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Special educational supplement

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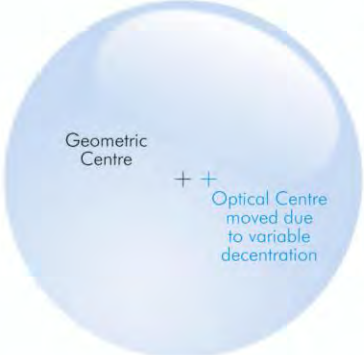

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Important changes in legislation

Rosemary Bailey FBDO (Hons) CL explains the changes in legislation affecting the ordering and use of certain ophthalmic drugs by registered dispensing opticians and contact lens opticians

The background

In recent years it has become more difficult for dispensing opticians (DOs) managing practices to order pharmaceutical products – such as anaesthetics and mydrilates - as the law required those products to be ordered by those permitted to use them – that was optometrists and ophthalmic medical practitioners (OMPs). The issue was brought to the Association's attention in 2007, and the General Optical Council (GOC) was approached to see if and how the situation could be remedied.

Meetings took place between ABDO, the GOC and the Medicines and Healthcare products Regulatory Agency (MHRA). In due course it was agreed that the matter should be brought to the attention of the Commission for Human Medicines (CHM), with a view to changing the legislation to permit registered DOs to order the products for use in the practice by those permitted to do so. Representation to the CHM took place in the summer and the changes to the legislation were enacted in December 2009.

Since 2005 when the contact lens regulations changed, there has been no clear authorisation for contact lens opticians (CLOs) to use anaesthetics in the course of contact lens fittings. Although it would be rare for anaesthetic to be instilled in high street contact lens practice, it may be necessary to use it in complex fittings - and perhaps if the CLO is working with an ophthalmologist to assess potential visual acuity prior to surgery, etc.

The new legislation states that CLOs on the CL Specialty Register may instil a range of anaesthetics in the course of their professional practice. It is very important that CLOs consider the full implications of using an anaesthetic during contact lens fitting and do so only if specifically appropriate for that fitting or assessment.

The legislation

Registered dispensing opticians may now order the following products for use in their practices:

- Amethocaine hydrochloride
- Chloramphenicol
- Cyclopentolate hydrochloride
- Fusidic acid
- Lignocaine hydrochloride
- Oxybuprocaine hydrochloride
- Proxymetacaine hydrochloride
- Tropicamide

Specialty registered contact lens opticians may now use the following anaesthetics in the course of their professional practice:

- Lignocaine hydrochloride
- Oxybuprocaine hydrochloride
- Proxymetacaine hydrochloride

Finally, a further piece of legislation was enacted at the same time - permitting the sale and supply of chloramphenicol - under its 'P' license - by registered dispensing opticians and specialty registered contact lens opticians. The restrictions of the pharmacy classification are:

- SOLELY for use in acute bacterial conjunctivitis
- Maximum pack size of:
  - 10ml of 0.5% drops
  - 4 gms of 1% ointment
- only to adults or children over two years of age
- for a maximum of 5 days

The full documents (Statutory Instruments 2009 No 3062 and 3063) are available via:

[i] www.opsi.gov.uk/si/si2009/uksi_20093063_en_1

[ii] www.opsi.gov.uk/si/si2009/uksi_20093062_en_1

Guidance and knowledge update

Articles to refresh knowledge of the products involved in the new legislation follow this introduction. All DOs and CLOs are advised to read them (and gain CET points) to be reminded of the products and any associated issues.

The ABDO Advice and Guidance is being changed to support the new status.

What do these changes mean for dispensing opticians and contact lens opticians?

- It is no longer necessary for a registered DO or CLO to involve an optometrist or OMP in the purchase of pharmaceutical products to be used during the eye examination.
- On the specific occasions that it would be needed, specialty registered CLOs may use anaesthetic in the course of their professional practice, during the fitting of contact lenses.
- If a registered DO or CLO is able to define that a patient has acute bacterial conjunctivitis, they may sell and supply chloramphenicol within the limitations of its 'P' license. DOs and CLOs are not permitted to sell and supply the product in any other circumstances.

The changes have taken considerable time and effort to bring to fruition. It is important that all registered DOs and CLOs understand the implications of the new legislation and its associated boundaries. ■

Topical ocular anaesthetics

By Linda Rapley BSc(Hons) FCOptom Cert Ed to support the legislation allowing dispensing opticians to order, and CLOs to use, certain prescription-only medicinces

Competencies covered: Professional conduct, ocular examination, contact lenses
Target group: Dispensing opticians, optometrists

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) have recently amended the Medicines Act 1968 to allow dispensing opticians to order and stock certain Prescription Only Medicines (POMs) for use by optometrists. This has been common practice for DOs in the past, and is now supported in law. These POMs include four local anaesthetics; amethocaine hydrochloride, oxybuprocaine hydrochloride, lignocaine hydrochloride and proxymetacaine hydrochloride.

In addition, the new legislation allows registered CLOs to obtain oxybuprocaine, lignocaine and proxymetacaine for use in the course of their practice. It must be stressed that these are only for use within the practice and may not, under any circumstances, be issued to the patient. This article will discuss local anaesthetics and their use.

Introduction

Anaesthesia can be defined as a reversible lack of awareness. This can be a total lack of awareness i.e. unconsciousness, or only affect part of the body. The drugs that are used in optometry are commonly referred to as local anaesthetics, which implies that their effect is limited to a producing a loss of awareness of a small specific region of the body. However, they are in fact a subset of local anaesthetics as they affect a surface rather than a region; these are topical anaesthetics.

The action of local anaesthetics is to prevent the transmission of nerve impulses. This will produce paralysis if it is the motor nerves which stimulate muscles that are affected, or numbness if sensory nerves are affected. Numbness includes analgesia (the loss of pain sensation) and loss of nociception, which is the perception of potentially harmful mechanical, thermal and chemical stimuli. The different sensations (pain, temperature, pressure etc.) are detected by a range of specialised receptors known as nociceptors which are found at the end of sensory nerve fibres. The mechanism by which these stimulate nerve impulses is still uncertain.

Nerve impulse propagation

In order to understand the mode of action of local anaesthetics, it is necessary to consider how nerves transmit signals, so a brief description of the anatomy and physiology of neurones follows.

A nerve cell or neurone consists of a cell body and its processes (fibres); one axon and one or more dendrites. Associated with nerve fibres are Schwann cells which are supporting neuroglial cells **(Figure 1)**. These neuroglial cells produce a layer of a fatty substance called myelin around some nerve fibres and this layer acts as an insulator. The cell membrane of the nerve fibre is electrically charged (polarised) and the nerve impulse is in the form of a wave of depolarisation that passes along the fibre.

