Reference Safety Information – Fleet Mineral Oil Enema

FLEET® MINERAL OIL ENEMA
A LUBRICANT LAXATIVE

COMPOSITION:
FLEET® Mineral Oil Enema unit, with a 2-inch, pre-lubricated Comfortip®, delivers 118 mL of mineral oil, 100%, in a ready-to-use squeeze bottle **not made with natural rubber latex**. FLEET® Mineral Oil Enema is sodium-free. The unit is disposable after a single use.

ACTION AND USES:
FLEET® Mineral Oil Enema serves to soften and lubricate hard stools, easing their passage without irritating the mucosa. Results approximate a normal bowel movement in that only the rectum, sigmoid, and part or all of the descending colon are evacuated. FLEET® Mineral Oil Enema is indicated for relief of fecal impaction; is valuable in relief of occasional constipation when straining must be avoided (in hypertension, coronary occlusion, proctologic procedures, or postoperative care); is indicated for removal of barium sulfate residues from the colon after barium administration and is indicated for obtaining the laxative benefits of mineral oil while avoiding possible untoward effects of oral administration such as (1) interference with intestinal absorption of fat-soluble vitamins A, D, E and K and other nutrients, (2) danger of systemic absorption, or (3) possible risk of lipid pneumonia due to aspiration. It is generally effective in 2 to 15 minutes.

WARNINGS:
DO NOT ADMINISTER TO CHILDREN UNDER 2 YEARS OF AGE.

GENERAL LAXATIVE WARNINGS
INFORMATION FOR PATIENT
Ask a doctor before using any laxative if you have
- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

Stop using this product and consult a doctor if you have
- rectal bleeding
- no bowel movement within 15 minutes of using this product
- if constipation continues after one week of use

These symptoms may be signs of a serious condition.
As with any drug, if you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product.

Keep this and all drugs out of the reach of children to prevent accidental ingestion. In case of accidental overdose or ingestion, seek professional assistance or contact a Poison Control Center right away.
**DOSAGE AND ADMINISTRATION:**
Use only 1 enema per 24 hours.

<table>
<thead>
<tr>
<th>Age</th>
<th>Daily Dose (per 24 hours)</th>
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<tbody>
<tr>
<td>adults and children 12 years and older</td>
<td>one bottle</td>
</tr>
<tr>
<td>children 2 to 11 years</td>
<td>One-half bottle</td>
</tr>
<tr>
<td>children under 2 years</td>
<td>DO NOT USE</td>
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</table>

**One-half bottle preparation:** Unscrew cap and remove 4 Tablespoons of liquid with a measuring spoon. Replace cap and follow DIRECTIONS on back of carton.

**Positions for using this enema:**
- **Left-side position:** Lie on left side with knee 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.

**REMOVE ORANGE PROTECTIVE SHIELD FROM ENEMA COMFORTIP® BEFORE INSERTING.**
- 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.
- **DISCONTINUE USE IF RESISTANCE IS ENCOUNTERED. FORCING THE TIP INTO RECTUM CAN 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. A small amount of liquid will remain in the bottle after squeezing.
- Remove tip from rectum and discard bottle. The enema will usually cause a bowel movement within 2 to 15 minutes. Do not retain liquid for more than 15 minutes.
- Stop using this product and consult a doctor if you don’t have a bowel movement within 15 minutes of using this product.
The diaphragm at base of nozzle prevents reflux and assures controlled flow of the enema solution. The enema should be used at room temperature.

**PROFESSIONAL DOSAGE AND ADMINISTRATION**
FLEET® Mineral Oil Enema should not be used in children under 2 years of age and should be used with caution in children of any age. In general, careful consideration of the use of enemas in children is recommended.
Proper and safe use of FLEET® Mineral Oil Enema also requires that the product be administered according to the Directions. Healthcare professionals should remember when administering the product to gently insert the enema into the rectum with the tip pointing toward the navel. Insertion may be made easier by having the patient bear down as if having a bowel movement. Care during insertion is necessary due to lack of sensory innervation of the rectum and due to the possibility of bowel perforation. Once inserted, squeeze the bottle until nearly all the liquid is expelled. If resistance is encountered on insertion of the nozzle or in administering the solution, the procedure should be discontinued. Forcing the enema can result in perforation and/or abrasion of the rectum.

**QUESTIONS?** Call 1-866-255-6960 or visit www.fleetlabs.com