

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.

Private Label Mineral Oil 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 tablespoonfuls 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.

CVS Label

Drug Facts	Purpose
Active ingredient Mineral Oil	Lubricant Laxative
Use For relief of occasional constipation or irregularity. Generally produces bowel movement in 6 to 8 hrs.	
Warnings ■ Do not use ■ if you have difficulty swallowing ■ in children under 12 years of age ■ if you are pregnant ■ for a period longer than 1 week ■ if you are bedridden or aged ■ if you are presently taking a stool softener laxative	
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	
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 pregnant or 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 (1-800-222-1222) 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 yrs and over: 1 to 2 tablespoons (15 to 30 mL), maximum 3 tablespoons (44 mL) in 24 hours ■ Children under 12 years, consult a doctor.	
Other information Keep tightly closed and protect from direct sunlight.	
Inactive ingredient dl-alpha-tocopherol as a preservative.	
Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02896 © 2018 CVS Pharmacy V-30204	
CVS Quality Member Since 1969	
4232291 50428 27794 2	



Leader Label



Drug Facts	Purpose
Active ingredient Mineral Oil 100%	Lubricant Laxative
Use For relief of occasional constipation or irregularity. Generally produces bowel movement in 6 to 8 hrs.	
Warnings Do not use ■ if you have difficulty swallowing ■ in children under 12 years of age ■ if you are pregnant ■ for a period longer than 1 week ■ if you are bedridden or aged ■ if you are presently taking a stool softener laxative	
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	
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 pregnant or 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 (1-800-222-1222) 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 yrs and over: 1 to 2 tablespoons (15 to 30 mL), maximum 3 tablespoons (44 mL) in 24 hours ■ Children under 12 years, consult a doctor.	
Other information Keep tightly closed and protect from direct sunlight.	
Inactive ingredient dl-alpha-tocopherol as a preservative.	
Questions or Comments? 1-800-682-3435	
DISTRIBUTED BY: MINERAL HEALTH DUBLIN, OH 43007 www.minhealth.com 1-800-220-4218 © 2018 Cardinal Health	
CVN 5480041 96295 13630 2	
REV. 12/18	

MINERAL OIL HEAVY

mineral oil liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9135
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:0395-9135-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/18/2018	
2	NDC:0395-9135-32	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/18/2018	

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

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(0395-9135) , analysis(0395-9135) , pack(0395-9135) , label(0395-9135)

Revised: 6/2020

Humco Holding Group, Inc.