The extracellular fluid contains a higher concentration of positively charged

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This article has been approved for **2 CET points** by the **GOC**. It is open to all FBDO members, including associate member optometrists. Insert your answers to the twelve multiple choice questions (MCQs) online at www.abdo.org.uk, or on the answer sheet inserted in this issue and return by **22 June 2010** to **ABDO CET, Courtyard Suite 6, Braxted Park, Great Braxted, Witham CM8 3GA** OR fax to **01621 890203**. Notification of your mark and the correct answers will be sent to you. If you complete online, please ensure that your email address and GOC number are up-to-date. The pass mark is 60 per cent. The answers will appear in our August 2010 issue.

General Optical Council
Approved CET For Dispensing Optician Optometrist
C-13256

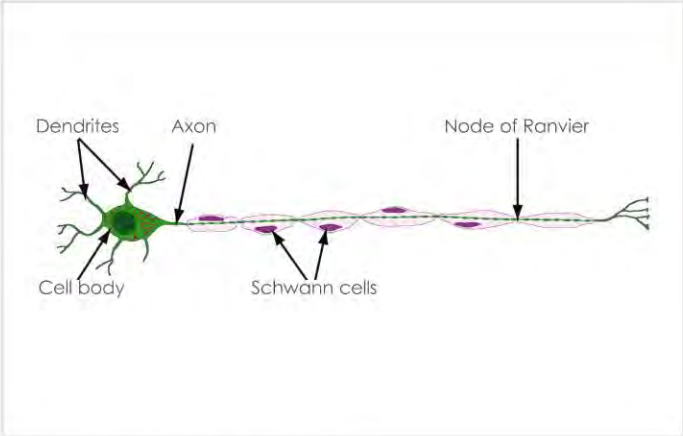


Figure 1: A neurone with Schwann cells

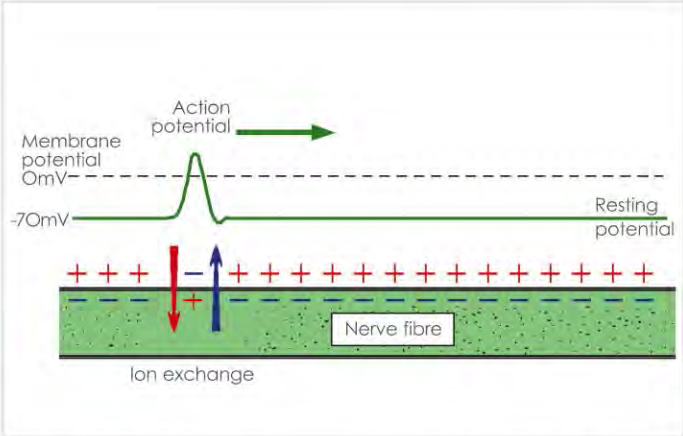


Figure 2: Nerve impulse. A wave of depolarisation travels along the nerve fibre as the Na+ ions pass through the membrane, briefly causing the internal potential to become positive

sodium (Na+) ions and negatively charged chlorine (Cl-) ions than the inside of the fibre. Internally, the nerve fibre has a higher concentration of positively charged potassium (K+) and negatively charged protein ions. The permeability of the membrane to the various ions depends on the membrane potential and, in its resting state, the cell membrane is relatively permeable to chlorine and potassium. There is a tendency for potassium to diffuse out of the cell along its concentration gradient leaving the inside of the fibre negatively charged with respect to the outside. This negative charge is the resting potential and is approximately –70mV. When the receptor at the tip of the fibre is stimulated, it produces a change in the potential, which has the effect of increasing the membrane permeability to sodium. Positively charged sodium floods into the cell, changing the membrane potential to around +30mV. This is referred to as the action potential **(Figure 2)**. Once the potential reaches a threshold value (usually around –55mV) the permeability to sodium of the neighbouring section of membrane is increased, which then depolarises and affects the next section, and thus the depolarisation travels along the nerve fibre.

When the internal charge becomes positive, the inflow of sodium slows and the membrane permeability to sodium reduces, preventing the potential from continuing to increase. Additionally, potassium permeability is increased, so potassium leaves the cell, thus the normal resting potential is rapidly restored.

In myelinated neurones, the insulating effect of the myelin covering prevents the passage of ions through the membranes except where there are gaps in the myelin. These gaps are the nodes of Ranvier and the nerve impulse appears to jump from one node to the next. This is known as saltatory conduction and gives a greater speed of conduction than in non-myelinated neurones. The speed of conduction also depends on the diameter of the fibre, larger fibres transmitting faster than smaller.

Corneal innervation

Sensory corneal innervation is supplied by 70-80 bundles of fibres which pass radially out through the limbus to join the ciliary nerves. These in turn pass to the nasociliary branch of the ophthalmic nerve. Most of the nerve terminals are found in a regular dense concentration just below the squamous surface cells of the corneal epithelium. These nerve terminals appear to be free nerve endings which are generally regarded as unspecialised nociceptors. The cornea is known to be extremely sensitive, with pain being the principal sensation recognised, although pressure at detection threshold may be perceived as touch. It is not easy to estimate the number of free nerve endings in the human cornea as corneal nerves degenerate rapidly after death, but in rabbits it has been found that the density of nerve endings in the cornea is 300-600 times that of the skin[1]. At the level of the anterior limiting lamina (Bowman's layer) the nerve fibres gain a Schwann cell covering **(Figure 3)**, but generally do not become myelinated until 0.5mm from the limbus. However, myelinated nerve fibres are occasionally seen in the mid-peripheral or even central cornea.

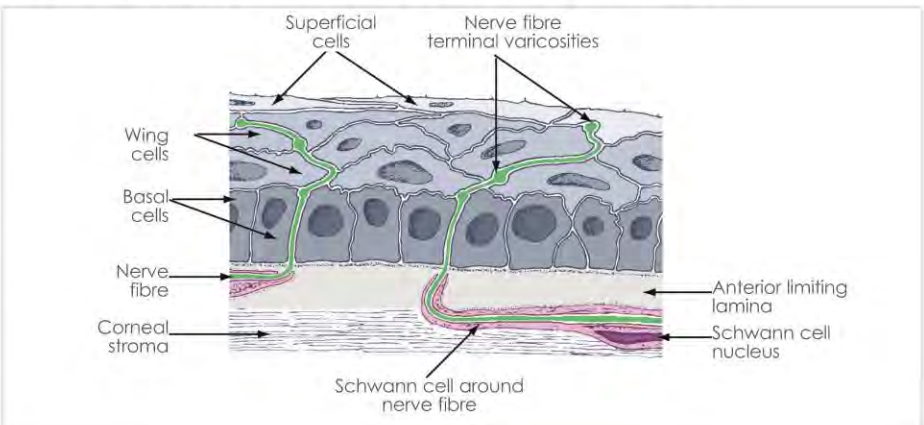
Each fibre bundle forming the corneal nerves collects stimuli from a large area of the cornea. These areas overlap, which has the effect of increasing sensitivity but reduces the ability to localise a stimulus.

