PRACTICE GUIDANCE: OTC CHLORAMPHENICOL EYE DROPS

Royal Pharmaceutical Society of Great Britain

Following reclassification from prescription-only to pharmacy medicine status, chloramphenicol 0.5% w/v eye drop solution is now available for sale over-the-counter (OTC) from registered pharmacies. This guidance outlines the OTC indications for the product, as well as important points to consider when counter prescribing

WHO TO REFER TO A DOCTOR

Refer the patient in the presence of any of the following:

- Contact lens use (or refer to an optometrist or contact lens practitioner)
- Patient is already using other eye drops or eye ointment
- Suspected foreign body in the eye
- Eye injury
- Associated pain or swelling around the eye or face
- Photophobia
- Vision is affected
- Severe pain within the eye
- Pupil looks unusual, ie, torn, irregular, dilated or non-reactive to light
- Cornea looks cloudy
- Eye movement is restricted
- Copious yellow-green purulent discharge that reaccumulates after being wiped away
- Eye inflammation associated with a rash on the scalp or face
- Patient feels unwell
- Conjunctivitis in the recent past
- Glaucoma
- Dry eye syndrome (keratoconjunctivitis sicca)
- Eye surgery or laser treatment in the past six months
- Personal or family history of bone marrow problems
- Patient is pregnant or breast-feeding
- Patient has recently returned from abroad
- No improvement is seen after 48 hours of treatment
- Symptoms get worse despite using chloramphenicol eye drops

POINTS TO CONSIDER WHEN RECOMMENDING CHLORAMPHENICOL

- OTC chloramphenicol is an antibiotic indicated for treatment of acute bacterial conjunctivitis in adults, the elderly and children aged two years and over.
- In general, if a patient with an eye problem presents with pain or visual impairment (eg, loss of vision, reduced or blurred vision or seeing halos around lights), then the condition is more likely to be serious and requires referral. See also "Who to refer to a doctor".
- Contact lens users should be referred to an optometrist, contact lens practitioner or doctor.
- If chloramphenicol is used following advice from an optometrist or contact lens practitioner or doctor, contact lenses should not be worn during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment.
- Bacteria and viruses are common causative agents of infective conjunctivitis but it may be clinically difficult to distinguish between bacterial and viral conjunctivitis.
- Use of chloramphenicol eye drops in infective conjunctivitis may help prevent secondary bacterial infection if the conjunctivitis is of viral origin (an unlicensed indication). In the pharmacy setting it may be appropriate to treat any superficial infective conjunctivitis with chloramphenicol, as long as there is no reason to refer the patient to a doctor. See "Who to refer to a doctor".
- Apply one drop into the infected eye every two hours for the first 48 hours and four-hourly thereafter. Sleep need not be interrupted in order to administer eye drops. The usual course of treatment is five days.
- Do not share bottles if more than one member of the family is affected.
- If a sale is made, advise patient to consult a doctor if symptoms do not improve within 48 hours of treatment. Advise the patient to seek immediate medical advice at any time if symptoms worsen.
- Try not to touch the eye or lashes with the nozzle as this may contaminate the medicine.
- Conjunctivitis is contagious. Advise patient to wash hands before and after touching the eyes and avoid sharing towels, facecloths, etc, and to dispose of any eye cosmetics that may be contaminated.
- Side effects are usually minor, such as a transient stinging or burning sensation in the eye. Transient blurring of vision can also occur with the drops and patients should be warned not to drive or operate machinery unless their vision is clear. See summary of product characteristics (SPC) for complete list.
- In a pharmacy setting, chloramphenicol eye drops should be stored in a refrigerator (2–8C). Once opened the eye drops should be discarded after five days.
- Chloramphenicol eye drops are contraindicated in those who have a history of hypersensitivity to chloramphenicol or to any other ingredient of the drops, myelosuppression during previous exposure to chloramphenicol and in patients with a family history of blood dyscrasias.

