

Submission

Chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use: proposed advisory statements for medicines

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About PSA

The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are close to 27,500 registered pharmacists,¹ of which approximately 80% work in the community sector.

PSA's core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and representing pharmacists' role as frontline health professionals.

Purpose

This submission is provided by PSA in response to the public consultation on proposed advisory statements on labels of non-prescription medicines containing chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use.

Recommendation

PSA supports the inclusion of the proposed advisory statements for chloramphenicol, propamidine, dibromopropamidine and sulfacetamide in the Required Advisory Statements for Medicine Labels. However we believe that the common statement on appropriate duration of use (which refers only to situations where an "infection does not start to improve within 48 hours") should be amended to include advice to seek immediate medical attention where symptoms of infection become worse or alarm symptoms develop.

¹ Based on data published by the Pharmacy Board of Australia in November 2013.

Comments on proposed advisory statements

PSA published a guidance document (see attached) for pharmacists in 2010 when chloramphenicol for ophthalmic use was included in Schedule 3. PSA also has a close working relationship with Optometrists Association Australia and consult each other on issues of relevance to both professions.

PSA has been aware of the concerns surrounding the use of ophthalmic chloramphenicol medicines by contact lens users and requests for use in young children. The guidance document for pharmacists is reviewed regularly to ensure rigorous and up-to-date advice is provided to the profession within the context and scope of pharmacists' practice.

With regards to the new advisory statements proposed for inclusion in the *Required advisory statements for medicine labels* (RASML), PSA notes the advice is overall consistent with information currently contained in the guidance document for pharmacists as summarised below.

	Proposed advisory statement (to consumers) for inclusion in RASML	Information contained in PSA's guidance document for pharmacists
1	Contact lens wearers should not use this product except on the advice of a doctor or optometrist.	Referral to an optometrist or general practitioner is required if the patient is a contact lens user. (<i>Explanatory notes</i> section F)
2	If your eye infection does not start to improve within 48 hours, seek immediate medical advice.	Symptoms should improve within 48 hours of commencing treatment. Patients should be advised to consult an optometrist or general practitioner if symptoms do not improve within this timeframe or become worse. The development of alarm symptoms (e.g. pain, loss of vision, photophobia) is likely to require urgent referral to an ophthalmologist. (<i>Explanatory notes</i> section M)
3	Do not use in children under 2 years of age except on medical advice. (For chloramphenicol only)	Referral to an optometrist or general practitioner would be appropriate for children <2 years. (<i>Explanatory notes</i> section H)

Proposed amendment

Consistent with the *Explanatory notes* in the PSA guidance document, the pharmacist would provide advice on the appropriate duration of use and expected treatment outcomes when the medicine is supplied to the consumer. However, to assist the consumer in maximising outcomes and particularly minimising risks of any unresponsive treatment or worsening infection, we believe additional advice is warranted around appropriate duration of use.

PSA suggests the current proposed statement “If your eye infection does not start to improve within 48 hours, seek immediate medical advice”, should be extended to include advice that immediate medical attention should be sought if:

- symptoms of infection worsen; or
- alarm symptoms (e.g. pain, loss of vision, photophobia) develop.

Some consumers may return to the pharmacy to seek further advice if their symptoms have not improved or have worsened. However, consumers may not necessarily have the opportunity or will to do so and may not remember all of the advice provided by the pharmacist during the initial consultation. PSA believes the inclusion of these additional messages will promote better monitoring and self-management by consumers over the duration of treatment.

Summary

PSA supports the application of the proposed advisory statements for ophthalmic medicines containing chloramphenicol, propamidine, dibromopropamidine and sulfacetamide but recommends the above amendments to strengthen the message to consumers around monitoring of symptoms and taking appropriate action where infection worsens or is unresponsive to treatment.

When the final decision on the proposed advisory statements is known, PSA will once again review its guidance document for pharmacists.

Attachment:

Provision of chloramphenicol for ophthalmic use as a Pharmacist Only medicine (Pharmaceutical Society of Australia; 2010, May).