Actions of local anaesthetics

Local anaesthetics act on the cell membrane to prevent the change in permeability to sodium ions which

Continued overleaf

Figure 3: Section through the anterior cornea (not to scale) showing sensory nerve fibres



Topical anaesthetic	Available as:	Containing:
Tetracaine	Minims tetracaine 0.5%	0.5% tetracaine hydrochloride
	Minims tetracaine 1%	1.0% tetracaine hydrochloride
Lidocaine	Minims lidocaine & fluorescein	4% lidocaine hydrochloride with 0.25% fluorescein
Oxybuprocaine	Minims oxybuprocaine 0.4%	0.4% oxybuprocaine hydrochloride
Proxymetacaine	Minims proxymetacaine 0.5%	0.5% proxymetacaine hydrochloride
	Minims proxymetacaine & fluorescein	0.5% proxymetacaine hydrochloride with 0.25% fluorescein

Table 1: Topical ocular anaesthetics

occurs with depolarisation. They also reduce the permeability to potassium ions in the resting state. These actions are brought about by the anaesthetic blocking the pores in the membrane through which the ions pass. As the concentration of the anaesthetic builds up, the action potential is reduced and the threshold for electrical excitability increases until propagation of the impulse is blocked. Smaller nerve fibres are affected more quickly than large fibres and in general, non-myelinated fibres are more susceptible than myelinated. The different sensory functions are served by a range of nerve fibre sizes, so there is a definite order in which the sensations are affected. Pain fibres are small and have a high firing rate, these are more readily blocked and thus pain is usually the first sensation to be abolished, followed by cold, warmth, touch and deep pressure, although there is considerable inter-subject variation in this order.

The duration of the anaesthetic effect depends on the length of time that the drug remains attached to the cell membrane. This is governed by the concentration of the drug used and the rate at which it is removed. However, there is a maximum concentration beyond which no further increase in anaesthetic effect is produced. The removal rate is increased in areas with rich blood supply because it is carried away into the systemic circulation. The chemical structure of the drug also affects the duration of the anaesthesia.

Uses of topical anaesthetics

By far the most common use of a topical anaesthetic in general optical practice is for contact tonometry, but there are a number of other procedures for which it may be needed. These include removal of a foreign body and gonioscopy (the examination of the angle of the anterior chamber).

Topical anaesthesia has a number of uses in contact lens fitting.

- It is required to allow impressions to be taken for scleral lenses.
- It is occasionally used in hospital contact lens practice for the assessment of potential visual outcome, when frequent blinking and lacrimation prevent a stable over-refraction.
- It will make the initial fitting of an RGP lens more comfortable and reduce watering, but should not be used in the normal course of fitting an RGP lens.
- Keratoconus patients may benefit from topical anaesthesia to ease the initial insertion. However, once fitted, the visual advantage of the contact lens subsequently outweighs the discomfort, and tolerance to the fitting lenses improves such that anaesthesia is usually not required after the first fitting session.

When the cornea has been anaesthetised, the practitioner must ensure that corneal sensation has returned before the patient leaves the practice, as there is a risk of corneal damage from foreign bodies entering an anaesthetised unprotected eye.

Choosing a topical anaesthetic

The first local anaesthetic to be used was cocaine, a potent naturally-occuring substance. However, it has a number of undesirable side-effects when used as a topical ocular anaesthetic including the production of mydriasis and damage to the corneal epithelium. Cocaine is also well-known as a CNS stimulant and some subjects who are sensitive to it may suffer serious cardiovascular effects with small doses. It is a controlled substance under the Misuse of Drugs Act, and a POM not legally available to optometric practices. However, it is occasionally used in ophthalmic surgery, where its action in constricting small blood vessels is beneficial.

The four drugs available for use in ophthalmic practice are synthetic substances which are all quite similar in their mode of action and the speed of onset of anaesthesia. They all produce a stinging sensation when instilled into the eye and the degree of this is one of the main differences between them. Details of some current products are shown in **Table 1**. Topical anaesthetics combined with fluorescein can eliminate the need for an additional procedure to instill fluorescein in a particularly sensitive eye.

Chemically, three of the four are of the ester type which are readily broken down by enzyme action and therefore produce anaesthesia of short duration. The fourth, lignocaine (also known as lidocaine) is an amide type local anaesthetic which is more resistant to enzyme action, producing a longer-lasting effect.

Amethocaine hydrochloride

This is now more commonly known as tetracaine and has been widely used in the past. Of the four topical anaesthetics, it produces the most discomfort on initial instillation, the majority of patients describing a burning sensation which lasts for 20-30 seconds[2,3]. Anaesthesia is adequate for tonometry within 20 seconds after the application of one drop of 0.5% tetracaine and it lasts for 10-25 minutes. It has been reported that

anaesthesia may last for up to 1 hour with 1%[4]. However, it may not produce effective anaesthesia of the sclera[5].

Another side effect of tetracaine is damage to the surface cells of the corneal epithelium, disrupting the microvilli and cell membranes and increasing the rate of cell loss[6]. Slit-lamp examination after the use of tetracaine commonly shows tiny superficial lesions in the corneal epithelium and these will increase if the anaesthetic application is repeated. The loss of microvilli can reduce mucus adherence and corneal wettability, shortening the tear breakup time[7]. Anaesthesia of the cornea reduces the blink rate and this, combined with an unstable tear film, causes increased tear evaporation, further contributing to epithelial damage. Carney *et al* also found that 1% tetracaine increases the fragility of the epithelium which renders it more prone to damage by mechanical insult such as could occur during tonometry or contact lens fitting[8]. However, the effects of a single instillation of tetracaine are usually mild and reversible within a few hours[6].

Oxybuprocaine hydrochloride
This is alternatively known as benoxinate. One drop of 0.4% oxybuprocaine will produce anaesthesia within one minute which is adequate for tonometry and will last for 10-20 minutes. A second drop after about 90 seconds will allow contact lens fitting and a third drop after a further 90 seconds provides anaesthesia sufficient for foreign body removal. This depth of anaesthesia will last for up to one hour[9]. The initial stinging produced by oxybuprocaine is less marked than tetracaine and does not last as long (10-15 seconds). Less damage to the cells of the corneal epithelium is usually noted with benoxinate in comparison with tetracaine[8].

Proxymetacaine hydrochloride
Proxymetacaine is available either alone, or combined with fluorescein 0.25% which is advantageous for applanation tonometry. One drop produces anaesthesia within 20 seconds and this will last for 10-20 minutes[4]. The initial stinging produced by proxymetacaine lasts for 10-15 seconds[10] and is significantly less severe than both tetracaine and oxybuprocaine[2,3]. Staining of the cornea following the use of proxymetacaine has been reported implying that it causes epithelial damage, however this may only affect susceptible individuals[11] and is less commonly found than in tetracaine use.

