

**HUMCO MINERAL OIL HEAVY- mineral oil liquid**  
**Humco Holding Group, Inc.**

*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.*

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**Humco Mineral Oil USP Heavy**

Drug Facts

**Active ingredient**

Mineral Oil Heavy

**Purpose**

Laxative

**Use**

For relief of occasional constipation or irregularity. Generally produces bowel movement in 6 to 8 hrs.

**Warnings**

Do not take this product if you have abdominal pain, nausea, vomiting, change in bowel habits persisting more than 2 weeks, rectal bleeding or kidney failure are present, or use for a period of longer than 1 week unless directed by a doctor. Frequent or prolonged use may result in the dependence on laxatives.

Do not administer to infants or young children, bedridden or aged patients unless directed by a doctor.

**Ask a doctor before use if**

you are currently taking a stool softener laxative.

If pregnant or breast feeding ask a health professional before use.

**When using this Product discontinue use**

and consult a doctor if there is a failure to have a bowel movement after use.

**Keep out of reach of children**

In case of accidental overdose, seek professional assistance or contact Poison Control Center immediately. In case of eye contact wash gently with water for 15 minutes.

**Directions**

Adults and children 12 yrs and older: 1 to 2 tablespoonfulls at bedtime.

Children 6 to 12 yrs. of age: 1 to 3 teaspoonfuls at bedtime.

Children under 6 yrs. of age: Consult a doctor before use.

**Inactive ingredient**

dl-alpha-tocopherol as a preservative.

**Other information**

Keep tightly closed and protect from direct light.

**Principal display panel**

# MINERAL OIL HEAVY

ODORLESS - TASTELESS - CRYSTAL CLEAR

\* Safety Sealed  
**Gastro-intestinal**

**USP**

LUBRICANT  
LAXATIVE

- Lubricant laxative for relief of occasional constipation or irregularity



A trusted name  
in home health care

128 FL oz  
(1 Gal) 3.8 L

**\*WARNING:** Do not use if Tamper Evident Seal is broken or missing. This product is sealed with either a shrink band around cap imprinted "Sealed For Your Protection" or foil seal under cap.

### Drug Facts

Active ingredient	Purpose
Mineral Oil Heavy.....	Lubricant laxative

**Indications:** For relief of occasional constipation or irregularity. This product generally produces bowel movement in 6 to 8 hours.

**Warnings:** Do not take this product if you have abdominal pain, nausea, vomiting, change in bowel habits persisting for more than 2 weeks, rectal bleeding or kidney failure are present, or use for a period of longer than 1 week unless directed by a doctor. Do not administer to children under 6 years of age, or pregnant women, to bedridden patients or to persons with difficulty swallowing. As with any drug, if you are nursing a baby, seek the advise of a health professional before using this product. **Caution:** to be taken only at bedtime. Do not use at any other time or administer to infant, except upon the advice of a physician.

■ Do not use this product if you are presently taking a stool softener laxative.

When using this product discontinue use and consult a doctor if there is a failure to have a bowel movement after use.

If pregnant or breast feeding ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

#### Directions:

■ Adults and children 12 yrs and older: 15 to 45 milliliters at bedtime.

■ children 6 to 12 yrs of age: 5 to 15 milliliters at bedtime.

■ children under 6 yrs. of age: consult a doctor before use.

**Inactive ingredient:** dl-alpha-tocopherol as a preservative.

**Other information:** Keep tightly closed and protect from direct sunlight.

R013018



Packed by: HUMCO, Texarkana, TX 75501  
Questions or Comments? 1-800-662-3435

## HUMCO MINERAL OIL HEAVY

mineral oil liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-1685
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 ACETATE, DL- (UNII: WR1WPI7EW8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-1685-28	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/14/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/25/1998	

**Labeler** - Humco Holding Group, Inc. (825672884)

**Registrant** - Pharma Nobis, LLC (118564114)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-1685) , analysis(0395-1685) , pack(0395-1685) , label(0395-1685)

Revised: 3/2022

Humco Holding Group, Inc.