

KONDREMUL- kondremul liquid

Insight Pharmaceuticals

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.

KONDREMUL®

LUBRICANT LAXATIVE

Drug Facts

Active ingredient (in each 5 mL/teaspoonful)

Mineral Oil 2.5 mL

Purpose

Lubricant Laxative

Uses

- relieves occasional constipation
- generally produces bowel movement in 6 to 8 hours

Warnings

Do not use

- for children under 6 years of age, pregnant women, bedridden patients or persons with difficulty swallowing.

Ask a doctor before use if you have

- abdominal pain, nausea or vomiting.
- 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

When using this product do not take with meals

Stop use and ask a doctor if

- you notice rectal bleeding or fail to have a bowel movement after use of a laxative. This may indicate a serious condition. Discontinue use and consult a doctor.
- you need to use this product more than 1 week

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
- shake well before using
- adults and children 12 years of age and over:
6–18 teaspoons per day or as directed by a doctor
- children 6 to under 12 years of age:

2–6 teaspoons per day or as directed by a doctor

- the maximum daily dose may be taken as a single dose or divided in up to 3 equal parts
- children under 6 years of age: consult a doctor

Inactive Ingredients

Acacia, Benzoic Acid, Carrageenan (Irish Moss), Ethyl Vanillin, Glycerin, Mapiene Triple Oil, Purified Water, Titanium Dioxide, Vanillin

QUESTIONS

Call 1-800-344-7239

Distributed by:

INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 480 mL Bottle Label

**Do Not Purchase if perforated ring
at bottom of cap is broken or missing.**

KONDREMUL®

LUBRICANT LAXATIVE

Mineral Oil (microemulsion)

FOR RELIEF OF OCCASIONAL CONSTIPATION

Promotes gentle, predictable regularity of normal bowel movement. Creamy liquid pours easily and leaves no oily aftertaste. All dosages may be administered plain or mixed with warm or cold water, milk or cocoa. Pleasant tasting and smooth acting, it passes through stomach and upper intestine without upset or dehydration. Assures soft stool by retaining moisture balance and mixing thoroughly with bowel content. Permits passage of stool without straining.

SHAKE WELL BEFORE USING

Store at room temperature 15°-25°C (59°-77°F)

16 FL. OZ. (480 ML)

69871C

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Distributed by:

INSIGHT Pharmaceuticals Corp.
Langhorne, PA 19047-1749

69872D

KONDREMUL

kondremul liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63736-012 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP) | Mineral Oil | 2.5 mL in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0KO0R) | |
| Acacia (UNII: 5C5403N26O) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Benzoic Acid (UNII: 8SKN0B0MIM) | |

Titanium Dioxide (UNII: 15FIX9V2JP)

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|--|
| Color | WHITE (Opaque white) | Score | |
| Shape | | Size | |
| Flavor | VANILLA | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63736-012-16 | 480 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part334 | 06/05/2009 | |

Labeler - Insight Pharmaceuticals (176792315)

Revised: 1/2010

Insight Pharmaceuticals