Lignocaine hydrochloride
Lignocaine (or lidocaine) was one of the first synthetic local anaesthetics to be produced. Like proxymetacaine, lignocaine hydrochloride is supplied combined with fluorescein 0.25%. Data relating to the speed of onset and duration of anaesthesia of 4% lidocaine is not readily available. However, a study quoted by Mishima found that the peak effect of 2% lidocaine was reached after about 2 minutes and that normal corneal sensitivity was restored in 40-45 minutes[12]. Lidocaine and fluorescein produces more discomfort for the patient when instilled than the proxymetacaine and fluorescein combination and this lasts for 20-30 seconds[10].

Adverse reactions and toxicity

The commonly-found occurrence of punctate lesions in the corneal epithelium after topical anaesthetic use has already been discussed. In some older patients (over age 50), this may be more severe and take the form of a localised or diffuse loss of superficial cells, which occurs up to 30 minutes after instillation. This is usually mild and requires no treatment, but can occasionally reduce VA to 6/24 or worse[4]. In the most severe cases, stromal oedema, conjunctival hyperaemia and lacrimation will be present and the patient will complain of photophobia and pain as the anaesthestic effect diminishes. Moderate cases can be treated as a corneal abrasion with ocular lubricants as required. Cold compresses and systemic analgesia may be necessary in the worst cases. Any adverse reaction should be fully described in the patient's record.

Another undesirable effect of these drugs is the inhibition of cell division and migration. This can prevent (oxybuprocaine and proxymetacaine) or slow (tetracaine) the healing of epithelial defects. Only lidocaine appears not to cause this effect[13,14]. The use of topical anaesthetics for analgesia following corneal injury is therefore inappropriate.

Severe corneal toxicity is only likely to occur following prolonged use of topical anaesthetics. This could take the form of of corneal ulceration, thinning and even perforation. There are numerous reports of anaesthetic abuse leading to severe keratitis and loss of the eye[4,15].

The permeability of the cornea to some other drugs is increased by local anaesthetic agents, this may be a consequence of the damage to the corneal epithelium. This prolongs the effect of these other drugs. Mordi et al found that 0.5% proxymetacaine instilled before 1% tropicamide produced longer lasting cycloplegia and mydriasis than tropicamide alone[16]. The addition of preservatives, in particular benzalkonium chloride, to a local anaesthetic increases the corneal permeability still further[17].

Allergic responses sometimes occur with multi-dose products but these are often caused by the preservative rather than the local anaesthetic. The risk of this is eliminated with the use of Minims which are preservative-free. Reactions to local anaesthetics themelves are rare but may occur with repeated use and are more likely with the ester types. There will be conjunctival hyperaemia, lacrimation, swelling of the eyelids and the subject will complain of an itching sensation[4]. These effects will usually occur within 5-10 minutes of instillation and may be treated with topical decongestants and cold compresses. The event should be noted in the patient's record and, if the use of a local anaesthetic is necessary at a future visit, an allergic episode could be avoided by using a different type of drug.

Systemic effects caused by these drugs are uncommon, but the practitioner should be aware that they are extremely toxic, for example, 5ml of 2% tetracaine would be a lethal dose[5]. Fortunately, the amounts used in normal optical practice are extremely small, and excess quantities overflow down the face. However, drugs instilled into the conjunctival sac are rapidly absorbed into the general circulation and if too large a dose is administered (eg more than 5 drops per eye[18]), the level in the blood could be high enough to produce a systemic reaction. High blood levels could also occur if the drug is absorbed unusually fast, and this may happen if the patient has marked conjunctival hyperaemia. Early signs of systemic toxicity are nervousness,

Continued overleaf

Figure 4: Instillation

tremors, convulsions and rapid/irregular heart rate. Later signs are loss of consciousness, respiratory depression, lowered blood pressure and weak heartbeat, followed by death if no treatment is given. Fortunately, if respiratory and cardiovascular support is applied, these drugs are quickly metabolised and eliminated by the body allowing recovery to occur.

Special precautions and contraindications

Instillation from a Minim is shown in **Figure 4**. In general, the drugs being discussed are very safe and, when properly administered, present little risk of adverse reactions. However, there are a few circumstances where extra care should be taken.

It is generally recommended that tetracaine, oxybuprocaine and proxymetacaine should only be used on pregnant women or nursing mothers if essential. Lidocaine and fluorescein have been used for many years and no adverse effects have been recorded during pregnancy and lactation, however this has not been rigorously researched[19].

The corneal epithelium of diabetics has been found to be more susceptible to the damaging effects of topical anaesthetics than that of non-diabetic subjects[20]. This appears to be the case for both Type 1 and Type 2 diabetes.

There are few reports of ocular local anaesthetics interacting with other drugs. However, tetracaine should not be used in patients taking sulphonamides (antibacterials). Also patients taking neostigmine and pyridostigmine (used in myasthenia gravis) should not be given multiple doses of the ester type anaesthetics.

Storage

It goes without saying that all drugs should be stored securely and out of the reach of children. Oxybuprocaine, tetracaine and lidocaine should all be stored in a cool dark place at a maximum temperature of 25°C. Tetracaine in particular is affected by light. Proxymetacaine should be stored at 2-8°C, although it may be kept at room temperature for no more than one month.

Clinical notes for using topical anaesthetics

- Explain to the patient why you are giving them a topical anaesthetic and ask whether they have ever had an adverse reaction to previous eye drops.
- Ensure that you are using the correct drug and that it is the required concentration. All Minims look similar and it is only too easy to pick up the wrong one! Also check the expiry date.
- Instill only the minimum number of drops into each eye to produce the required depth of anaesthesia. One drop per eye is usually adequate.
- After the procedure / contact lens fit etc. has been performed, check the cornea for damage.
- Make a note on the patient's record of which drug has been used and the quantity and any adverse effect or corneal damage.
- Corneal anaesthesia produces loss of the normal blink reflex and so there is a risk of damage by the entry of an undetected foreign body. The patient should not be allowed to leave the practice until corneal sensitivity is restored. The durations of anaesthesia given in this article are average values only and there is considerable inter-subject variation. Thus it is advisable to test that the blink reflex has returned using a wisp of tissue or cotton wool. If the patient is unable to wait, they should be warned not to rub their eyes until the anaesthesia has worn off and to avoid getting dust or grit into them.
- Advise the patient not to insert contact lenses for at least one hour after the instillation of the drops.
- It is good practice to give the patient a leaflet stating what drops have been instilled. This could also give advice on action to be taken should they suffer any adverse reaction.

