

SALINE ENEMA- saline enema enema
Blossom 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.

Enema, Saline

Active Ingredient

(in each 118 ml delivered dose)

Dibasic sodium phosphate 7g

Monobasic sodium phosphate 19g

Purpose

Saline Laxative

Purpose

- Gentle relief of occasional constipation

Warnings:

For rectal use only

As a doctor before use if you have:

- abdominal pain, nausea or vomiting
- notice a sudden change in bowel habits that persists over a period of 2 weeks

- **If pregnant or breast feeding**, ask a health professional before use.

Indications & Usage

- If you have rectal bleeding or failure to have a bowel movement after use of a laxative because this may indicate a serious condition
- you need to use a laxative for more than one week

Keep out of reach of children

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Other information:

- Store at room temperature 20 Deg C - 25 Deg C (68 Deg F - 77 Deg F)
- This product produces bowel movement in 2 to 15 minutes

Dosage & Administration

Single daily dose

Adults and children 12 years and older - 1 bottle

Children 2 to under 12 years - 1/2 bottle

Children under 2 years - Do not use. Consult a physician.

How to use this enema:

REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING.

Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with the other hand and pull gently to remove.

See image on box

Positioning

Left-side position: Lie on left side with knee bent and arms at rest.

See image on box

Knee-chest position: Kneel, then lower head and chest forward until the left side of face is resting on surface. Position arms comfortably.

See image on box

Administering Enema

- With steady pressure, gently insert enema with tip pointing toward navel.
- Squeeze bottle until recommended dose is expelled (it is not necessary to empty unit completely. Bottle contains more liquid than needed for effective use. A small amount of liquid will remain in bottle after squeezing).
- Remove tip from rectum.
- Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care.
- Maintain position until urge to evacuate is strong (usually 1 to 5 minutes).
- If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur.

INACTIVE INGREDIENT

Inactive ingredient: Water

Principal Display Panel

saline enema.jpg

CAUTION: REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING.
Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



Positioning
Left-side position: Lie on left side with knee bent and arms at rest.



Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



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- If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur.

Manufactured by:
Blossom Pharmaceuticals
Karaswade, Tivim, Bardez, Tivi, Goa,
Goa 403526, India

Made in India

Enema
Saline Laxative
Ready-To-Use
Latex Free

1 4.5 fl oz (133 ml)

NDC # 61767-002-01

Enema
Saline Laxative
Ready-To-Use
Latex Free

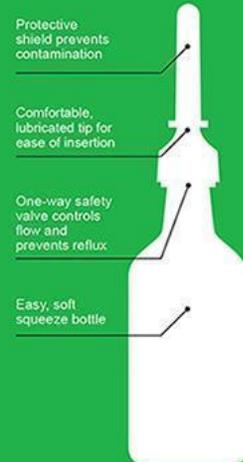
Enema
Saline Laxative
Ready-To-Use
Latex Free

Soft, Flexible,
Comfortable,
Lubricated Tip

Soft, Flexible,
Comfortable,
Lubricated Tip

• For Relief of Occasional Constipation

• Pre-mixed



TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP IS TORN OR DAMAGED IN ANY WAY, DO NOT USE

TAMPER EVIDENT: CARTON SEALED FOR SAFETY. IF PRINTED SEAL ON BOTTOM OR TOP FLAP IS BROKEN OR MISSING, DO NOT USE

Drug Facts

| Active Ingredients (in each 118 mL delivered dose) | Purpose |
|--|-----------------|
| Sodium Phosphate | |
| Dibasic USP 7 g | Saline laxative |
| Sodium Phosphate | |
| Monobasic USP 19 g | Saline laxative |

Uses
Gentle relief of occasional constipation

Warnings
For rectal use only

Dosage warning: Using more than one enema in 24 hours can be harmful.

Ask a doctor before use if you have

- a sodium-restricted diet
- abdominal pain, nausea or vomiting
- kidney disease, heart problems, or are dehydrated
- noticed a sudden change in bowel habits that lasts over 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product

- do not exceed recommended dose unless directed by a doctor. Serious side effects may occur from excess dosage.
- do not use for more than three days

Stop use and ask a doctor if

- you have rectal bleeding
- you have no bowel movement after use of a laxative

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
Do not use more unless directed by a doctor. See Warnings.

| | |
|-------------------------------------|----------------------------------|
| Adults & children 12 years and over | one bottle once daily |
| Children 2 to under 12 years | ½ bottle once daily |
| Children under 2 years | Do not use. Consult a physician. |

Other Information

- each 118 mL contains: Sodium 4.3 g
- store at room temperature 15°-30°C (59°-86°F)
- this product generally produces bowel movement in 1 to 5 minutes

Inactive Ingredients
Benzalkonium chloride, disodium EDTA, purified water

TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP IS TORN OR DAMAGED IN ANY WAY, DO NOT USE

Lot No. _____

Mfg. _____

Exp. _____

48mm 48mm 48mm 48mm

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61767-002 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-------------------|
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR) | SODIUM PHOSPHATE, DIBASIC | 7 g in 118 mL |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR) | SODIUM PHOSPHATE, MONOBASIC | 19 g in 118 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0K00R) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:61767-002-01 | 1 in 1 BOX | | |
| 1 | | 118 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part334 | 02/01/2014 | |

Labeler - Blossom Pharmaceuticals (677381470)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| Blossom Pharmaceuticals | | 677381470 | manufacture(61767-002) |