

**ACTIVE HYDROGEN PROFESSIONAL CREAM- menthol cream**  
**8.0 IDEAL BALANCE D.O.O. BEOGRAD**

*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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**Active HYDROGEN PROFESSIONAL cream**

**Warnings**

- **For external use only**
- **When using this product**
- 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 burning may occur upon application with disappearing effect in short period of time

***Purpose***

Topical 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

***Directions***

**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 one again.
- repeat the process minimum 3 times per day

**Children 12 years or younger:** ask a doctor

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

**Keep out of reach of children**

If swallowed get medical help or contact a Poison Control Center right away  
Use within 90 days after opening the product.

**Stop use and ask doctor if**

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

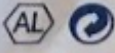
**Inactive Ingredients**

Ascorbic Acid, Aqua, Boric Acid, Butylated Hydroxytoluene, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Ethylhexanoate, Disodium Edta, Glycerol, Glyceryl Stearate (and) Cetareth-20 (and) Cetareth-12 (and) Cetearyl Alcohol (and) Cetyl Palmitate, Magnesium Oxide, Paraffinum Liquidum, Perfume, Phenoxyethanol (and) Ethylhexylglycerin, Propylene Glycol, Tocopheryl Acetate.

**Product label**



MANUFACTURER:  
for B.O Ideal Balance d.o.o.  
Savski nasip 11a,  
New Belgrade 11070 Serbia,  
manufactured by: PreCo d.o.o.  
Savski nasip 11a,  
New Belgrade 11070 Serbia



NET WT 1.70 OZ  
50ml e



## ACTIVE HYDROGEN PROFESSIONAL CREAM

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72901-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	70 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETEARETH-12</b> (UNII: 7V4MR24V5P)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CETEARYL ETHYLHEXANOATE</b> (UNII: 9M64UO4C25)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	

<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72901-002-01	1 in 1 CARTON	03/28/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/28/2019	

**Labeler - 8.0 IDEAL BALANCE D.O.O. BEOGRAD (506132408)**

Revised: 2/2022

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