ACTIVE HYDROGEN PROFESSIONAL- menthol gel
EXECUTIVE PRO SOLUTIONS DOO

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.

Active hydrogen

Warnings

- For external use only

• use only as directed

• do not bandage or use with heating pad or medicated patch

• avoid contact with eyes and mucous membranes

• do not apply to open wounds or damaged, broken or irritated skin

• a slight burningmay occur upon application with disappearing

Purpose

External analgesic

Uses

Reduces and stops the inflammatory process, eliminates pain, reduces swelling, speeds up recovery process after injuries, neutralizes excretion of lactic acid in the muscles

Dosage and Administration

adults and children over 12 years:
• apply a thin layer to the target - the sore spot
• massage into painful area until thoroughly absorbed into skin

• repeat the process several (4 to 5) times • wipe over with wet hand to remove any sense of tension

• repeat the process minimum 3 times per days Children 12 years or younger: ask a doctor

Keep out of reach of children

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away

Stop use and ask doctor if

• condition worsens
• redness is present

• irritation develops
• symptoms persist for more then 7 days or clear up and occur again within a few days

Active ingridients

Menthol 1.2 %

Inactive Ingridients

Aqua, Ascorbic Acid, Boric, Acid, Carboxy Methyl Cellulose, Magnesium Oxide, Potassium Sorbate, Glycerol.

Product Label

ACTIVE HYDROGEN PROFESSIONAL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72316-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
AQUA REGIA (UNII: X3TT5X989E)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BORIC ACID (UNII: R57ZHV85D4)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCEROL (1-(12-HYDROXYSTEARATE)) (UNII: X84XWP4TOC)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72316-001-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/11/2018	

Labeler - EXECUTIVE PRO SOLUTIONS DOO (506157273)

Establishment

Name	Address	ID/FEI	Business Operations
8.0 IDEAL BALANCE D.O.O. BEOGRAD		506132408	manufacture(72316-001)

Revised: 5/2018 EXECUTIVE PRO SOLUTIONS DOO