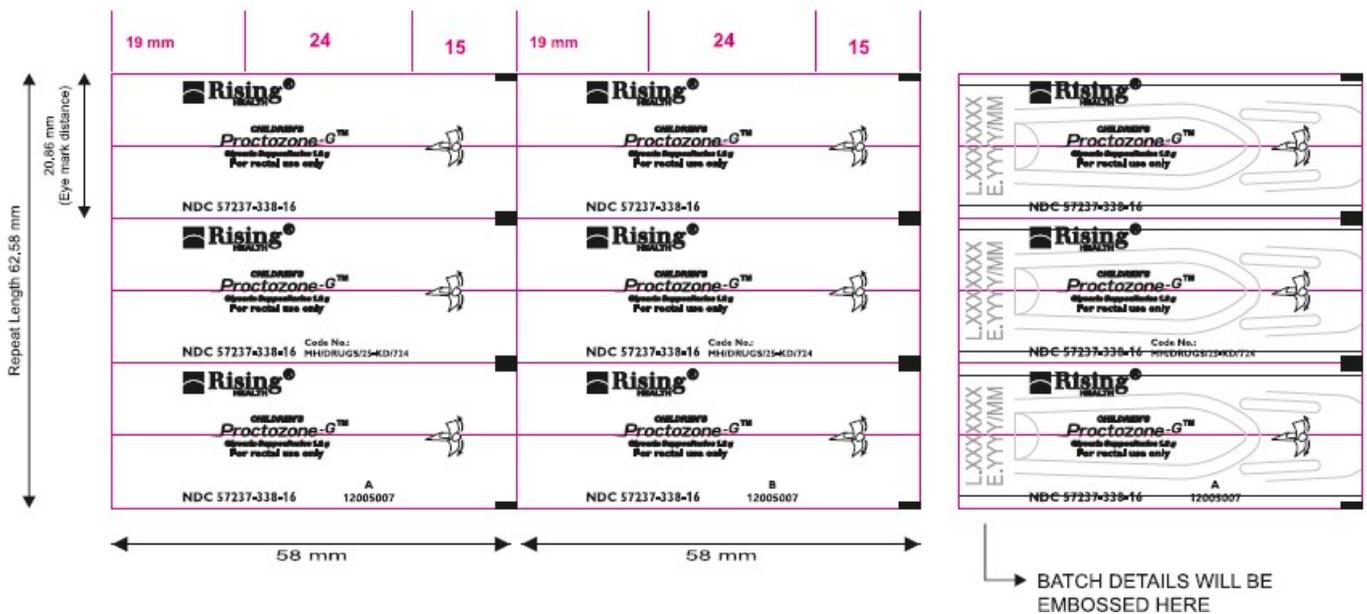
1806



Front Foil (57237-338-16)

Annotation: Lot No. and Exp. Date will be embossed on each cavity on back foil as follows:  
 LXXXXXX  
 E,YYYY/MM

Winding direction



Back Foil (57237-338-16)

|   |           |   |    |    |   |    |
|---|-----------|---|----|----|---|----|
|   | 17        | 29  | 14 | 17 | 29  | 14 |
| Repeat Length 62.58 mm<br>20.86 mm<br>(Eye mark distance) |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   |           | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |    | Dist. By:<br>Rising Pharma Holdings, Inc.<br>Store at 20-25°C (68-77°F)<br> |    |
|   | 120.00 mm |   |    |    |   |    |

**NDC 57237-338-52 (5 blisters of 5 suppositories)**

|   |   |
|---|---|
| <b>Drug Facts (Continued)</b>   | <b>Drug Facts</b>   |
| <b>Directions</b><br>Tear off one suppository from the strip if the suppository seems soft, place it in the refrigerator before use or run cold water over it before removing the foil wrapper.<br>Gently remove suppository by peeling apart the wrapper (see illustration 1).<br>Rub a water-based lubricant over the tip or dip it in water. It will help you slide it in smoothly.<br>Lie on your side and insert 1 suppository, tapered end first, about the length of your finger into the rectum (see illustration 2).<br>Hold the suppository for about 15 - 20 minutes to allow time for it to melt.<br>Children 2 to under 6 years of age: 1 suppository once daily.<br>Children under 2 years: ask a doctor. | <b>Active ingredient (in each suppository)</b><br>Glycerin USP, 1.2 grams.<br><b>Purpose</b><br>Laxative  |
| <b>Other Information</b><br>Keep away from excessive heat.  | <b>Uses</b><br>For relief of occasional constipation.<br>This product usually produces bowel movement in 1/4 to 1 hour.   |
| <b>Inactive ingredients</b><br>purified water, sodium stearate.   | <b>Warnings</b> For rectal use only.<br>Do not use for longer than 1 week unless directed by a doctor.<br>Ask a doctor before use if the child has:<br>■ Stomach pain, nausea or vomiting.<br>■ A sudden change in bowel habits lasting more than 2 weeks.<br>When using this product your child may have rectal discomfort or a burning sensation.<br>Stop use and ask a doctor if you have:<br>■ Rectal bleeding.<br>■ No bowel movement after using this product.<br>These may indicate a serious condition. |
| <b>Questions or Comments:</b> call 1-844-474-7464   | Keep out of reach of children.<br>If swallowed, get medical help or contact a Poison Control Center right away.   |

