

## **SALINE LAXATIVE- saline laxative enema**

### **Major 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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## **MAJOR® SALINE ENEMA LAXATIVE**

### **Drug Facts**

<b>Active ingredients (in each 118mL delivered dose)</b>	<b>Purpose</b>
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<sup>®</sup>

NDC 0904-6320-78

Compare to the  
active ingredients of  
Fleet<sup>®</sup> 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<sup>®</sup>  
Ready-to-Use  
**Enema**  
Saline Laxative

MAJOR<sup>®</sup> NDC 0904-6320-78  
Compare to the active ingredients of Fleet<sup>®</sup> Saline Enema<sup>®</sup>

Ready-to-Use  
**Enema**  
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For relief of occasional constipation  
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**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.

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

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For rectal use only.

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• 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

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**Drug Facts (continued)**

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**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<sup>®</sup>.

Distributed by:  
**MAJOR<sup>®</sup> PHARMACEUTICALS**  
Livonia, MI 48152



Image not actual size

# SALINE LAXATIVE

saline laxative enema

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/11/2013	

**Labeler** - Major Pharmaceuticals (191427277)

## Establishment

Name	Address	ID/FEI	Business Operations
NATUREPLEX LLC		062808196	MANUFACTURE(0904-6320)