

ENEMA - mineral oil enema
H and P Industries, Inc. dba Triad Group

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.

Drug Facts

Active ingredient

Mineral Oil, 100%

Purpose

Lubricant Laxative

Use

- For relief of occasional constipation. This product generally produced bowel movement in 2 to 15 minutes.

Warnings

For rectal use only.

Do not use

- **If you have abdominal pain, nausea, or vomiting, unless directed by a doctor.**
- **Longer than one week unless directed by a doctor.**
- **More than one enema per day unless directed by a doctor.**

Ask a doctor before use

- if you have noticed a sudden change in bowel habits that persist over a period of 2 weeks

Stop use and ask a doctor if

- use results in unusual pain or other side effects.
- you have rectal bleeding or failure to have a bowel movement after use of a laxative. This may indicate a serious condition.

If pregnant or breastfeeding,

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.

Directions

Single Daily Dose

Do not use more unless directed by a doctor.

See Warnings.

Adults and children 12 years and older	One bottle (4 oz.) 120 mL delivered dose
Children 2 years to 12 years old	1/2 Adult dose (2 oz.) 60 mL delivered dose
Children under 2 years of age	Ask a doctor

Dosage:

- **Adults and children 12 years of age and older:** rectal enema dosage is 120 milliliters in a single daily dose.
- **Children 2 to 12 years of age:** rectal enema dosage is 60 milliliters in a single daily dose, 1/2 of a bottle. (Children's dose of 60 milliliters can be measured by removing mineral oil from the bottle until the words "Mineral Oil" on the front face of the bottle are just covered).
- **Children under 2 years of age:** ask a doctor.

Directions for inserting enema

Positioning:

Left side position: Lie on left side with right knee bent and arms resting comfortably.

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

CAUTION: Remove orange protective shield before inserting. To do so, hold bottle upright with one hand and pull gently to remove.

- with steady pressure, gently insert enema tip into rectum with a side to side movement with tip pointing toward navel.
- stop using if tip is hard to insert. Forcing 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 the liquid is released. Remove from rectum. 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.

Other Information

This product does not contain Dry Natural Rubber or Natural Rubber Latex.

Principal Display Panel

TRIAD

Ready-To-Use
MINERAL OIL
enema, USP

protective shield prevents contamination

lubricated tip assures ease of insertion

one way safety valve prevents reflux

easy to grip and squeeze bottle

carton sealed for safety

4 1/2 fl. oz. (133 ml)

CAT. No. 10-2113
Triad Disposables
Brookfield, WI 53045

ENEMA

mineral oil enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-2113
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
mineral oil (UNII: T5L8T28FGP) (mineral oil - UNII:T5L8T28FGP)	mineral oil	118 mL in 118 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-2113-0	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	05/22/1996	

Labeler - H and P Industries, Inc. dba Triad Group (050259597)

Registrant - H and P Industries, Inc. dba Triad Group (050259597)

Establishment

Name	Address	ID/FEI	Business Operations
H and P Industries, Inc. dba Triad Group		050259597	manufacture

Revised: 11/2009

Hand P Industries, Inc. dba Triad Group