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Multiple choice questions (MCQs): Topical ocular anaesthetics

1. Which statement about nerve fibres is untrue?
a. They have a higher positive charge inside the fibre than outside
b. The concentration of sodium ions is higher outside than inside
c. Small nerve fibres conduct their signal slower than larger ones
d. The concentration of potassium ions is lower outside than inside

2. Which statement about corneal nerves is true?
a. The nerve endings are mostly pain receptors
b. The fibres terminate in the anterior limiting lamina
c. The nerve fibres acquire Schwann cells 0.5mm from the limbus
d. They join the nasociliary branch of the maxillary nerve

3. Which local anaesthetic tends to produce the least discomfort when instilled?
a. Lidocaine hydrochloride
b. Oxybuprocaine hydrochloride
c. Proxymetacaine hydrochloride
d. Tetracaine hydrochloride

4. Which local anaesthetic is not an ester type?
a. Lidocaine hydrochloride
b. Oxybuprocaine hydrochloride
c. Proxymetacaine hydrochloride
d. Tetracaine hydrochloride

5. Which statement about tetracaine is untrue?
a. It is available in Minims as tetracaine hydrochloride 0.5% and 1%
b. It may not produce good anaesthesia of the sclera
c 5ml of 2% tetracaine would be a lethal dose
d. It should be stored in a refrigerator

6. Which statement about the use of topical anaesthetics is true?
a. The patient may leave the practice 15-20 minutes after instillation of the drops
b. Signs of systemic toxicity are nervousness, tremors and rapid heart rate
c. Local anaesthetics decrease the permeability of the cornea to other topically applied drugs
d. To ensure adequate anaesthesia at least 5 drops of topical anaesthetic should be instilled into each eye.

7. Which statement about lidocaine is true?
a. It appears not to inhibit healing of the corneal epithelium
b. It is more readily broken down by the body than the other anaesthetic drugs
c. It should be stored in a refrigerator.
d. It should not be used on patients taking sulphonamides.

8. Which statement is true?
a. Allergic reactions are more common with the amide type anaesthetics than the esters
b. Corneal anaesthesia increases the blink rate
c. Type 1 diabetics are more prone to corneal damage than Type 2 following the instillation of topical anaesthetics
d. Corneal permeability is increased if topical anaesthetic drops contain preservatives

9. Which local anaesthetic is not available to optometric practices?
a. Benoxinate
b. Cocaine hydrochloride
c. Lignocaine
d. Proxymetacaine hydrochloride

10. What is a major advantage of using Minims for drug administration?
a. They do not contain a preservative
b. It is impossible to administer a dangerous dose
c. They remain sterile even when opened
d. They can be stored at any temperature

11. There are some circumstances when special precautions need to be taken in the use of local anaesthetics. Which statement is untrue?
a. Lignocaine is the safest topical anaesthetic for pregnant women
b. Lignocaine is the safest topical anaesthetic for those taking neostigmine
c. Amethocaine is the safest topical anaesthetic for those taking sulphonamides
d. Systemic toxicity may occur if a hyperaemic eye is anaesthetised.

12. Which group of factors affects the duration of the anaesthetic effect?
a. Concentration of drug, firing rate of fibres and fibre myelination
b. Chemical structure of drug, removal rate and drug concentration.
c. Rate of removal of drug, firing rate of fibres and fibre size
d. Drug concentration, removal rate and fibre myelination

The deadline for posted or faxed response is 22 June 2010 to the address on page 4. The module code is C-13256

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Chloramphenicol - why not . . .

Angela McNamee BSc(Hons) MCOptom FBDO(Hons)CL FBCLA CertEd recommends a cautious and responsible approach to its supply and use

Competencies covered: Professional conduct, ocular examination, contact lenses
Target group: Dispensing opticians, optometrists

In December 2009, important changes in legislation were brought about under The Medicines (Exemptions and Miscellaneous Amendments) Order 2009. As a result of these changes, all dispensing opticians now have the right to sell or supply the anti-infective drug chloramphenicol, but only in very specific circumstances. With this right comes much responsibility and, before advising on its use, dispensing opticians need to be aware of the factors covered in this article, which outlines the history, actions and uses of the drug, as well as highlighting some precautions which should be noted before considering its sale or supply.

What is chloramphenicol?

Introduced into clinical use in 1948, chloramphenicol has become the anti-infective most familiar to UK optometrists, and probably the one most prescribed by UK GPs for anterior eye infections, being described in the British National Formulary[8] as being the "drug of choice for superficial eye infections".

The anti-infectives include drugs which are effective against bacteria, fungi, viruses and amoebae. Chloramphenicol is specifically an antibiotic, ie a substance capable of destroying or weakening certain micro organisms, especially bacteria.

Like many other drugs, chloramphenicol may be used topically, meaning that it is applied to a localised surface part of the body, for example by drops, or it may be used systemically, where it is applied to the entire system, for example by mouth or injection.

Microbiology

Before describing the more specific actions of chloramphenicol, it may be useful to review some of the basics about bacteria.

These single-celled, self-replicating organisms are approximately 1 to 5 microns in size. They may be classified by their shape, most being either spherical and known as cocci (singular coccus, from the Greek kokkos, meaning grain or seed), or rod-shaped and known as bacilli (singular bacillus, from the Latin *baculus*, meaning stick).

They may also be aerobic (capable of growing in air) or anaerobic (only growing in the absence of oxygen), and many bacteria are facultative anaerobes, who will use oxygen if it is present but are capable of growing without it. Aerobic and anaerobic bacteria **(Figure 1)** can be identified by growing them in liquid culture: In **1** aerobic (oxygen-needing) bacteria gather at the top of the test tube in order to absorb maximal amount of oxygen; in **2** anaerobic bacteria gather at the bottom to avoid oxygen; in **3** facultative anaerobes gather mostly at the top, because they prefer aerobic respiration but, as they can grow without oxygen, they can be found all along the test tube.

A further way of classifying bacteria refers to the way that they react to a particular method of laboratory staining, known as Gram's stain, which has been used for over a hundred years and is still a common method of identifying bacteria in hospital microbiology laboratories **(Figure 2)**. Briefly, it involves smearing some of the bacteria onto a glass slide, then applying methylene blue (or crystal violet) and iodine stains, and rinsing in ethyl alcohol, before applying a red counter stain. Those organisms which resist the alcohol rinse and retain the original dark stain are termed Gram-positive. Those which are decoloured

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This article has been approved for **2 CET points** by the **GOC**. It is open to all FBDO members, including associate member optometrists. Insert your answers to the twelve multiple choice questions (MCQs) online at www.abdo.org.uk, or on the answer sheet inserted in this issue and return by **22 June 2010** to **ABDO CET, Courtyard Suite 6, Braxted Park, Great Braxted, Witham CM8 3GA** OR fax to **01621 890203**. Notification of your mark and the correct answers will be sent to you. If you complete online, please ensure that your email address and GOC number are up-to-date. The pass mark is 60 per cent. The answers will appear in our August 2010 issue.