OTC INDICATION AND DOSAGE

Chloramphenicol is indicated for the topical treatment of acute bacterial conjunctivitis in adults, the elderly and children aged two years and over. Apply one drop into the infected eye every two hours for the first 48 hours and four hourly thereafter. Sleep need not be interrupted in order to administer eye drops. The usual course of treatment is five days.

HOW TO ADMINISTER

Patients should be advised to wash and dry hands before and after use. Tilt the head back and gently pull the lower eyelid out to form a pouch. Squeeze the bottle to release one drop into the lower eyelid. Try not to touch the eye or lashes with the nozzle. Blink several times to help spread the drug. Repeat the process for each drop used. Eye infections tend to spread to the other eye (and to other people — avoid sharing towels, facecloths, etc), so it is usual to use the drops in both eyes if they are both infected.

Patients sometimes get a taste of eye drops in the mouth or a feeling that drops are running down the throat. Pressing a finger against the inner corner of the eye (by the nose) for about a minute after using the drops may help to stop the drops draining into nose and throat.

HOW CHLORAMPHENICOL WORKS

Chloramphenicol is a broad-spectrum bacteriostatic antibiotic active against a wide variety of Gram-negative and Gram-positive organisms. Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis*, particularly in

children. Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staphylococcus epidermidis* and some strains of *Staph aureus*, and streptococci such as *Streptococcus pneumoniae*, *Str pyogenes*, and the viridans streptococci. Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus, frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

CONJUNCTIVITIS

Conjunctivitis is an acute inflammation of the conjunctiva, the transparent surface covering the white of the eye and the inside of the eyelids. In the conjunctiva there are tiny blood vessels, which are normally almost invisible. The conjunctiva can become inflamed due to infection, allergy or irritation. The blood vessels dilate and become more obvious, making the eye look red or pink.

Chloramphenicol is the first-line choice for acute bacterial conjunctivitis but it may be clinically difficult to distinguish bacterial from viral conjunctivitis. In the pharmacy setting it may be appropriate to treat any superficial infective conjunctivitis with chloramphenicol eye drops, as long as there is no reason to refer the patient to a doctor. Immediate use of chloramphenicol eye drops in all cases of infective conjunctivitis (bacterial and viral origin) has the following advantages: increased rate of resolution of bacterial infection reduces the risk of transmission; prevention of secondary bacterial infection with viral conjunctivitis (an unlicensed indication); possible reduction of the (slight) risk of complications.

Before diagnosing infective conjunctivitis it is essential to exclude serious causes of a red eye that can lead to permanent impairment of vision and to distinguish it from allergic and irritant causes (see "Who to refer to a doctor"). Other minor eye conditions (eg, blepharitis) should also be differentiated.

Infective conjunctivitis

Bacteria and viruses can both cause infective conjunctivitis. Herpes virus and *Chlamydia trachomatis* are less common, but potentially more serious, infective causes. Herpes virus may cause eye inflammation associated with a rash on the scalp or face (see "Who to refer to a doctor").

Typical symptoms of infective conjunctivitis (bacterial or viral) are: eyes look inflamed and red or pink, eye discomfort described as burning or gritty (but not sharp or significant pain) and discharge.

The discharge is sticky and mucopurulent in bacterial infections and more watery in viral infections. Bacterial conjunctivitis can also make it difficult to open the eye in the morning because of dried crusts.

Infective conjunctivitis usually starts in one eye and then spreads to the other. Vision is not usually affected in infected conjunctivitis, but associated discharge may commonly cause blurring, particularly on waking. Photophobia (intolerance to light) is absent.

Viral infections are usually caused by the adenovirus and may be associated with an upper respiratory infection.

Children and the elderly have an increased incidence of infective conjunctivitis. Contact lens wearers have an increased risk of acquiring infection.

