

**ASSURED- hydrocortisone cream**  
**Zhejiang Jingwei Pharmaceutical Al Co., Ltd.**

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**Active ingredients**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses**

- temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to:
  - eczema
  - psoriasis
  - poison ivy, oak, sumac
  - insect bites
  - detergents
  - jewelry
  - cosmetics
  - soaps
  - seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should be under advice and supervision of a doctor

**. Warnings. For external use only**

- in the genital area if you have a vaginal **Do not use** discharge. Consult a doctor
- for the treatment of diaper rash. Consult a doctor.

**When using this product**

- avoid contact with eyes.
- do not use more than directed unless told to do so by a doctor.
- do not put directly into rectum by using fingers or any mechanical device or applicator.

**Stop use and ask a doctor if**

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor.
- rectal bleeding occurs.

. If swallowed, get medical **Keep out of reach of children** help or contract a Poison Control Center right away.

**Directions**

• : **for relieving of skin irritation, inflammation, and rashes**

•adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

•children under 2 years of age: ask a doctor

• s: **for external anal and genital itching, adult**

•when practical, clean the affected area with mild soap and warm water and rinse thoroughly

•gently dry by patting or blotting with toilet tissue or soft cloth before applying

•apply to affected area not more than 3 to 4 times daily

•children under 12 years of age: ask a doctor

**Other information**

•store at room temperature 68° - 77° F (20° - 25° C)

aloe barbadensis leaf juice, cetyl alcohol, **Inactive ingredients**

dimethicone, EDTA, ethylparaben, glycerin, glyceryl monostearate,

isohexadecane, maltodextrin, methyl gluceth-20, methyparaben, petrolatum,

phenoxyethanol, polysorbate 80, propylene glycol, sodium citrate, stearic

acid, tocopherol, water, zingiber officinale (ginger) root extract

1-800-639-3803 Weekdays 9 AM to 4 PM EST **Questions?**



# ASSURED

hydrocortisone cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55621-018 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE    | 1 g in 100 g |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)        |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)         |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)           |          |
| <b>EDETIC ACID</b> (UNII: 9G34HU7RV0)           |          |
| <b>ETHYLPARABEN</b> (UNII: 14255EXE39)          |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)              |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4) |          |
| <b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)         |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)          |          |
| <b>METHYL GLUCETH-20</b> (UNII: J3QD0LD11P)     |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)         |          |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)            |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)        |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)        |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)        |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)          |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)            |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>GINGER</b> (UNII: C5529G5JPQ)                |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55621-018-28 | 1 in 1 CARTON                                     | 05/25/2018           |                    |
| 1 |                  | 28 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category           | Citation | Date       | Date |
|--------------------|----------|------------|------|
| OTC Monograph Drug | M017     | 05/25/2018 |      |

**Labeler** - Zhejiang Jingwei Pharmaceutic AI Co., Ltd. (530876549)

Revised: 10/2023

Zhejiang Jingwei Pharmaceutic AI Co., Ltd.