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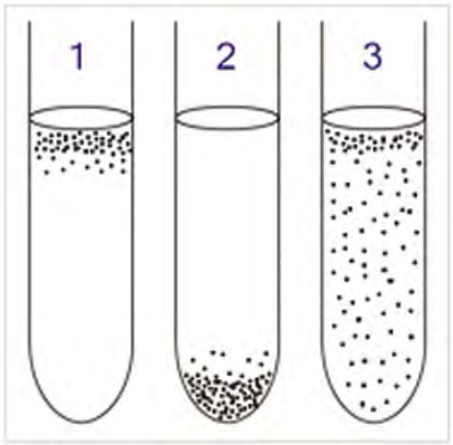

Figure 1: Aerobes and anaerobes

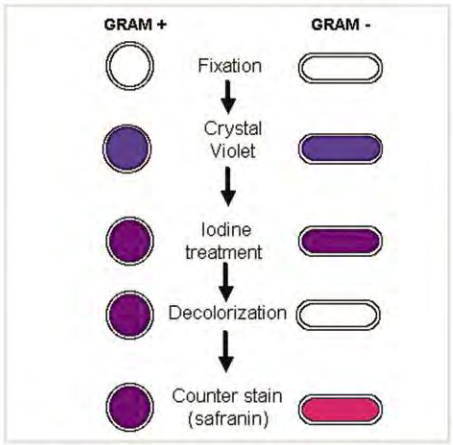

Figure 2: Gram's stain method

Figure 3

by the alcohol and then take up the red stain are termed Gram-negative **(Figure 3)**.

For example: *stapylococcus aureus*, implicated in one form of blepharitis, is a Gram-positive coccus which is falcultatively anaerobic. *Clostridium tetani*, which causes tetanus, is a Gram-positive bacillus and an anaerobe, surviving underground in the soil, and hence posing a potential threat to gardeners with open cuts.

What does chloramphenicol do?

Antibiotics can be bacteriocidal (killing the bacteria) or bacteriostatic (inhibiting the growth of the bacteria but not killing them). Chloramphenicol is a bacteriostatic drug and, as such, does not directly kill bacteria. Instead its action prevents the bacterial cells from manufacturing the proteins essential for them to make copies of themselves. Hence their numbers do not increase. It is known as a broad-spectrum antibiotic, and is highly effective against **most** Gram-positive and Gram-negative bacteria.

There is a low level of bacteria naturally present at the anterior eye and eyelids. The tear film however contains considerable amounts of the antibacterial enzyme lysozyme. Tear film drainage also removes bacteria. It is only when the numbers of bacteria present exceed the defensive properties of the tears that infection may occur; hence the importance of maintaining an adequate quantity and quality of tears.

Common bacterial causes of eye infection

The bacteria most implicated in bacterial conjunctivitis include the gram-positive *staphylococcus epidermidis, staphylococcus aureus* and *streptococcus pneumoniae*; and the gram-negative *pseudomonas aeruginosa* and *haemophilus influenzae*[6].

A very common, non-contact lens-related corneal infection is marginal keratitis, in which *staphylococcus aureus* bacteria from the lid margins infect the periphery of the cornea **(Figure 4)**. Those most implicated in contact lens-related keratitis are *streptococcus pneumoniae*, and the gram-negative *pseudomonas aeruginosa* and *serratia marascens*. Of these, *pseudomonas aeruginosa* is arguably the most devastating, with its excellent ability to adhere to cell surfaces and to secrete cytotoxins that can rapidly destroy corneal epithelium[7] **(Figure 5)**. Untreated, pseudomonas infection can quickly lead to ulceration, stromal melting and corneal perforation.

Chloramphenicol can deal with most of the organisms mentioned above however it is significant that it is **not** effective against most strains of *pseudomonas aeruginosa*. In addition, it is ineffective against the majority of non-bacterial micro organisms, including: viruses, such as *herpes simplex*; protozoa, such as *acanthomoeba*; and most fungi. Interestingly however, in 2007, researchers in New Zealand found that frogs bathed in a solution of Chloramphenicol became resistant to the killer disease, *chytridiomycosis*, a fungal disease which has been blamed for the extinction of one-third of the 120 frog species lost since 1980[5] **(Figure 6)**.

Risks associated with chloramphenicol use

Chloramphenicol has been available for use by optometrists since 1989 yet a recent survey[1] showed that only 14% of optometrists regularly use

Continued overleaf

Figure 4: Marginal keratitis

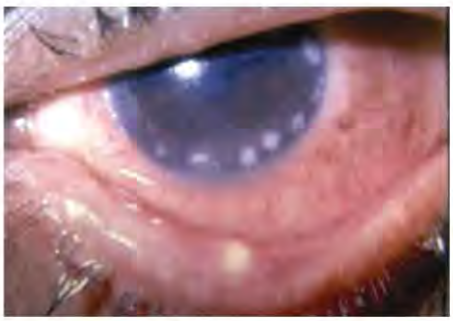

Figure 5: Pseudomonas aeruginosa corneal ulcer

Figure 6: Chloramphenicol saves frogs

Figure 7: Chloramphenicol eye drops

either this or the, more recently available, antibiotic fusidic acid in practice. This may in part be due to an awareness of associated risks.

Aplastic anaemia

While chloramphenicol is widely used throughout the world, it is rarely used in the US due to a possible association with aplastic anaemia: a condition in which the bone marrow fails to produce sufficient new blood cells.

Anaemia is usually taken to mean a reduction in red blood cells (erythrocytes), which carry oxygen but, in aplastic anaemia, white blood cells (leukocytes), essential to the immune system, and platelets (thrombocytes), essential for blood clotting, are also deficient. Successful treatment usually involves bone marrow transplant but this is not without its risks and complications. Left untreated, the disease may lead to rapid death.

Topical chloramphenicol-induced aplastic anaemia is in fact extremely rare, with one UK study finding only 11 suspected cases (all non-fatal) in over 200 million uses over a 10 year period[2]. The fatality rate of systemic chloramphenicol use is higher, and so this is now limited to a few life-threatening diseases, such as typhoid fever. Royal Pharmaceutical Society guidance[3] advises avoiding the use of topical chloramphenicol in those taking bone marrow suppressant drugs (used for example in anti-cancer chemotherapy and rheumatoid arthritis).