GTIN No. 00100000000000  
 SR. No.: XXXXXXXXXX00000000  
 LOT: XXXXXXXX  
 EXP: YYYYMM

UNVARNISHED AREA FOR OPZ

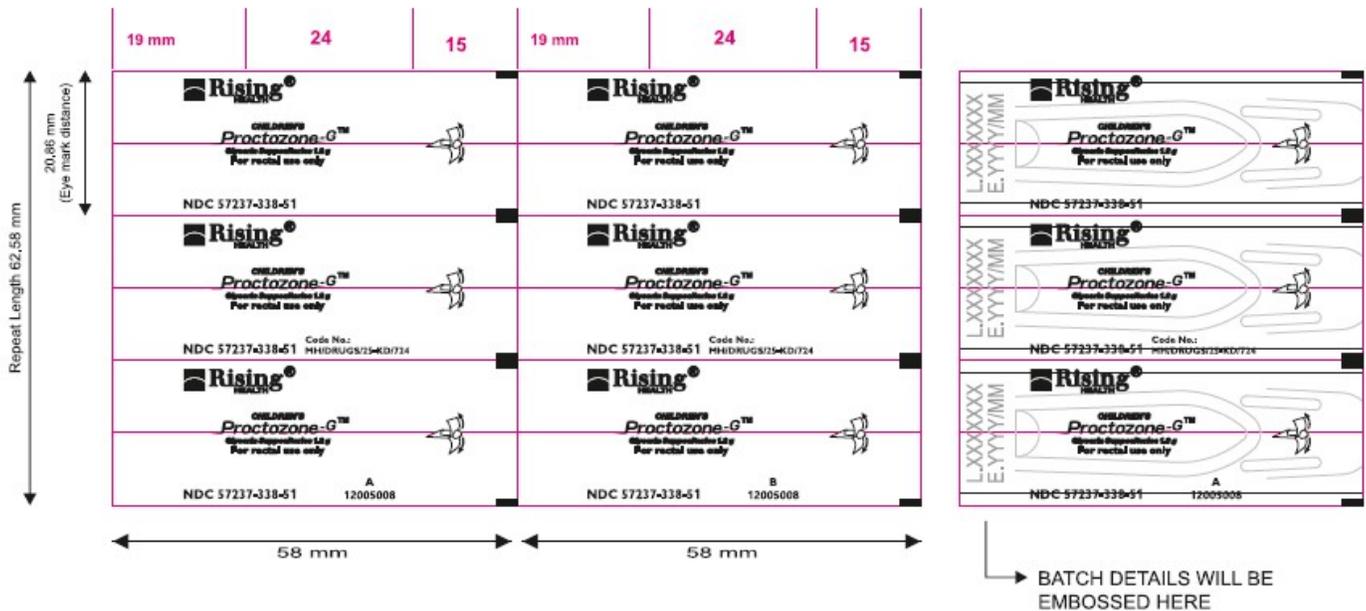


## Front Foli (57237-338-51)

Annotation: Lot No. and Exp. Date will be embossed on each cavity on back foil as follows:

L:XXXXXX

E:YYYY/MM



## Back Foil (57237-338-51)



## PROCTOZONE-G

glycerin suppository

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:57237-338 |
| <b>Route of Administration</b> | RECTAL         |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN          | 1.2 g    |

### Inactive Ingredients

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

### Product Characteristics

|                 |               |                     |  |
|-----------------|---------------|---------------------|--|
| <b>Color</b>    | white (clear) | <b>Score</b>        |  |
| <b>Shape</b>    | BULLET        | <b>Size</b>         |  |
| <b>Flavor</b>   |               | <b>Imprint Code</b> |  |
| <b>Contains</b> |               |                     |  |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:57237-338-21 | 2 in 1 CARTON  | 07/31/2025           |                    |
| 1 | NDC:57237-338-16 | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:57237-338-52 | 5 in 1 CARTON  | 07/31/2025           |                    |
| 2 | NDC:57237-338-51 | 5 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M007.54                                  | 07/31/2025           |                    |

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

## Establishment

| Name                     | Address | ID/FEI    | Business Operations  |
|--------------------------|---------|-----------|--|
| Bliss GVS Pharma Limited |         | 675630493 | manufacture(57237-338) , analysis(57237-338) , pack(57237-338) |

Revised: 1/2026

Rising Pharma Holdings, Inc.