

## **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**

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Mineral oil

##### **Purpose**

Intestinal lubricant

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Relieves occasional constipation (irregularity).

#### **Warnings**

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##### **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 occasional 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 movement after 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**

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- 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

Reorder No. 4720 NDC# 67777-404-01

**Mineral Oil USP**  
Lubricant Laxative



16 fl. oz. (1 pt) 473 mL

**Drug Facts** TAMPER EVIDENT: DO NOT USE IF THE UNDER CAP PRINTED SAFETY FOIL IS BROKEN OR MISSING.

Active ingredient	Purpose
Mineral oil	intestinal lubricant

**Uses** • relieves occasional constipation (irregularity) • generally produces bowel movement in 6 to 8 hours

**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  
**Ask a doctor before use if you have** • stomach reflux • abdominal pain, nausea, or vomiting • noticed a sudden change in bowel habits that persists over a period of 2 weeks  
**When using this product** • do not take with meals • take only at bedtime  
**Stop use and ask a doctor if** • rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.  
**If pregnant or breast-feeding**, ask a health professional before use.  
**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.

**Directions** • do not take with meals • take only at bedtime • maybe taken as a single daily dose or in divided doses


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**Inactive Ingredient** Butylated hydroxytoluene (BHT), Butylated hydroxyanisole (BHA)

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

Made in India



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## 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	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	99 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Butylated hydroxyanisole (UNII: REK4960K2U)	

### Packaging

#	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