Bacterial resistance

Over time, bacteria can acquire unique attributes which render them resistant to antibiotics. They can do this by mutating spontaneously. If this mutation allows them to survive the onslaught of the antibiotic, they will pass the mutation to their offspring. Those bacteria which have not mutated will be killed off by the antibiotic, allowing further proliferation of the mutated strains. Thus so called 'killer bugs' such as MRSA (*Methicillin Resistant Staphylococcus Aureus*) may spread quickly, both within an individual and from one person to another. Chloramphenicol however has a good record with regard to bacterial resistance, and has been shown to be effective against MRSA-induced conjunctivitis where other antibiotics have failed[4].

Other risks

Rare adverse effects of topical use, as listed in Royal Pharmaceutical Society Guidance, may include severe hypersensitivity (allergic) reactions, including angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis[3]. In addition, young infants, whose livers are immature, cannot metabolise chloramphenicol, and its use should be avoided by children under two, and pregnant and lactating women.

Side effects as listed in the BNF[6] are *"blood disorders including reversible and irreversible aplastic anaemia (with reports of resulting leukaemia), peripheral neuritis, optic neuritis, headache, depression, urticaria, erythema multiforme, nausea, vomiting, diarrhoea, stomatitis, glossitis, dry mouth; nocturnal haemoglobinuria reported; grey syndrome (abdominal distension, pallid cyanosis, circulatory collapse) may follow excessive doses in neonates with immature hepatic metabolism".*

Availability of chloramphenicol eye preparations

History

In the UK, drugs may be classed as either: POM (prescription only medicines); P (available without prescription at a pharmacy); or GSL (general sales list, available in non-pharmaceutical outlets).

Cloramphenicol eye preparations were originally all classified as prescription only medicines (POMs). Legislation in 1989 however allowed optometrists access to a special list of POMs, including eyedrops containing 0.5% chloramphenicol and ointment containing 1% chloramphenicol, which they could supply to patients, provided it was in the course of their professional practice and in an emergency.

Subsequently most optical practices have kept a supply of the 0.5% drops in 0.5ml Minim containers, to use in such situations. It has been common practice amongst some to instil a drop of chloramphenicol from a Minim, as prophylaxis, following minor corneal abrasion, although the instillation of a single drop may have questionable effect[13].

Provision had also been made for several pharmacy (P) medicines to be available for supply in such circumstances.

In recent years many POMs have been reclassified as pharmacy (P) medicines. These have included the 0.5% chloramphenicol eye drops (in 2005) and the 1% ointment (in 2007) **(Figure 7)**, as well as others including some antihistamines, mast cell stabilisers and ocular lubricants. Parallel legislative changes in 2005[9] also brought about a relaxation of the rules governing the supply of pharmacy (P) medicines by optometrists, effectively removing the 'emergency only' restriction which had formerly applied to these preparations.

The current situation

Hence chloramphenicol became one of a number of preparations which could be sold or supplied by optometrists, directly to patients, without the need for an emergency

situation to exist. The 2009 legislation has extended these rights to dispensing opticians, who may now sell or supply chloramphenicol in the course of their professional practice. However it should be noted that this only applies to chloramphenicol in its Pharmacy (P) classification. This classification states that its supply is restricted to a maximum pack size of 10ml (drops) and 4g (ointment), and only for the treatment of acute bacterial conjunctivitis in adults and children over two years, for a maximum of five days.

An alternative route available to optometrists is to supply the chloramphenicol via a signed order to a pharmacist, when its use is more flexible and may include for example prophylactic use for corneal abrasions, or following foreign body removal.

Should dispensing opticians supply chloramphenicol?

Professional guidelines

At the time of writing ABDO is in the process of updating its guidelines.

College of Optometrists guidelines state that:
"In order to separate prescribing and supply, it is good practice for the supply of therapeutic agents to be made by pharmacists wherever possible. Optometrists should not supply therapeutic drugs to patients unless it is in the patient's best interests for them to do so."

The separation of the prescribing and supply of any drug is generally considered safe practice, with the patient having the benefit of having two professionals ensure that the drug is supplied at the correct dosage and with the correct instructions regarding its use.

"If they are supplying therapeutic drugs to their patients, practitioners have a duty to ensure that this drug is appropriate for the patient. This will mean the optometrist has to make a diagnosis of the patient's condition. Supply should normally only be made following an eye examination, or within a reasonable time afterwards."
In the use of chloramphenicol by dispensing opticians this would imply that an examination resulting in a diagnosis of acute bacterial conjunctivitis would be necessary before the drug is supplied. It is interesting to note that pharmacists[3] are advised to refer contact lens wearers with suspected acute bacterial conjunctivitis to "an optometrist, contact lens practitioner or doctor"

"Patients should be made aware of the need to have their condition periodically reassessed to determine whether or not the drug is still appropriate." In the case of bacterial conjunctivitis patients it would be good practice to ask the patient to return promptly if the condition does not improve within 48 hours, or if they develop pain, photophobia or blurred vision.

"All actions and advice should be noted on the patient record." This is standard advice which should be obvious to any dispensing optician.

"Optometrists should be aware of the indications, cautions, contraindications and side effects of any medicinal products supplied. Patients should be made aware of how to use the drug and what to do in the case of an adverse event occurring. Patients should be asked about any previous drug-induced adverse event and known drug allergies". The supply of any drug is not a matter to be taken lightly. Practitioners who supply drugs clearly have a duty of care to their patients and may leave themselves vulnerable to litigation in the event of any inappropriate use.

Correct disposal of chloramphenicol

Chloramphenicol is classified as 'hazardous waste' and as such, on disposal, it needs to be kept in a rigid, leakproof container, and then sent for specialist incineration. Its disposal needs to be documented on a consignment note, and practices that produce hazardous waste are also required to keep a register of their hazardous waste records. (Registration with the Environment Agency is also required, but only if the hazardous waste exceeds 200kg in a 12-month period.)

The 'hazardous waste' classification has been applied to chloramphenicol because it is considered to be a carcinogen, however this is based on its effects on the environment, and does not mean that the use of drops or ointment can cause cancer.

How effective is it?

Acute bacterial conjunctivitis typically resolves without treatment in five to seven days. A 2005 study in *The Lancet*[10] compared chloramphenicol use with placebo in 326 children diagnosed with acute conjunctivitis, and found that there was very little difference between the two groups in terms of rate of cure, complications or recurrence. The NHS website, *Clinical Knowledge Standards*[11], acts as a reference source for GPs on the treatment of various conditions. This states that, for most people, use of a topical ocular antibiotic makes little difference to recovery from infective conjunctivitis.

What advice can be given to patients presenting with signs and symptoms of acute bacterial conjunctivitis?

