

ACTIVE HYDROGEN PROFESSIONAL GEL- menthol gel

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.

active HYDROGEN Professional gel

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

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

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

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

Active ingredient

Menthol 1.2 %

Inactive Ingredients

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

Product Label

active HYDROGEN[®] PROFESSIONAL gel

ACTIVE HYDROGEN PROFESSIONAL GEL contains the maximum concentration of the molecular hydrogen and is primarily intended for professional athletes and all those exposed to extreme physical exertion during workout and training.

ACTIVE HYDROGEN PROFESSIONAL GEL is the first product in the world based on the revolutionary discovery that is reflected in the synergy of nature and the latest scientific researches regarding the powerful antioxidant effect of molecular hydrogen.

- ✓ REDUCES AND STOPS THE INFLAMMATORY PROCESS
- ✓ REDUCES AND ELIMINATES PAIN AFTER INJURIES AND INFLAMMATIONS
- ✓ LEADS TO A REDUCTION AND DISAPPEARANCE SWELLING AND BRUISING
- ✓ NEUTRALIZES NEGATIVE EFFECTS OF EXCRETION OF LACTIC ACID IN THE MUSCLES
- ✓ SPEEDS UP RECOVERY PROCESS AFTER INJURIES

DRUG FACTS

| Active Ingredients | Purpose |
|--------------------|-------------------|
| Menthol 1.2% | 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

Warnings: For external use only

When using this product: use only as directed • do not massage 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

Stop use and ask a 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

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 30 days after opening the product.**

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 several 15 to 20 times • wipe over with wet hand to remove any sense of tension • repeat the process maximum 3 times per days
Children 12 years or younger: ask a doctor

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

Contraindications: Not known
Side effects: Not known
Storage: Store closed in a dry and dark place

Rest before indicated on the bottom of the box, **KEEP CARTON AS IT CONTAINS IMPORTANT INFORMATION. PLEASE READ AND UNDERSTAND THE ABOVE DRUG FACTS BEFORE USING.**

Close cap tightly after use.

NET WT 3,5 OZ 100ml e

816070001094392

FAST RECOVERY!

THE MOST POWERFUL NATURAL ANTIOXIDANT

- ✓ Eliminates pain
- ✓ Reduces swelling
- ✓ Speeds up recovery process after injuries

NET WT 3,5 OZ 100ml e

Molecular hydrogen is the most powerful natural antioxidant that neutralizes harmful free radicals, converting them to safe water molecules! Belongs into the category of innovative medical gases, which shows positive effects in a variety of medical conditions, including acute and chronic diseases and injuries of the musculoskeletal, locomotor system (tendons, muscles, ligaments and joints).

MADE IN SERBIA

Manufacturers: Apil Health Balance d.o.o., Beograd, Serbia
info@activehydrogenproducts.com
www.activehydrogenproducts.com

BEST BEFORE:

ACTIVE HYDROGEN PROFESSIONAL GEL

menthol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72901-001 |
| 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:72901-001-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 03/13/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 03/13/2019 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|------------------------|
| 8.0 IDEAL BALANCE D.O.O. BEOGRAD | | 506132408 | manufacture(72901-001) |

Revised: 3/2019

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