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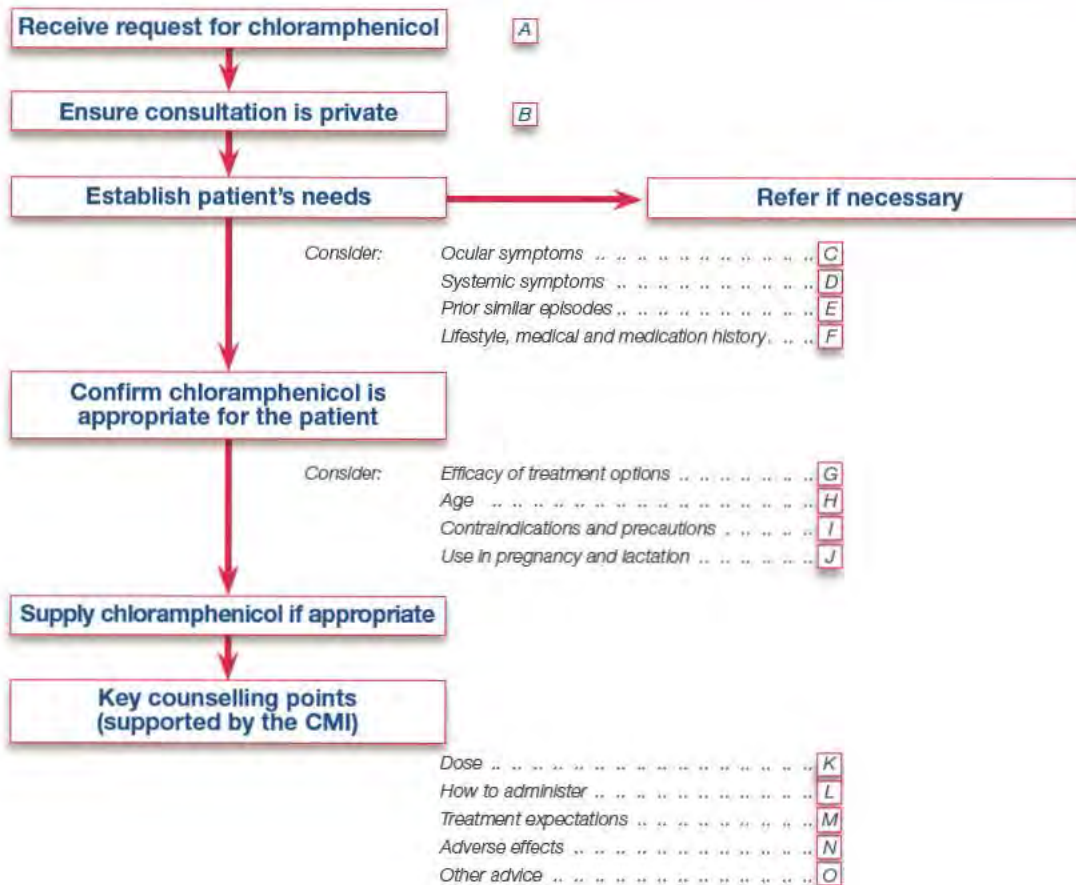
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Provision of chloramphenicol for ophthalmic use as a *Pharmacist Only* medicine



Explanatory notes

Pharmacists are expected to exercise professional judgment in adapting the guidance provided to specific presenting circumstances.

A. Professional Standards

The professional standards¹ outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in response to a direct product or symptom-based request.

B. Privacy

Pharmacists must meet their obligations in relation to respecting the patient's privacy and confidentiality in the provision of *Pharmacist Only* medicines and associated patient counselling.²

C. Ocular symptoms³

Bacterial conjunctivitis is typically characterised by:

- Discharge that may be sticky and mucopurulent. Patients may find it difficult to open their eyes in the morning, due to dried crust. The discharge may cause some blurring, particularly upon waking.
- Red or pink conjunctiva (the transparent surface that covers the white of the eye and the inside of the eyelid).
- A burning or gritty sensation in the eye.

It usually starts in one eye and then spreads to the other.

Other common conditions can produce similar ocular symptoms; however:

- Viral conjunctivitis is associated with a more watery discharge.
- Allergic conjunctivitis is associated with a watery discharge and itching.

It is essential to exclude serious causes of a red eye that can lead to permanent impairment of vision.

Referral to an optometrist or general practitioner is required in the presence of any of the following:

- Photophobia
- Severe pain in the eye or pain and swelling around the eye
- Loss of, reduced or blurred vision
- Restriction of eye movement

- Cloudy cornea
- Copious yellow-green purulent discharge that accumulates after being wiped away
- Contact lens wear
- Pupils that look abnormal, i.e. irregular, torn, dilated or not reactive to light
- Injury to the eye or suspicion of a foreign body in the eye
- A history of welding without eye protection immediately prior to onset of symptoms.

D. Systemic symptoms³

Bacterial conjunctivitis does not typically present with any systemic symptoms.

Systemic symptoms may assist in differentiating bacterial conjunctivitis from other common conditions that can produce similar ocular symptoms:

- Viral conjunctivitis is often associated with an upper respiratory tract infection.
- Allergic conjunctivitis is often associated with symptoms of hayfever or allergic rhinitis.

Referral to an optometrist or general practitioner is required if:

- The patient feels unwell.

E. Prior similar episodes

Referral to an optometrist or general practitioner is required if the patient has had similar symptoms in the past few weeks.

