

## **FLEET- mineral oil and witch hazel**

**C.B. Fleet Company, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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### **Fleet Gentle Relief Kit**

#### **Mineral Oil enema**

#### **Drug Facts**

##### **Active ingredient (in each 118 mL delivered dose)**

Mineral Oil 100%

#### **Purpose**

Lubricant laxative

#### **Uses**

- for relief of occasional constipation
- for relief of fecal impaction
- for removal of residue after barium administration

This product usually produces a bowel movement in 2 to 15 minutes.

#### **Warnings**

For rectal use only

#### **Do not use**

when abdominal pain, nausea, or vomiting are present unless directed by a doctor

#### **Ask a doctor before using this product if you**

- have a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

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

- rectal bleeding
- no bowel movement within 15 minutes of using this product

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 (1-800-222-1222) right away.

## Directions

Single Daily Dosage (per 24 hours)

adults and children 12 years and over	1 bottle per day
children 2 to under 12 years	one-half bottle
children under 2	DO NOT USE

## Other information

- sodium-free
- for complete Professional Use, Warnings and Precautions, consult the Reference Safety Information on our website

## Questions?

1-866-255-6960 or [www.fleetlabs.com](http://www.fleetlabs.com)

**Tamper Evident** bottle sealed for safety. If bottle wrapper with Fleet® emblem is torn, damaged or missing, do not use.

## Hemorrhoidal Relief Wipes

### Drug Facts

#### Active ingredient

Witch hazel 50.0%

#### Purpose

Astringent

#### Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- aids in protecting irritated anorectal areas

#### Warnings

##### For external use only

##### When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

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

- bleeding occurs
- condition worsens or does not improve within 7 days

##### 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 (1-800-222-1222) right away.

**Directions**

- adults: unfold wipe and cleanse the area by gently wiping, patting or blotting. if necessary, repeat until all matter is removed from the area.
- use up to 6 times daily or after each bowel movement and before applying topical hemorrhoidal treatments and then discard
- children under 12 years of age: consult a doctor

**Other information**

- store at 20°-25°C (68°-77°F)
- for best results, flush only one or two wipes at a time

**Inactive ingredients**

aloe vera leaf, anhydrous citric acid, bronopol, disodium cocoamphodiacetate, glycerin, iodopropynyl butylcarbamate, PEG-75 lanolin, propylene glycol, sodium citrate, water

**PRINCIPAL DISPLAY PANEL**

**Fleet®**

**LUBRICANT LAXATIVE HEMORRHOIDAL WIPES**

**Gentle Relief Kit**

2 MINERAL OIL enemas - 2 Bottles 4.5 fl oz (133 mL) each

2 hemorrhoidal wipes WITCH HAZEL WITH ALOE - 2 Individually Wrapped Flushable Wipes

### MINERAL OIL enema

**Drug Facts**  
**Active ingredient**  
 (in each 118 mL delivered dose) **Purpose**  
 Mineral oil 100%.....Lubricant laxative

**Use**  
 • for relief of occasional constipation  
 • for relief of fecal impaction  
 • for removal of residue after barium administration  
 This product usually produces a bowel movement in 2 to 15 minutes.

**Warnings**  
**For rectal use only**  
 Do not use when abdominal pain, nausea, or vomiting are present unless directed by a doctor.  
 Ask a doctor before using this product if you  
 • have a sudden change in bowel habits lasting more than 2 weeks  
 • already used a laxative for more than 1 week.  
 Stop use and ask a doctor if you have  
 • rectal bleeding  
 • no bowel movement within 15 minutes of using this product  
 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 (1-800-222-1222) right away.

**Directions**  
**Single Daily Dosage (per 24 hours)**  
 adults and children 12 years and over 1 bottle per day  
 children 2 to under 12 years one-half bottle  
 children under 2 DO NOT USE

**Other information**  
 • sodium-free  
 • for complete Professional Use, Warnings and Precautions, consult the Reference Safety Information on our website

**Questions?** 1-866-255-6810 or www.fleetusa.com

Tamper Evident: bottle sealed for safety. If bottle wrapper with Fleet® emblem is torn, damaged or missing, do not use.

### HEMORRHOID AND IRRITATION RELIEF flushable wipes WITH ALOE

**Drug Facts**  
**Active ingredient Purpose**  
 Witch hazel 50%.....Astringent

**Use**  
 • helps relieve the local itching and discomfort associated with hemorrhoids  
 • temporary relief of irritation and burning  
 • aids in protecting irritated anorectal areas

**Warnings**  
**For external use only**  
**When using this product**  
 • do not exceed the recommended daily dosage unless directed by a doctor  
 • do not put this product into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**  
 • bleeding occurs  
 • condition worsens or does not improve within 7 days

**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 (1-800-222-1222) right away.

**Directions**  
 • adults: unfold wipe and cleanse the area by gently wiping, patting or blotting. If necessary, repeat until all matter is removed from the area.  
 • use up to 6 times daily or after each bowel movement and before applying topical hemorrhoidal treatments and then discard  
 • children under 12 years of age: consult a doctor

**Other information**  
 • store at 20°-25°C (68°-77°F)  
 • for best results, flush only one wipe at a time

**Inactive ingredients**  
 aloe vera leaf, anhydrous citric acid, bronopol, disodium cocosulfonediacetate, glycerin, isocrotonyryl butylcarbamate, PEG-75 lanolin, propylene glycol, sodium citrate, water

**How to use this enema:**

- REMOVE GREEN WRAPPER WITH FLEET® EMBLEM AND CHANGE 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 bends down, as if having a bowel movement. This helps relax the muscles around the area.
- Do not force the enema tip into rectum as this 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.
- Remove Comfortip® from rectum and maintain position until urge to evacuate is strong (usually 2 to 18 minutes).
- Do not retain enema solution for more than 15 minutes.
- If constipation continues after one week of use, consult your doctor.

**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 flexed comfortably.

**Complete enema in a disposable squeeze bottle with soft, pre-lubricated Comfortip®**

## Fleet®

LUBRICANT LAXATIVE | HEMORRHOIDAL WIPES

### Gentle Relief Kit

2 MINERAL OIL enemas

- Works differently!\*
- Lubricates inside for a gentle experience

with extra lubricated gentle glide comfortip®

2 hemorrhoidal wipes WITH HAZEL WITH ALOE Flushable!

2 Bottles 4.5 Fl Oz (133 mL) each Individually Wrapped Flushable Wipes

2 Bottles 4.5 Fl Oz (133 mL) each Individually Wrapped Flushable Wipes

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 Made in USA

<b>FLEET</b>				
mineral oil and witch hazel kit				
<b>Product Information</b>				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0705	
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0705-00	1 in 1 CARTON; Type 0: Not a Combination Product	02/15/2019	
<b>Quantity of Parts</b>				
Part #	Package Quantity		Total Product Quantity	
Part 1	1 BOTTLE, WITH APPLICATOR		133 mL	
Part 2	1 CARTON		2	
<b>Part 1 of 2</b>				

## FLEET

mineral oil enema

### Product Information

Route of Administration RECTAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	100 g in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/01/2002	

## Part 2 of 2

## FLEET

witch hazel cloth

### Product Information

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	5 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

<b>BRONOPOL</b> (UNII: 6PU1E16C9W)	
<b>DISODIUM CO COAMPHODIACETATE</b> (UNII: 18L9G3U51M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	02/15/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/15/2019	

**Labeler** - C.B. Fleet Company, Inc. (003119054)

Revised: 6/2020

C.B. Fleet Company, Inc.