

MINERAL OIL- mineral oil liquid
DZA Brands LLC

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 99.9%

Purpose

Lubricant laxative

Use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 6 to 8 hours

Do not use

- if you have difficulty swallowing
- in children under 6 years of age
- if you are pregnant
- for a period longer than week
- if you are bedridden or aged

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you are

- presently taking a stool softener laxative
- taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work

When using this product

do not take with meals. Take only at bedtime.

Stop use and ask a doctor

if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

If breast feeding

ask a health professional before use

Keep out of reach of children

in case of overdose, get medical help or contact a Poison Control Center right away

Directions

- do not take with meals
- take only at bedtime
- may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over - 1 to 3 Tablespoons (15 - 45 mL) maximum 3 Tablespoons (45 mL) in 24 hours

children 6 to under 12 years of age - 1 to 3 teaspoons (5 - 15 mL) maximum 3 teaspoons (15 mL) in 24 hours

children under 6 years of age - do not use, consult a doctor

Other information

keep tightly closed. Protect from sunlight

Inactive ingredients

mixed tocopherols (added as a stabilizer)

Disclaimer

This product is not manufactured or distributed by Roberts Pharmaceutical Corp., distributor of Roberts Mineral Oil

Adverse reactions

Distributed by DZA Brands, LLC 2110 Executive Drive, Salisbury, NC 28147

For product questions or comments contact us at 1-866-322-2439

Please include UPC and code from the package.

Principal display panel

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

healthy

accents

mineral oil

USP

Lubricant laxative

relieves occasional constipation

odorless - tasteless - colorless

compare to Roberts

Mineral Oil

active ingredient

16 FL OZ (1 PT) 473 mL

Made in the USA with US and foreign components



MINERAL OIL

mineral oil liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-831
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	999 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-831-43	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/22/2007	

Labeler - DZA Brands LLC (090322194)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55316-831)

Revised: 7/2013

DZA Brands LLC