

SUNMARK- mineral oil
ATLANTIC BIOLOGICALS CORP.

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.

Mineral Oil

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)

Adverse reaction section

DISTRIBUTED BY:

ALTANTIC BIOLOGICALS CORP.

20101 NE 16TH PLACE

MIAMI, FL 33179

Principal Display Panel

Mineral Oil USP

Lubricant Laxative

For relief of occasional constipation

Tasteless, Odorless, Colorless

30mL CUP

NDC 17856-0832-01

17856-0832-01

**MINERAL OIL 99.9%
LUBRICANT LAXATIVE**



Rev.01/19

See package insert for indications and dosage schedule

Protect from sunlight.
KEEP OUT OF THE REACH OF CHILDREN.

**17856-0832-01
MINERAL OIL**

Dosage: 30 ML

Qty: 50 Cups



GTIN: 1785608321
S/N: 00000000000001
Exp: 10/10/20
Lot: 000000

OTC



17856083201

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals
Corp, Miami FL 33179

Call to Reorder: 800.509.7592

SUNMARK

mineral oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0832(NDC:49348-831)
Route of Administration	ORAL		

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:17856-0832-1	50 in 1 BOX, UNIT-DOSE	12/02/2022	
1	NDC:17856-0832-2	30 mL in 1 CUP, UNIT-DOSE; 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	04/10/2019	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-0832)

Revised: 12/2022

ATLANTIC BIOLOGICALS CORP.