

ULTRA MASSAGECREAM- acetyl glucosamine cream
PK Bio Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENTS

Acetyl Glucosamine

INACTIVE INGREDIENTS

Water, Glycerin, Zea Mays (Corn) Kernel Extract, Acetyl Glucosamine, Dimethyl Sulfone

PURPOSE

- Involved in helping the production of hyaluronic acid Helps increase moisture in the skin
- Care for damaged skin due to external irritation

WARNINGS

For external use only

When using this product

- if following abnormal symptoms persist, discontinue use

Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes

- Stop immediately and consult a doctor if you experience

- 1) Hypersensitivity symptoms such as erythema, itching and dermatitis. 2) Skin Irritation
- 3) Following Instructions when using medication

(1) For external use only (Do not use internally)

(2) Avoid getting into the eyes (if contact occurs, wash well with clean water)

- Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

- Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin.

It is not recommended to use this one areas that have been medically treated with a cast or bandage.

■ Do not use in combination with soap or antibacterial cleansing agents.

KEEP OUT OF REACH OF CHILDREN

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Uses

Pour a small amount into hands, spread evenly and rub into the body

Directions

for external use only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Product name: Ultra Massage Cream (Volume: 60ml)

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| <i>Drug Facts</i> |
| <i>Active Ingredients</i> Acetyl Glucosamine 12% |
| <i>Uses</i> <ul style="list-style-type: none"> ■ Involved in helping the production of hyaluronic acid Helps increase moisture in the skin ■ Care for damaged skin due to external irritation |
| <i>Warning</i> For external use only When using this product <ul style="list-style-type: none"> ■ if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes ■ Stop immediately and consult a doctor if you experience <ol style="list-style-type: none"> 1) Hypersensitivity symptoms such as erythema, itching and dermatitis. 2) Skin Irritation 3) Following Instructions when using medication <ol style="list-style-type: none"> (1) For external use only (Do not use internally) (2) Avoid getting into the eyes (if contact occurs, wash well with clean water) ■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur. ■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage. ■ Do not use in combination with soap or antibacterial cleansing agents. |
| <i>Directions</i> <ul style="list-style-type: none"> ■ Pour a small amount into hands, spread evenly and rub into the body |
| <i>Other Information</i> <ul style="list-style-type: none"> - read the directions and warnings before use - avoid freezing and excessive heat above 40 degree C (104 degree F) |
| <i>Inactive Ingredients</i> Water, Glycerin, Zea Mays (Corn) Kernel Extract, Acetyl Glucosamine, Dimethyl Sulfone |
| <i>Questions or Comments?</i> Call 070-8790-3014 |

ULTRA MASSAGECREAM

acetyl glucosamine cream

Product Information

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|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81712-0001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|---------------------|
| N-ACETYLGLUCOSAMINE (UNII: V956696549) (N-ACETYLGLUCOSAMINE - UNII:V956696549) | N-ACETYLGLUCOSAMINE | 12 g in 100 mL |
| ADENOSINE (UNII: K72T3FS567) (ADENOSINE - UNII:K72T3FS567) | ADENOSINE | 0.04 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81712-0001-1 | 60 mL in 1 TUBE; Type 0: Not a Combination Product | 03/31/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 03/31/2021 | |

Labeler - PK Bio Co., Ltd. (695816631)

Registrant - PK Bio Co., Ltd. (695816631)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|-------------------------|
| PK Bio Co., Ltd. | | 695816631 | manufacture(81712-0001) |

Revised: 3/2021

PK Bio Co., Ltd.