

## RAMACETINE HC

Eye Ointment

### Composition

Chloramphenicol	5%
Hydrocortisone acetate	1%

### Action

Chloramphenicol possesses a wide range of antibacterial activity and is effective against virtually all bacterial pathogens known to cause diseases of the eye. It penetrates the non-inflamed eye better than any other antibiotic, irrespective of the mode of administration, and resistance to it is slow to develop, moderate in degree and not necessarily permanent. Preparations of chloramphenicol for local treatment are well tolerated.

Chloramphenicol is bacteriostatic. Since it is lipid soluble, it diffuses through the bacterial cell membrane and reversibly binds to the 50 S subunit of bacterial ribosomes, where transfer of amino acids to growing peptide chains is prevented, possibly by suppression of peptidyl transferase activity. This inhibits peptide bond formation and subsequent protein synthesis.

Hydrocortisone acetate has both the anti-inflammatory and antiallergic activity. This combination yields excellent results in inflammation of the anterior uvea (iritis, iridocyclitis).

### Indications

- Chloramphenicol is used to treat superficial infections of the conjunctiva and/or cornea when caused by susceptible organisms including Gram-positive and Gram-negative bacteria, as well as certain Rickettsia.
- Steroid-responsive allergic and inflammatory ocular conditions for which corticosteroids are indicated, and where bacterial infection or a risk of bacterial ocular infection exists.
- Ocular corticosteroids-containing preparations are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical or thermal burns, or penetration of foreign bodies.
- It is also effective in certain virus-like infections.

### Contraindications

- Known hypersensitivity to the active components.
- Epithelial herpes simplex keratitis (dendritic keratitis).
- Acute infectious stages of vaccinia and varicella.
- Viral diseases of the cornea and conjunctiva.
- Mycobacterial infection of the eye.
- Fungal diseases of ocular structures.
- The use of this preparation is contraindicated following uncomplicated removal of a corneal foreign body

### Warnings

Prolonged use of this preparation may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation.

In diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids in the eye.

Prolonged use of chloramphenicol should be avoided, because of absorption and of hypersensitivity reactions, including bone marrow hypoplasia.

**Pregnancy***Category C*

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

**Nursing Mothers**

It is unknown whether topical application of corticosteroids can result in sufficient system-ic absorption to produce detectable quantities in breast milk. Therefore, caution should be exercised when topical corticosteroids are applied to nursing women.

**Adverse Reactions**

Signs of local irritation with subjective symptoms of itching or burning, angioneurotic edema, urticaria, vesicular and maculopapular dermatitis have been reported in patients using chloramphenicol on the skin. These sensitivity reactions are causes for discontinuing medication. Hydrocortisone acetate may cause posterior subcapsular cataracts, increased intraocular pressure, glaucoma and exophthalmos.

**Precautions**

In acute purulent conditions of the eye, corticosteroids may mask infection or aggravate existing infection.

If local infection should continue or become severe, or in the presence of systemic infection, appropriate antibacterial therapy should be instituted. If a favourable response is not obtained, the use of this preparation should be temporarily discontinued, until the infection has been controlled. Rarely, filtering blebs have been reported when topical steroids have been used following cataract surgery.

If this preparation is used for 10 days or more, intraocular pressure should be routinely monitored, even though this may be difficult in children and uncooperative patients.

The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid and chloramphenicol use.

Use of corticosteroids in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires particular caution. Periodic slit-lamp microscopy is essential. Patients should be cautioned to refrain from undertaking tasks requiring visual acuity, until they feel able to do so.

**Dosage and Administration**

Patients should be cautioned to report to their physician if no improvement in their condition occurs after 4-5 days of treatment.

A small amount of ointment should be placed in the lower conjunctival sac every 3 hours or more frequently if necessary. Application should be continued day and night for the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye appears normal.

**Presentation**

Tube of 3.5 grams.