

**MINERAL OIL- mineral oil liquid**  
**CARDINAL HEALTH 110, LLC. DBA LEADER**

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**Leader 831.000/831AA**  
**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.

**Warnings**

for this product

**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 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 to 45 mL)  
maximum 3 Tablespoons (45 mL) in 24 hours

children 6 to under 12 years of age - 1 to 3 teaspoons (5 to 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)

**Questions?**

1-888-593-0593

**Adverse reaction**

DIST. BY CAH DUBLIN, OH 43017

[www.myleader.com](http://www.myleader.com)

1-800-200-6313

**Principal Display Panel**

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

LEADER™

NDC 70000-0663-1

Mineral Oil

Lubricant Laxative

For relief of occasional constipation

100% Money back Guarantee

Odorless Tasteless, Colorless

16 FL OZ (1 PT) 473 mL



L00215398A

CIN 5878038 REV. 11/23

**Drug Facts**

Active ingredient	Purpose
Mineral oil 99.9%	Lubricant laxative

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**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.

**Drug Facts (continued)**

**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 to 45 mL) maximum 3 Tablespoons (45 mL) in 24 hours
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children 6 to under 12 years of age	1 to 3 teaspoons (5 to 15 mL) maximum 3 teaspoons (15 mL) in 24 hours
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children under 6 years of age	do not use, consult a doctor
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**Other information** keep tightly closed. Protect from sunlight.

**Inactive ingredients** mixed tocopherols (added as a stabilizer)

**Questions? 1-888-593-0593**

MADE BY OHIO DUBLIN, OH 43017  
www.aceco.com  
1-800-309-6383

**MINERAL OIL**

mineral oil liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0663
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0663-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	04/17/2023	

**Labeler** - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

**Registrant** - Nice-Pak Products, LLC (119091520)

## Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(70000-0663)

Revised: 1/2026

CARDINAL HEALTH 110, LLC. DBA LEADER