SALINE ENEMA- sodium phosphate, dibasic and sodium phosphate, monobasic enema
Dynarex Corporation

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

Uses:
- Gentle relief of occasional constipation

Warnings:

For rectal use only

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

As a doctor before use if you have:
- a sodium-restricted diet
- abdominal pain, nausea or vomiting
- kidney disease, heart problems, or are dehydrated
- 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.

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.

Stop use and ask a doctor if:
- If you have rectal bleeding
- you have no bowel movement after use of a laxative. This may indicate a serious condition

Keep out of reach of children

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

Other information:

- **Each 118 mL contains:** Sodium 4.3 g
- Store at room temperature 15 Deg C - 30 Deg C (59 Deg F - 86 Deg F)
- This product generally produces bowel movement in 15 minutes.

Directions

Do not use more unless directed by a doctor

See Warnings

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.

Inactive ingredient

Water

Indications and Usage

- For relief of occasional constipation

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 more than three days.

Use of this product:

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

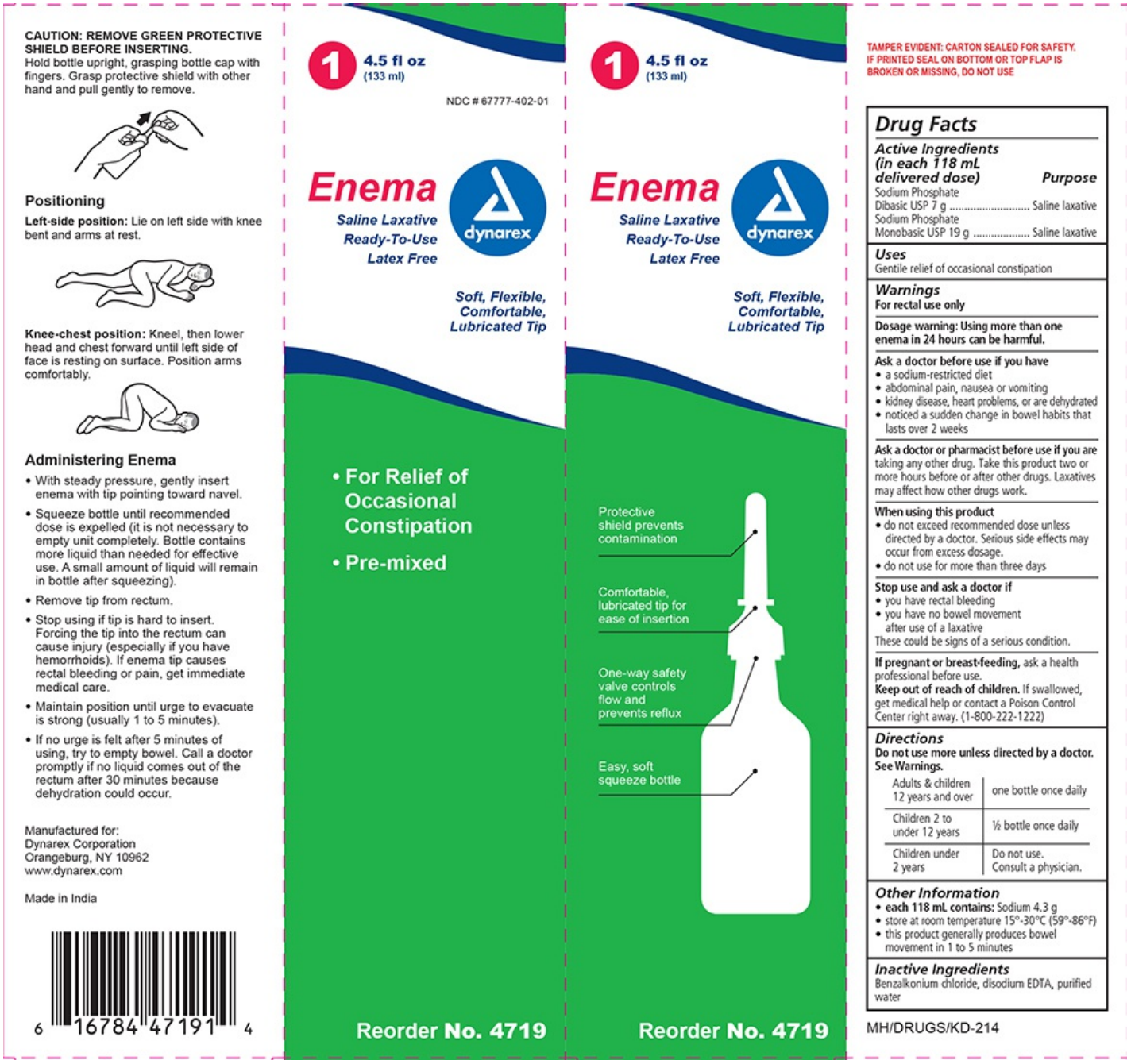
Left-side position: Lie on left side with knees bent and arms at rest. (see diagram on box)

Knee-chest position: Kneel, then lower headand chest forward until left side of face is resting on surface. Position arms comfortably. (see diagram 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.

Principal Display Panel



Saline enema.jpg

Saline enema

SALINE ENEMA

saline enema enema

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:67777-402
Route of Administration	RECTAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

SODIUM PHOSPHATE, DIBASIC (PHOSPHATE ION)	SODIUM PHOSPHATE, DIBASIC	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC (PHOSPHATE ION)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-402-01	48 in 1 CASE		
1		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	08/29/2012	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Pvt. Ltd.		864201135	manufacture(67777-402)

Revised: 2/2013 Dynarex Corporation