

OTODINE- chlorhexidine gluconate solution

Nextmune AB

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.

Otodine™

Ear cleaning chlorhexidine digluconate solution to remove excess ear wax in dogs and cats

Active Ingredient(s):

Chlorhexidine digluconate 0.15%.

Inactive Ingredient(s):

1,2-Hexanediol; Caprylyl Glycol, deionized water; erythritol; propanediol; Tris-EDTA.

Indications: For cleaning and removal of excess cerumen (ear wax) in dogs and cats.

Properties: The active ingredient(s) in Otodine™ provide an effective cleansing action which helps to remove excess ear wax.

Directions for use:

Flood the ear canal with the cleaning solution. Gently massage the ear canal to break up wax and debris. Using a cotton ball, remove any excess solution left in the ear. Otodine may be used 1 to 2 times a day. The solution will also clean the ear flap and surrounding skin of the ear. Do not rinse.

Precautionary statements:

For use in the ears of dogs and cats only. May cause eye irritation. Consult a veterinarian before using on pregnant, lactating or breeding animals; puppies; kittens; or animals with a pre-existing medical condition. Use with caution in older animals. If an animal has an adverse reaction to treatment, discontinue use and contact your veterinarian.

Storage: Store at room temperature. Do not freeze.

Warning: Keep out of reach of children.



iCF™
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Knowledge
www.icfpet.com

Distributor:

Nextmune US, LLC
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Made
in **Spain**

Manufacturer:

iCF™
Evolution of
Knowledge

a division of

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PRINCIPAL DISPLAY PANEL - 100 ml Bottle Carton

Otodine™

Ear
cleaning

Chlorhexidine digluconate
solution to remove
excess ear wax

in cats and dogs

Developed in Italy

iCF™
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Knowledge

3.38 fl. oz.(100 ml)



OTODINE

chlorhexidine gluconate solution

Product Information

| | | | |
|--------------------------------|------------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:86127-009 |
| Route of Administration | AURICULAR (OTIC) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L) | CHLORHEXIDINE GLUCONATE | 1.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| water (UNII: 059QF0KO0R) | |
| erythritol (UNII: RA96B954X6) | |
| propanediol (UNII: 5965N8W85T) | |
| Tromethamine (UNII: 023C2WHX2V) | |
| Edetate Sodium (UNII: MP1J8420LU) | |
| 1,2-Hexanediol (UNII: TR046Y3K1G) | |
| Caprylyl Glycol (UNII: 00YIU5438U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|-----------------------------|-----------------------------|---------------------------|
| 1 | NDC:86127-009-03 | 1 in 1 CARTON | | |
| 1 | | 100 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| UNAPPROVED DRUG OTHER | | 01/01/2021 | |

Labeler - Nextmune AB (352950223)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------|----------------|---------------|----------------------------|
| NEXTMUNE Italy SRL | | 435856461 | MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Medichem SA | | 464043381 | API MANUFACTURE |

Revised: 1/2022

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