Contact lens wearers should be told not to wear their lenses until the condition has completely resolved, and to discard their lenses and lens case. Infected secretions should be cleaned away from the lids and lashes with cooled boiled water or sterile saline. Sterile saline or ocular lubricants (preferably in unit dose containers) can also be used to irrigate the eyes, thereby reducing the bacterial load. Patients should wash hands frequently, particularly after touching the eyes, and should be advised not to share towels, flannels or pillows, as person-to-person spread is very common.
Such patients should always be told to seek urgent medical attention if they develop marked pain, photophobia or reduced vision.

Recognising acute bacterial conjunctivitis

Patients with acute bacterial conjunctivitis will typically have redness of the bulbar and tarsal conjunctiva, which is generalised but often greatest at the fornices. They will have a mucopurolent, yellowy discharge, which may lead to the eyelids being stuck together on waking, and may show as encrustation on the lashes **(Figure 8)**. They may complain of a gritty or burning feeling, but not pain. Although vision is not affected, transient blurring may occur due to the discharge. There will often be a history of contact with another infected person. Although initially unilateral, it frequently spreads to the other eye.

Continued overleaf

Figure 8: Bacterial conjunctivitis

Figure 9: Viral conjunctivitis

Figure 10: Locating the preauricular lymph nodes

Differential diagnosis

Viral conjunctivitis **(Figure 9)** will also present with a red eye but the discharge will be watery. Patients may have a history of flu-like symptoms, and there may be swelling or tenderness of the preauriclar nodes **(Figure 10)**. Follicles may be present in the lower fornices. It is usually a unilateral condition, although adenovirus often affects both eyes. Clinically, it can be quite difficult to differentiate bacterial and viral conjunctivitis.

Allergic conjunctivitis also presents with red eyes, is usually bilateral, and accompanied by papillae of the tarsal conjunctiva, itching, and oedema of the conjunctiva and lids.

There are many other possible causes of red eye, and a full discussion of these is beyond the scope of this article. Patients with marked pain, photophobia or reduced vision should always be referred.

Patient instructions for chloramphenicol 0.5% drops

Administration

Patients should wash their hands before and after use. They should tilt the head back and insert one drop into the lower eyelid, avoiding contact between the bottle nozzle and the lids or lashes **(Figure 11)**. To avoid drops being tasted in the mouth or going down the throat, they may press a finger against the inner canthus for a minute after insertion.

Figure 11

Dosage

The instructions are to 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. (However the 1% ointment may be used at bedtime, when it won't impair vision and will have a longer residence time in the eye.) The usual course of treatment is five days. Patients should be reminded of the importance of completing the course of treatment.

They should be told to return or seek medical attention if there is no improvement in the first 48 hours, and always if they develop pain, photophobia, or reduced vision. Transient blurring may occur due to the instillation of the drop, and driving should be avoided if this is present.

Contact lens wearers

Contact lens wear should be avoided during treatment and for at least 24 hours after treatment is finished. Contact lens wearers should also be told not to wear their lenses until the condition has completely resolved, and to discard their lenses and lens case. The 1% ointment is probably best avoided in contact lens wearers, in case some residue remains when wear is recommenced.

Storage

In a pharmacy or practice setting, chloramphenicol eye drops should be stored in a refrigerator (2–8°C), and this would be the best advice to give to patients also. However, given the frequency of dosing, this may not always be practical. Once opened, the eye drops should be discarded after five days.

Summary

For most of its applications, chloramphenicol is classified as a prescription only (POM) medicine, however it is included on a special list of POMs which optometrists may use in the course of their practice and in an emergency. In very restricted circumstances, chloramphenicol 0.5% drops and 1% ointment are classified as pharmacy (P) medicines, and as such are available for optometrists and dispensing opticians to sell or supply directly to their patients without the need for an emergency situation. These restrictions dictate that it may only be used for acute bacterial conjunctivitis, in adults and children over two, and for a maximum of five days.

Although long established as the drug of first choice for the treatment of acute bacterial conjunctivitis, its indiscriminate use in this self-limiting disease has been questioned[12], with research concluding that there is little difference between choramphenicol use and that of a placebo[10].

Although incidence is extremely rare, there is a theoretical link between the use of topical chloramphenicol and the life-threatening disease aplastic anaemia. Severe allergic reaction represents another possible risk factor in its use, as does the potential for the development of bacterial resistance. Also the disposal of unwanted chloramphenicol is subject to rigorous legislation.

Given all of the above caveats, many dispensing opticians may wonder if they really want to become involved in its sale or supply.

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Multiple choice questions (MCQs):

Chloramphenicol - why not . . .

1. An antibiotic is used principally for the treatment of
a. Dry eye
b. Allergies
c. Bacterial infection
d. Viral linfection

2. Which one of the following does not describe a class of bacteria?
a. Coccus
b. Anaerobe
c. Gram-positive
d. Herpetic

3. Which one of the following is not a common bacterial cause of eye infection?
a. Candida albicans
b. Staphylococcus aureus
c. Haemophilus influenzae
d. Streptococcus pneumoniae

4. Chloramphenicol's principal action is
a. Bacteriocidal
b. Virocidal
c. Bacteriostatic
d. Virostatic

5. As a pharmacy (P) medicine, chloramphenicol is available in
a. 1.5% drops and 0.5% ointment
b. 0.5% drops and 1% ointment
c. 0.5% drops and 1.5% ointment
d. 1% drops and 2% ointment

6. The maximum treatment time allowed for the use of chloramphenicol as a pharmacy (P) medicine is
a. Ten days
b. Two weeks
c. Two days
d. Five days

7. Acute bacterial conjunctivitis
a. Typically resolves spontaneously
b. Usually requires aggressive treatment
c. Rarely spreads to the other eye
d. Rarely spreads to other people

8. Which one of the following is not a sign or symptom of acute bacterial conjunctivitis?
a. Red eye
b. Photophobia
c. Sticky discharge
d. Gritty or burning feeling

9. The recommended storage temperature for chloramphenicol eye drops is
a. 12 to18°C
b. -1 to -5°C
c. 2 to 8°C
d. 9 to 11°C

10. As a pharmacy (P) medicine, chloramphenicol may be used for the treatment of
a. Corneal abrasions
b. Prophylaxis following foreign body removal
c. Acute bacterial conjunctivitis
d. Acute allergic conjunctivitis

11. Regarding contact lens wear, which statement is correct
a. All wearers may safely wear their lenses whilst using chloramphenicol
b. Wearers should avoid wearing their lenses for at least six months after stopping chloramphenicol use
c. Wearers should avoid wearing their lenses for at least 24 hours after stopping chloramphenicol use
d. Only soft lens wearers may wear their lenses whilst using chloramphenicol

12. Which one of the following is not a means of classifying bacteria?
a. Bacilli or cocci
b. Alcoholic or non-alcoholic
c. Gram-positive or gram-negative
d. Aerobic or anaerobic

The deadline for posted or faxed response is 22 June 2010 to the address on page 4. The module code is C-13175

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