

## **ENEMA MINERAL OIL- mineral oil enema**

**Natureplex LLC**

*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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### **Enema Mineral Oil**

#### ***Drug Facts***

#### **Active ingredient (in each 120 ml delivered dose)**

Mineral oil 100%

#### **Purpose**

Lubricant laxative

#### **Use**

- for relief of occasional constipation
- this product generally produces bowel movement in 2 to 15 minutes

#### **Warnings**

**For rectal use only.**

#### **Caution**

**To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.**

#### **Do not use**

- on children under 13 years of age
- on pregnant women
- on persons with difficulty swallowing
- on bedridden patients
- if you are presently taking a stool softener laxative
- or take with meals

#### **Ask a doctor before use if you**

- have already used a laxative for more than 3 days
- have abdominal pain, nausea, or vomiting
- have a sudden change in bowel habits that persist over a period of 2 weeks

#### **Stop use and ask a doctor if**

- you have rectal bleeding
- you have no bowel movement within 30 minutes of enema use

**As with any drug, if you are nursing a baby,** seek the advice of a health professional before using this product.

**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)**

**Rectal enema dosage is 120 ml in a single daily dosage (per 24 hours).**

Adults & children 13 years old and older	1 bottle
Children under 13 years old	DO NOT USE

**Other information**

- Store at 15 to 30°C (59 to 86°F).
- **Tamper Evident:** DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

**Inactive ingredient**

None

**Questions or comments?**

1-866-323-0107 or [www.natureplex.com](http://www.natureplex.com)

**PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton**

**\*Compare To Fleet® Mineral Oil Enema**

*Natureplex™*

**READY TO USE**

**Enema**

**Mineral**

**Oil**

**Sodium**

**Free**

**For**

**Relief Of**

**Occasional**

**Constipation**

**Not Made**

**With**

**Natural**

**Rubber**

**Latex**

**Soft,**

**Easy To**

**Use**

**Bottle**

**NDC 67234-019-01**

**1**

**Bottle**

4.5 Fl Oz  
(133 mL)

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

Natureplex

READY TO USE

# Enema

**CAUTION:**  
REMOVE ORANGE  
PROTECTIVE  
SHIELD FROM  
ENEMA TIP  
BEFORE  
INSERTING

3070B  
V03

CARTON SEALED  
FOR SAFETY. IF  
SAFETY SEAL ON  
THE TOP FLAP IS  
BROKEN OR  
MISSING, DO  
NOT USE.

\*Compare To Fleet® Mineral Oil Enema

Natureplex

READY TO USE

# Enema

Mineral  
Oil  
Sodium  
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For  
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Not Made  
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Latex



1  
Bottle  
4.5 Fl Oz  
(133 mL)

NDC 67234-019-01

Natureplex Enema

### Drug Facts

**Active Ingredient Purpose**  
(in each 120 ml delivered dose)  
Mineral oil 100%.....Lubricant laxative

### Use

- for relief of occasional constipation
- this product generally produces bowel movement in 2 to 15 minutes

### Warnings

For rectal use only.

Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.

Do not use on children under 13 years of age on pregnant women on persons with difficulty swallowing on bedridden patients if you are presently taking a stool softener laxative or take with meals

Ask a doctor before use if you have already used a laxative for more than 3 days have abdominal pain, nausea, or vomiting have a sudden change in bowel habits that persist over a period of 2 weeks

Stop use and ask a doctor if you have rectal bleeding you have no bowel movement within 30 minutes of enema use

As with any drug, if you are nursing a baby, seek the advice of a health professional before using this product.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

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### Inactive ingredient

None

### Questions or comments?

1-866-323-0107 or www.natureplex.com

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



\*Compare To Fleet® Mineral Oil Enema

Natureplex

READY TO USE

# Enema

Mineral  
Oil  
Sodium  
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For  
Relief Of  
Occasional  
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Not Made  
With Natural  
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Latex

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



### How To Use This Enema

- REMOVE ORANGE 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 knee bent and arms at rest.



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



### 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. This helps relax the muscles around the anus.
- Do not force the enema tip into rectum as this may cause injury.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
- Remove tip from rectum and maintain position until urge to evacuate is strong (usually 2 to 15 minutes).
- Discontinue use if resistance is encountered, forcing the enema can result in injury.
- Retain enema in accordance with doctor's instructions.

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

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



Natureplex

OLIVE BRANCH, MS  
38654

# ENEMA MINERAL OIL

mineral oil enema

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67234-019
<b>Route of Administration</b>	RECTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Mineral Oil</b> (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	118 g in 118 mL

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67234-019-01	1 in 1 CARTON	01/05/2013	
1		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL	part334	01/05/2013	

**Labeler** - Natureplex LLC (062808196)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Natureplex LLC		062808196	MANUFACTURE(67234-019)

Revised: 1/2020

Natureplex LLC