F. Lifestyle, medical and medication history

Referral to an optometrist or general practitioner is required if the patient:^{3,4}

- Has glaucoma or dry eye syndrome
- Is using other eye drops or eye ointments at the time of presentation
- Is a contact lens user (as they have a greater risk of serious eye infection by *Pseudomonas aeruginosa*, which is not susceptible to chloramphenicol and may require hospital admission)
- Has had eye surgery or laser treatment in the past six months
- Has a history of bone marrow problems – individual or family (local application of chloramphenicol has been associated with rare cases of bone marrow hypoplasia, including aplastic anaemia and death)
- Has recently travelled overseas.

G. Efficacy of treatment options

The majority of acute bacterial conjunctivitis cases spontaneously resolve within five days.

There are generally no complications if left untreated. The purpose of treatment is to speed resolution and reduce the likelihood of transmission.

All cases of bacterial conjunctivitis may be treated with chloramphenicol ophthalmic preparations provided there is no reason to refer the patient.³ However, in mild cases, it may be sufficient to use propamidine 0.1% eye drops.⁵

H. Age

Bacterial conjunctivitis has a higher incidence in children and the elderly.³

Chloramphenicol ophthalmic preparations can be used in children of any age.^{6,7} However, pharmacists should consider that in infants, the eyes are developing and it is difficult to exclude serious causes of a red eye that can lead to permanent impairment of vision without ocular examination.

Referral to an optometrist or general practitioner would be appropriate for children <2 years.³

I. Contraindications and precautions

Ophthalmic chloramphenicol is contraindicated in patients with a history of hypersensitivity and/or toxic reaction to chloramphenicol or to any other ingredient in the drops or ointment base, and in patients with a family history of blood dyscrasias.⁴

J. Use in pregnancy and lactation

Ophthalmic chloramphenicol is classed category A by the Australian Drug Evaluation Committee.⁴

Although the use of systemic chloramphenicol by the mother may cause serious toxicity in the infant or fetus, topical chloramphenicol in the recommended dose is safe to use during pregnancy, and single courses of eye drops are considered safe in breastfeeding.^{4,8}

K. Dose

For bacterial conjunctivitis use chloramphenicol 0.5% eye drops, one or two drops every two hours initially, decreasing to six-hourly as the infection improves. Chloramphenicol 1% eye ointment may be used at bedtime.⁵

Alternatively the eye ointment may be applied every three hours.⁴

Treatment should continue for at least two days after the eye appears normal.^{3,4}

L. How to administer

Conjunctivitis is contagious. Before and after application, hands should be washed and dried. To administer eye drops or ointment, the head should be tilted back and the lower eyelid gently pulled out to form a pouch.

For drops, the bottle should be squeezed to release one drop into the lower eyelid. Do not touch the eyelids or lashes. See APF21⁹ for more detailed instructions. This process should be repeated for application of each drop, and for the other eye, if both eyes are infected.

For ointment, 1.5 cm should be applied into the lower eyelid.

M. Treatment expectations

Symptoms should improve within 48 hours of commencing treatment. Patients should be advised to consult an optometrist or general practitioner if symptoms do not improve within this timeframe or become worse. These may indicate infection by non-susceptible organisms.³ The development of alarm symptoms (e.g. pain, loss of vision, photophobia) is likely to require urgent referral to an ophthalmologist.

N. Adverse effects

Adverse effects are usually minor and may include a transient stinging sensation in the eye when applying the drops. Local allergic reactions manifest as eye redness and swelling. Transient blurring of vision may occur, and patients should be advised not to drive or operate machinery unless their vision is clear.³ Serious adverse effects include hypersensitivity reactions that may manifest as angioneurotic oedema, fever, anaphylaxis and vesicular and maculopapular dermatitis. Superinfection with candida may also occur. Treatment should be immediately discontinued in such cases.³

O. Other advice

Prior to opening, the drops should be stored in the fridge (2–8°C). After opening, the drops and ointment can be stored below 25°C for up to one month and should then be discarded.⁴

Provision of a CMI leaflet and *Red and dry eyes* Self Care Fact Card or other printed information for consumers is appropriate.

References

1. Pharmaceutical Society of Australia. Standards for the provision of Pharmacy Medicines and Pharmacist only medicines in community pharmacy. In: Professional Practice Standards (version 3). Canberra: PSA, 2006.
2. Guidelines for pharmacists. Professional practice and the Privacy Act. Canberra: PSA, 2001.
3. Royal Pharmaceutical Society of Great Britain. Practice Guidance: OTC chloramphenicol eye drops. June 2005.
4. eMIMS December 2009.
5. eTG complete [CD-ROM]. Melbourne: Therapeutic Guidelines Limited; 2009 Nov.
6. British National Formulary for children. 2009. Accessed online 8/4/10.
7. Paediatric Handbook, 8th ed. Melbourne: Royal Children's Hospital, 2009.
8. Drugs and Breastfeeding. Melbourne: Royal Women's Hospital, 2006.
9. Sansom LN, ed. Australian Pharmaceutical Formulary and Handbook, 21st edn. Canberra: PSA, 2009.