# HEB READY TO USE LAXATIVE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema HEB

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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# HEB<sub>®</sub> READY TO USE ENEMA LAXATIVE

#### Drug Facts

Active ingredients (in each 118 mL delivered dose)	Purpose
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

For rectal use only.

#### Dosage warning

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

#### 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	1 bottle once daily	
age and older		
Children 2 to under 12 years of	Use Pediatric Enema	
age	obe i culture Litelia	
Children under 2 years of age	DO NOT USE	

#### Other information

- each 118 ml contains 4.3 g sodium
- 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?

Call 866-323-0107

#### **PRINCIPAL DISPLAY PANEL - 2 Bottle Carton**

Compare to Fleet<sup>®</sup> Enema active ingredients\*

NDC 37808-989-24

 $H\text{-}E\text{-}B_{\mathbb{R}}$ 

Ready-to-Use Enema

Saline Laxative

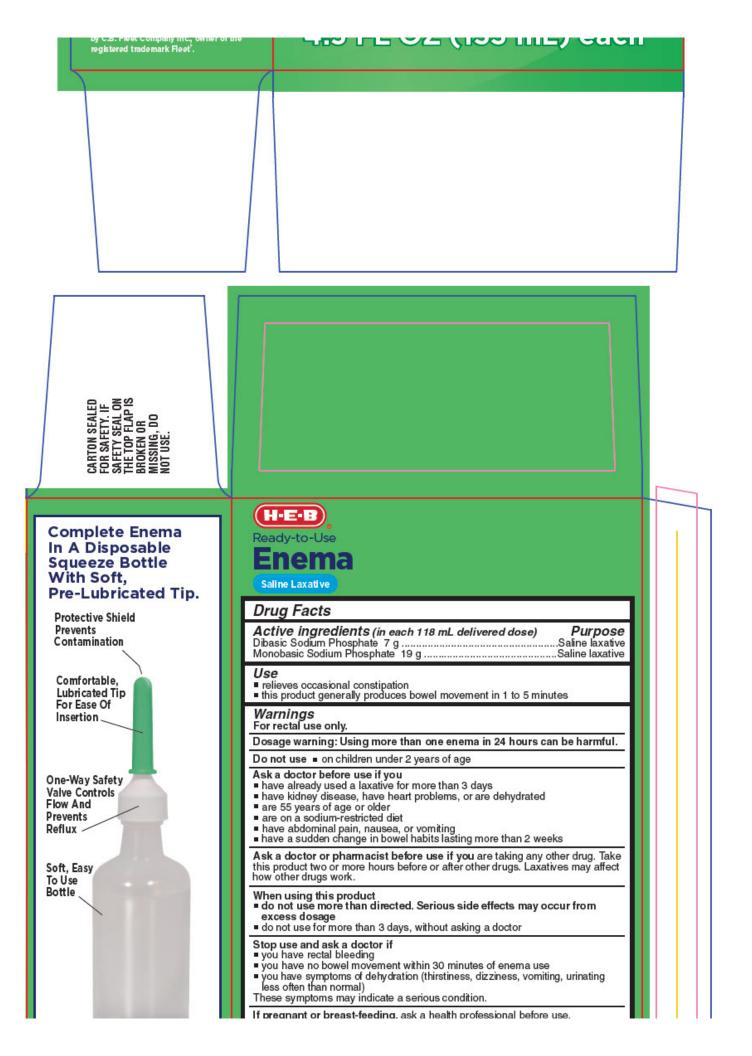
Relief of Occasional Constipation

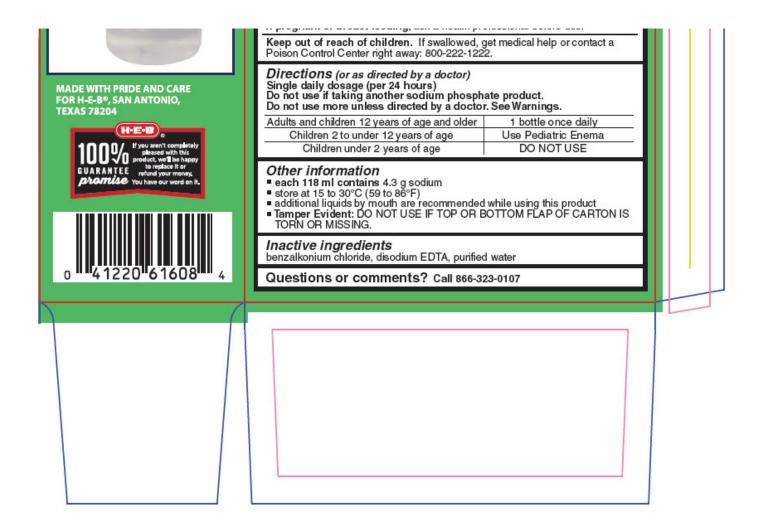
Latex Free

2 Bottles

#### 4.5 FL OZ (133 mL) each







#### **PRINCIPAL DISPLAY PANEL - 3 Bottle Carton**

Compare to Fleet<sup>®</sup> Enema active ingredients\*

NDC 37808-990-24

 $H\text{-}E\text{-}B_{\mathbb{R}}$ 

Ready-to-Use Enema

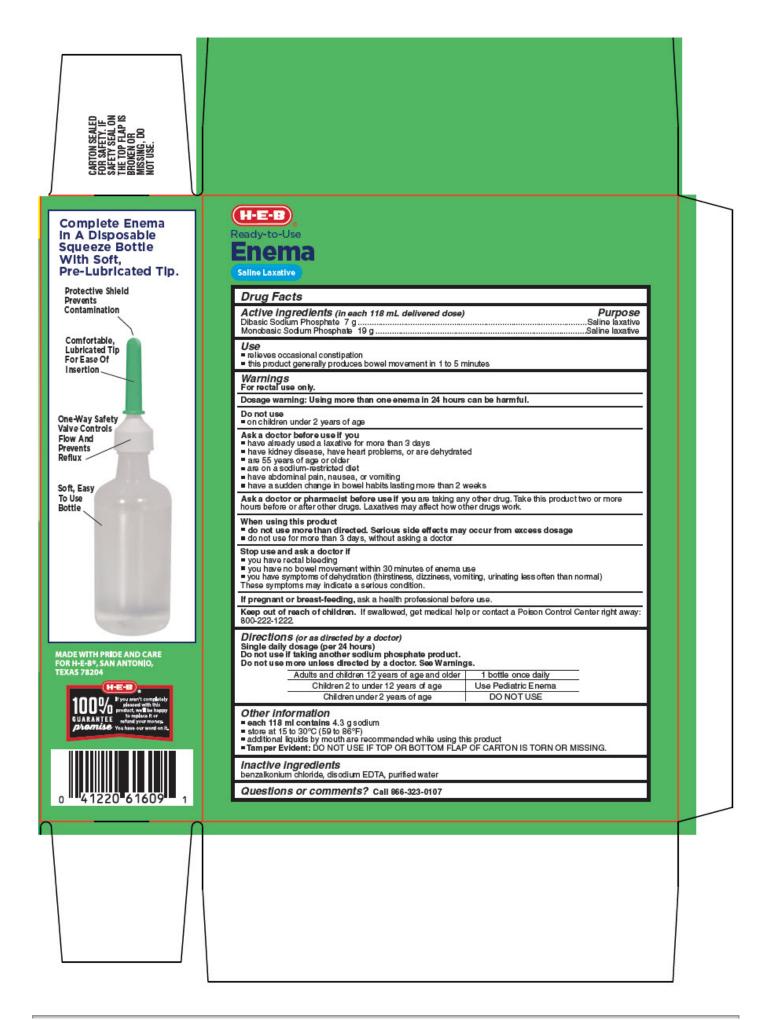
Saline Laxative

Relief of Occasional Constipation

Latex Free

3 Bottles 4.5 FL OZ (133 mL) each





#### HEB READY TO USE LAXATIVE sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:37808-989 **Route of Administration** RECTAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) SODIUM PHOSPHATE, 7 g in 133 mL (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37) DIBASIC, UNSPECIFIED FORM SODIUM PHOSPHATE. SO DIUM PHO SPHATE, MO NO BASIC, UNSPECIFIED FORM (UNII: 3980 JIH2SW) 19 g MONOBASIC, UNSPECIFIED (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37) in 133 mL FORM **Inactive Ingredients