GOOD SENSE READY TO USE LAXATIVE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema Good Sense

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.

GOOD SENSE® READY TO USE ENEMA LAXATIVE

Drug Facts

Active ingredients (in each 118mL 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

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	1 bottle once
and older	daily
Children 2 to under 12 years of age	Use Pediatric
Cililaten 2 to under 12 years of age	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?

866-323-0107

Distributed by: Perrigo Direct, Inc.

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

NDC 50804-004-01

 $\mathsf{GOODSENSE}_{\mathbb{R}}$

Latex Free

Ready To Use Enema

Saline

Laxative

- For Relief Of Occasional Constipation
- Pre-Mixed
- Soft, Flexible Pre-Lubricated Tip

Compare to active ingredients of Fleet® Enema Saline*

ONE UNIT 4.5 FL. OZ. (133mL)

GOODSENSE.

Ready To Use

GOODSENSE.

■ POSITIONING: 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

REMOVE PROTECTIVE SHIELD BEFORE

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



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.



GOODSENSE.

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

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Distributed by: Perrigo Direct, Inc. Peachtree City, GA 30269 www.PerrigoDirect.com 1-866-323-0107 ood Sense® is a registered trademark of L. Perrigo Company

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

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Drug Facts (continued)

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	1 bottle
12 years of age and older	once daily
Children 2 to	Use Pediatric
under 12 years of age	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
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Questions or comments?

Complete Enema In A Disposable Squeeze Bottle With Soft, Flexible Pre-Lubricated Tip.

Protective Shield **Prevents Contamination**

Comfortable.Lubricated Tip For Ease Of Insertion

One-Way Safety Valve Controls Flow And Prevents Reflux

Soft, Easy To

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

Allergic reaction to materials containing Latex is a growing and serious medical problem.

GOOD SENSE 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:50804-004
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 CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 133 mL		
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	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:50804- 004-01	1 in 1 CARTON	12/04/2018		
1		133 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:50804- 004-02	2 in 1 CARTON	12/04/2018		
2		133 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/04/2018	
final	partos i	12,01,2010	

Establishment				
Name	Address	ID/FEI	Business Operations	
Natureplex LLC		062808196	MANUFACTURE(50804-004)	

Revised: 7/2021 Good Sense