# DYNAREX LAXATIVE- mineral oil liquid Dynarex Corporation

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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# **Dynarex Mineral Oil Laxative**

# **Active Ingredient**

Active Ingredient Purpose

Mineral oil Intestinal lubricant

# Purpose

# **Purpose**

Relieves occassional constipation (irregularity).

# Warnings

# Warnings

# Do not use:

- If you have difficulty swallowing.
- In children under 12 years of age.
- If you are pregnant.
- For a period longer than 1 week.
- If you are bedridden or aged.

# **Indications & Usage**

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• For relief of occassional constipation (irregularity).

# When using this product

- Do not take with meals
- Take only at bedtime

# Ask a doctor before use if you have

- Stomach reflux
- Abdominal pain, nausea, or vomiting
- Notice a sudden change in bowel habits that persist over a period of 2 weeks

# Stop use and ask a doctor if

• Rectal bleeding or failure to have a bowel movementafter use. These could be signs of a serious condition.

# **Dosage & Administration**

#### **Directions**

• Do not take with meals

- Take only at bedtime
- May be taken as a single daily dose or in divided doses.

age	dose
adults and children over 12 years	1 to 3 tablespoons (15 to 45 ml) Maximum 3 tablespoons (45ml) in 24 hours
children under 12 years	Consult a doctor

# Keep Out Of Reach Of Children

# **Keep Out Of Reach Of Children**

- Keep this and all drugs out of the reach of children
- In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

#### Other information

# Other information

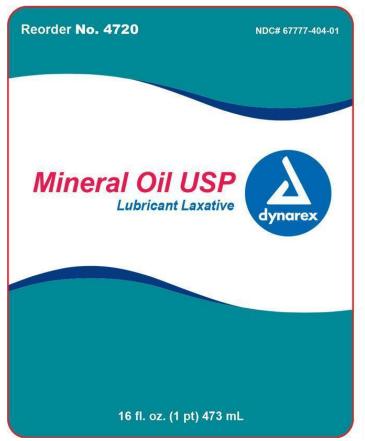
- ¶Keep tightly closed
- Protect from sunlight

# **Inactive ingredients**

Inactive ingredients: Butylated hydroxytoluene (BHT), Butylated hydroxyanisole (BHA)

# **Principal Display Panel**

Dynarex Mineral Oil Laxative 4270 Min oil.jpg





keep tightly closed • protect from sunlight

Butylated hydroxyanisole (BHA)

Inactive Ingredient Butylated hydroxytoluene (BHT),

Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com

Made in India



# DYNAREX LAXATIVE

mineral oil liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67777-404

Route of Administration ORAL

# Active Ingredient/Active Moiety

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

# **Inactive Ingredients**

Ingredient Name
Strength
butylated hydroxytoluene (UNII: 1P9 D0 Z171K)
Butylated hydroxyanisole (UNII: REK4960K2U)

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-404-01	473 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/05/2014	

# Labeler - Dynarex Corporation (008124539)

# **Registrant** - Dynarex Corporation (008124539)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mistair Health & Hygiene Pvt Ltd		677604297	manufacture(67777-404)	

Revised: 3/2014 Dynarex Corporation