Ingredient Name** Strength BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) EDETATE DISODIUM (UNII: 7FLD91C86K) WATER (UNII: 059QF0KO0R) Packaging **Marketing Start Marketing End Item Code Package Description** # Date Date 1 NDC:37808-989-2 in 1 CARTON 10/25/2018 24 133 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-1 Package **Marketing Information** Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date OTC MONOGRAPH NOT FINAL part334 10/25/2018

#### HEB READY TO USE LAXATIVE

sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-990			
Route of Administration	RECTAL					
Active Ingredient/Active Mojety						

			Ingredient Name	Basis of Stre	ength	Strength
	ODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)       SODIUM PHOSPHATE,         PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)       DIBASIC, UNSPECIFIED FORM				,	7 g in 133 mL
SODIUM PHO SPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)SODIUM PHOSPH MONOBASIC, UN FORM					,	19 g in 133 mL
In	active Ingred	ients				
			Ingredient Name		Stre	ngth
BE	ENZALKONIUM C	HLORIDE	(UNII: F5UM2KM3W7)			
ED	ETATE DISODIU	M (UNII: 7F	LD91C86K)			
WA	ATER (UNII: 059Q	F0KO0R)				
Pa	ackaging Item Code		Package Description	Marketing Start		ting End
Pa #	Item Code		Package Description	Marketing Start Date		ting End ate
<b>P</b> a #	0 0	3 in 1 CAR		-		-
<b>Pa</b> #	Item Code NDC:37808-990-			Date		-
<b>Pa</b> #	Item Code NDC:37808-990-	133 mL in 1	TON	Date		-
Pa # 1 1 1	Item Code NDC:37808-990-	133 mL in 1 Package	TON I BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-	Date		-
Pa # 1 1 1	Item Code NDC:37808-990- 24	133 mL in 1 Package	TON I BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-	Date 10/25/2018	D	ate
Pa # 1 1	Item Code NDC:37808-990- 24	133 mL in Package	TON I BOTTLE, PLASTIC; Type 1: Convenience Kit of Co- ion Application Number or Monograph Citation	Date 10/25/2018	D	ate

## Labeler - HEB (007924756)

### Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(37808-989, 37808-990)

Revised: 10/2018

HEB