

MINERAL OIL- mineral oil solution
Safecor Health, 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.

SAFECOR HEALTH
Mineral Oil USP 30 mL Unit Dose
Drug Facts

Active Ingredients

Mineral Oil USP

Purpose

Lubricant Laxative

Use:

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

WARNINGS:

Do not use * if you have difficulty swallowing * in children under 6 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 *abdominal pain, nausea, or vomiting *noticed a sudden change in bowel habits that persist over a period of 2 weeks.

Ask a Doctor or Pharmacist before use if you are: * presently taking a stool softener * taking any other drug. Take this product 2 or more hours before or after drugs. Laxatives may affect how other drugs work. Frequent or prolonged use may result in dependence.

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 care professional before use.

Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. In case of eye contact, flush with water.

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 mL to 45 mL), maximum 3 Tablespoons (45 mL) in 24 hours
Children 6 to under 12 years of age	1 to 3 teaspoons (5 mL to 15 mL), maximum 3 teaspoons (15 mL) in 24 hours
Children under 6 years	Do not use. Consult a doctor

Other information: Keep tightly closed. Protect from sunlight. For more info call 800-447-1006.

Inactive ingredients: Mixed tocopherols (added as a stabilizer)

NDC: 48433-202-30 Mineral Oil USP 30 mL Unit Dose Cup

Mfd. in the U.S.A.

Distributed by: Safecor Health, LLC

4060 Business Park Drive, Columbus, OH 43204

Rev: 05/2019 PN5471

Principal Display Panel - Lid Label

Delivers **30 mL**

NDC 48433-202-30

Mineral Oil USP

Lubricant Laxative

DO NOT TAKE WITH MEALS

348433202302

Pkg By: Safecor Health, LLC

Columbus, OH 43204

Delivers 30 mL
NDC 48433-202-30

Mineral Oil USP

Lubricant Laxative
DO NOT TAKE WITH MEALS



348433202302

Pkg By: Safecor Health, LLC
Columbus, OH 43204

PN5616.A

MINERAL OIL

mineral oil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-202
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	1000 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-202-30	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/2014	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	MANUFACTURE(48433-202)

Revised: 1/2022

Safecor Health, LLC