Lidocaine (2% w/v) + Beclometasone (0.025% w/v) + Clotrimazole (1% w/v) + Chloramphenicol (5% w/v)

# **Lodicain Ear Drop**

 $\begin{array}{l} Lidocaine~(2\%~w/v) + Beclometasone~(0.025\%~w/v) + \\ Clotrimazole~(1\%~w/v) + Chloramphenicol~(5\%~w/v) \\ Ear~Drops \end{array}$ 

#### **Description**

Lidocaine (2% w/v) + Beclometasone (0.025% w/v) + Clotrimazole (1% w/v) + Chloramphenicol (5% w/v) Ear Drops is a combination ear drop formulation used to treat ear infections and related symptoms such as pain, inflammation, and fungal infections. It combines four active ingredients with different mechanisms of action to provide broad-spectrum relief for ear conditions.

- Lidocaine: A local anesthetic that provides rapid relief from pain by blocking nerve signals in the ear.
- Beclometasone: A corticosteroid that helps reduce inflammation and swelling in the ear.
- Clotrimazole: An antifungal agent that treats fungal infections in the ear.
- Chloramphenicol: An antibiotic that combats bacterial infections within the ear.

This combination of agents allows for effective treatment of both bacterial and fungal infections, along with symptomatic relief from pain and inflammation.

# Composition

# Each ml of ear drops contains:

- Lidocaine (2% w/v): 20 mg
- Beclometasone (0.025% w/v): 0.25 mg
- Clotrimazole (1% w/v): 10 mg
- Chloramphenicol (5% w/v): 50 mg

Excipients: The formulation may contain various excipients such as glycerin, sodium chloride, and water for injection, used to adjust the volume and stability of the solution.

#### **Indications**

# This combination ear drop is indicated for:

- Acute or chronic otitis externa (outer ear infections), caused by bacterial or fungal pathogens.
- Otitis media (middle ear infections) with accompanying symptoms such as ear pain, swelling, and discharge.
- Ear pain due to infection, inflammation, or irritation.
- Fungal infections of the ear (e.g., candidiasis or aspergillosis).
- Post-surgical or post-trauma ear infection and inflammation.

# **Dosage and Administration**

- Recommended Dosage:
  - For adults and children over 2 years of age:
    - Instill 3 to 4 drops into the affected ear canal, 2 to 3 times a day.
  - For children under 2 years of age, it is recommended to consult a healthcare provider before use.
- Instructions for Use:
  - Before applying the drops, gently warm the bottle by holding it in your hands for a few minutes. Cold drops may cause discomfort.
  - Lie on your side or tilt your head so that the affected ear faces upward.
  - Instill the prescribed number of drops into the ear canal, ensuring that the drops reach the ear drum.
  - Remain lying down for a few minutes to allow the solution to spread within the ear canal.
  - Repeat the process as necessary based on your healthcare provider's instructions.
  - Avoid inserting objects into the ear canal after applying the drops.

#### **Contraindications**

Lidocaine + Beclometasone + Clotrimazole + Chloramphenicol Ear Drops should not be used in the following situations:

- Hypersensitivity to any of the active ingredients (Lidocaine, Beclometasone, Clotrimazole, or Chloramphenicol) or excipients.
- Perforated eardrum (unless specifically prescribed by a healthcare provider) as the medication may enter the middle ear.
- Viral infections of the ear (e.g., herpes simplex) or fungal infections that are not sensitive to clotrimazole.
- Children under 2 years of age unless prescribed by a doctor.

# **Warnings and Precautions**

- Ear Injury: Do not use this ear drop if you suspect a perforated ear drum, unless specifically prescribed by a healthcare provider, as it could cause further complications.
- Prolonged Use: Prolonged use of corticosteroids such as beclometasone may lead to thinning of the skin and other local side effects. It is recommended to follow the prescribed duration and dosage carefully.
- Allergic Reactions: If symptoms of an allergic reaction (e.g., rash, itching, swelling) occur, stop using the ear drops and seek medical advice.
- Systemic Absorption: Although this is a topical treatment, systemic absorption of corticosteroids and lidocaine can occur, especially with prolonged use. Caution is needed in individuals with conditions such as heart disease or those using other medications that may interact.
- Hearing Loss: If there is any persistent or worsening ear pain or hearing loss, discontinue use and consult a healthcare provider.
- Contact with Eyes: Avoid contact with the eyes, as this may cause irritation. If accidental

contact occurs, rinse the eyes with water immediately.

#### **Side Effects**

#### Possible side effects include:

- Ear irritation or itching
- Burning or stinging sensation in the ear after application
- Ear fullness or discomfort
- Dizziness or lightheadedness
- Allergic reactions, such as rash or swelling
- Hearing changes, such as ringing in the ear (tinnitus) or loss of hearing in rare cases.

Most side effects are mild and temporary, but if you experience any severe symptoms or reactions, discontinue use and seek medical advice immediately.

# **Drug Interactions**

- Other Ear Medications: Concurrent use with other topical ear treatments may lead to an increased risk of side effects. Avoid using other medications in the ear unless instructed by a healthcare provider.
- Corticosteroid Interactions: Systemic corticosteroids may interact with other medications that suppress the immune system. Caution should be used when combining with immunosuppressive drugs.
- Lidocaine: Lidocaine can interact with other antiarrhythmic drugs or medications that affect liver metabolism, potentially leading to increased blood levels and toxicity. Consult a healthcare provider before using other medications with lidocaine.

# **Storage Instructions**

• Storage: Store the ear drops in a cool, dry place, away from direct sunlight and moisture, at a temperature between 15°C and 25°C.

- Keep the bottle tightly closed when not in use to prevent contamination.
- Do not freeze the ear drops.
- Keep out of reach of children.

#### **Presentation**

Form: Ear drops (solution)

• Strength:

o Lidocaine: 2% w/v

o Beclometasone: 0.025% w/v

Clotrimazole: 1% w/vChloramphenicol: 5% w/v

• Pack Size: Available in 10 ml, 15 ml, and 30

ml bottles.

#### **Conclusion**

Lidocaine + Beclometasone + Clotrimazole + Chloramphenicol Ear Drops is a highly effective treatment for a range of ear infections, including bacterial and fungal infections, as well as the management of associated ear pain and inflammation. By combining a local anesthetic, corticosteroid, antifungal, and antibiotic, this formulation provides comprehensive care for ear conditions. Always follow your healthcare provider's instructions on dosage and duration of treatment for the best results and to minimize the risk of side effects.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

TM: Trademark Applied for