

SALINE LAXATIVE- saline laxative enema

Major Pharmaceuticals

MAJOR® SALINE ENEMA LAXATIVE

Drug Facts

<i>Active ingredients (in each 118mL delivered dose)</i>	<i>Purpose</i>
Dibasic Sodium Phosphate 7 g	Saline laxative
Monobasic Sodium Phosphate 19 g	Saline laxative

Use

- relieves occasional constipation
- this product generally produces bowel movement in 1 to 5 minutes

Warnings

Dosage warning

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

For rectal use only.

Do not use

- on children under 2 years of age

Ask a doctor before use if you

- have already used a laxative for more than 3 days
- have kidney disease, have heart problems, or are dehydrated
- are 55 years of age or older
- are on a sodium-restricted diet
- have abdominal pain, nausea, or vomiting
- have a sudden change in bowel habits lasting more than 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 use more than directed. Serious side effects may occur from excess dosage**

- do not use for more than 3 days, without asking a doctor

Stop use and ask a doctor if

- you have rectal bleeding
- you have no bowel movement within 30 minutes of enema use
- you have symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal)

These symptoms may indicate 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: 800-222-1222.

Directions (or as directed by a doctor)

Single daily dosage (per 24 hours)

Do not use if taking another sodium phosphate product.

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

Adults and children 12 years of age and older	1 bottle once daily
Children 2 to under 12 years of age	Use Pediatric Enema
Children under 2 years of age	DO NOT USE

Other information

- **each 118 ml contains** sodium 4.3 g
- store at 15 to 30°C (59 to 86°F)
- additional liquids by mouth are recommended while using this product
- **Tamper Evident:** DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

(800) 616-2471

Distributed by:

MAJOR® PHARMACEUTICALS

Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

MAJOR®

NDC 0904-6320-78

Compare to the
active ingredients of
Fleet® Saline Enema*

Ready-to-Use
Enema
Saline Laxative

For relief of occasional
constipation

Not made with natural
rubber latex

4.5 FL OZ (133 mL)

1 Bottle

MAJOR[®]
Ready-to-Use
Enema
Saline Laxative

MAJOR[®] NDC 0904-6320-78
Compare to the active ingredients of Fleet[®] Saline Enema[®]

Ready-to-Use
Enema
Saline Laxative

For relief of occasional constipation
Not made with natural rubber latex

4.5 FL OZ (133 mL)
1 Bottle

CAUTION:
REMOVE
PROTECTIVE
SHIELD
BEFORE
INSERTING.
PL 4000B
V17

Remove protective shield from enema tip before inserting.
Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



Positions for using this enema
Left-side position: Lie on left side with knees bent and arms resting comfortably.



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



How to use this enema
Administering enema:

- With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema bears down, as if having a bowel movement. Doing so helps relax muscles around anus.
- Do not force enema tip into 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.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty bottle completely, as it contains more liquid than needed.
- Remove tip from rectum and stay in 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.

Bottle, cap, and shield are
NOT MADE WITH NATURAL RUBBER LATEX



Rev. 02/21 M-139 Re-order No. 700202



Tamper Resistant
Do not use if top or bottom flap is torn or missing.

CARTON SEALED
FOR SAFETY.
DO NOT USE
IF TOP OR
BOTTOM FLAP
OF CARTON
IS TORN OR
MISSING.

Drug Facts

Active ingredients Purpose
(in each 118mL delivered dose)
Dibasic Sodium Saline laxative
Phosphate 7 g
Monobasic Sodium Saline laxative
Phosphate 19 g

Use
• relieves occasional constipation
• this product generally produces bowel movement in 1 to 5 minutes

Warnings
Dosage warning: Using more than one enema in 24 hours can be harmful.
For rectal use only.

Do not use
• on children under 2 years of age
Ask a doctor before use if you
• have already used a laxative for more than 3 days
• have kidney disease, have heart problems, or are dehydrated
• are 55 years of age or older
• are on a sodium restricted diet
• have abdominal pain, nausea, or vomiting
• have a sudden change in bowel habits lasting more than 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 use more than directed. Serious side effects may occur from excess dosage
• do not use for more than 3 days, without asking a doctor

Stop use and ask a doctor if
• you have rectal bleeding
• you have no bowel movement within 30 minutes of enema use
• you have symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal)
These symptoms may indicate 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: 800-222-1222.

Directions (or as directed by a doctor)
Single daily dosage (per 24 hours)
Do not use if taking another sodium phosphate product.
Do not use more unless directed by a doctor. See Warnings.

Adults and children 12 years of age and older	1 bottle once daily
Children 2 to under 12 years of age	Use Pediatric Enema
Children under 2 years of age	DO NOT USE

Drug Facts (continued)

Other information
• each 118 mL contains sodium 4.3 g
• store at 15 to 30°C (59 to 86°F)
• additional liquids by mouth are recommended while using this product
• Tamper Evident: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

Inactive ingredients
benzalkonium chloride, disodium EDTA, purified water

Questions or comments?
(800) 616-2471

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

Distributed by:
MAJOR[®] PHARMACEUTICALS
Livonia, MI 48152



Image not actual size

SALINE LAXATIVE

saline laxative enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6320
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII: NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 133 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII: NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 133 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6320-78	133 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/11/2013	04/30/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	07/11/2013	04/30/2027

Labeler - Major Pharmaceuticals (191427277)

Revised: 9/2025

Major Pharmaceuticals