Allergic conjunctivitis

Seasonal allergic conjunctivitis typically occurs in the hay fever season. Perennial allergic conjunctivitis occurs any time during the year when in contact with the allergen (primarily house dust mite).

Typical symptoms of allergic conjunctivitis are: eyes looks inflamed and red or pink, an itching sensation (which can be intense), discomfort and a watery discharge. Both eyes are affected at or about the same time unless the condition is associated with a local allergen or irritant. Photophobia may be mild or absent.

Allergic conjunctivitis tends to be recurrent and the condition is predictable as the patient comes into contact with the allergen. A personal or family history of asthma, eczema or rhinitis is often associated with seasonal or perennial allergic conjunctivitis.

Irritant conjunctivitis

Irritant conjunctivitis may have a mechanical or chemical cause. Common mechanical causes include eyelashes rubbing against the surface of the eye such as occurs with entropion (eyelashes turn inwards) or in the presence of a foreign body. If a foreign body is suspected or confirmed refer the patient to a doctor. Chemical causes (eg, getting shampoo in the eye, or chlorine in a swimming pool) are usually obvious and the conjunctivitis settles when the irritant is removed.

CONTRA-INDICATIONS

Chloramphenicol eye drops are contra-indicated in those who have a history of hypersensitivity to chloramphenicol or to any other ingredient of the drops, myelosuppression during previous exposure to chloramphenicol and in patients with a family history of blood dyscrasias including aplastic anaemia.

CAUTIONS

Patients should be advised to consult their doctor if symptoms do not improve within 48 hours.

Patients should also be advised to seek immediate medical advice at any time if symptoms worsen. Some other eye conditions can cause red eye and may be mistaken at first for conjunctivitis.

Patients should also be referred to their doctor if any of the features under "Who to refer to a doctor" apply. See SPC for additional information.

CONTACT LENS WEARERS

Contact lens wearers have a greater risk of eye infection and should be referred to an optometrist, contact lens practitioner or doctor.

If chloramphenicol eye drops are used following advice from an optometrist, contact lens practitioner or doctor, contact lenses should not be worn during the period of treatment. Hard contact lens users and disposable contact lens users can start using their lenses again after successful treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment.

ADVERSE EFFECTS

Side effects are usually minor, such as a transient burning or stinging sensation in the eye when applying drops. Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis. Treatment must be discontinued immediately in such cases. See SPC for full details.

Although some reports have suggested an association between the topical use of chloramphenicol in the eye and aplastic anaemia, this is extremely rare with eye drops and several studies have failed to prove a link.

Pharmacists are reminded to send a yellow card report to the Medicines and Healthcare products Regulatory Agency if a serious adverse drug reaction is suspected.

DRUG INTERACTIONS

Altough concerns over aplastic anaemia associated with ocular chloramphenicol have largely been discounted, concomitant administration of bone marrow depressant drugs should be avoided.

PREGNANCY AND BREASTFEEDING

Despite extensive use the safety of chloramphenicol eye drops during pregnancy and lactation has not been established. OTC chloramphenicol is not recommended for use during pregnancy or lactation.

STORAGE

In a pharmacy setting, chloramphenicol eye drops should be stored in a refrigerator (2–8°C).

Once opened, the eye drops should be discarded after five days.

Pharmacists are reminded to have a system in place to ensure chloramphenicol eye drops are stored separately in the refrigerator from other medication (eg chloramphenicol ear preparations) in order to reduce the risk of picking errors.

OVERALL ASSESSMENT

Chloramphenicol has a broad spectrum of action against most Gram-positive and Gram-negative bacteria and there is little evidence of bacterial resistance.

The reclassification of chloramphenicol eye drops from prescription-only to pharmacy medicine status allows pharmacists to provide an effective medicine that is regarded as the drug of choice for treating bacterial conjunctivitis.

This guidance on best practice when advising on chloramphenicol has been prepared by the Practice Division of the Royal Pharmaceutical Society of Great Britain

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