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 irregularit. 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 brest feeding ask a health professional before use.

When using this Product discotinue 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.

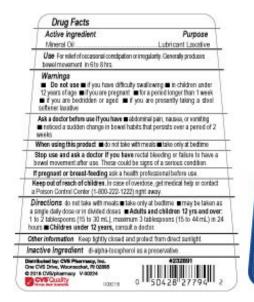
Inactive ingredient

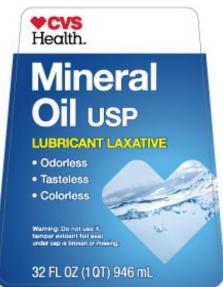
dl-alpha-tocopherol as a preservative.

Other information

Keep tightly closed and protect from direct light.

CVS Label





Leader Label





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	

l	Inactive Ingredients		
l	Ingredient Name	Strength	
l	.ALPHATO COPHEROL 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	0 1/3 1/2 0 2 0		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/18/20 18	

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.