Spersadex® comp.

Composition
Active substances: Chloramphenicol, dexamethasone sodium phosphate
Excipients: Macrogol 400, 0.1 mg benzalkonium chloride per ml as a preservative, vehicle excipients

Pharmaceutical form and quantity of active substance per unit
Eye drops
5 mg chloramphenicol per ml, 1 mg dexamethasone sodium phosphate per ml

Indications / Potential uses
Inflammation of the anterior segment of the eye in patients in whom corticosteroid therapy is indicated and there is either concurrent infection with bacteria susceptible to chloramphenicol, or a high risk of such infection.
Chloramphenicol is only indicated when the pathogen has been shown to be resistant to all other antibiotics.

Dosage and Administration
1 drop, instilled into the conjunctival sac 3–5 times daily.
In acute cases: up to 1 drop per hour.
Due to the possibility of adverse systemic effects, caution is required when administering corticosteroids to infants under 2 years of age. Spersadex comp. must not be used in neonates (see **Contraindications**).

Contraindications
- Hypersensitivity to either of the active substances or to any of the excipients.
- Corneal lesions and ulcerative processes, herpes simplex and other viral infections, mycosis.
- Glaucoma.
- Severe hepatic dysfunction and severe blood disorders due to bone marrow depression.
- Neonates.
- Family history of bone marrow depression.

Warnings and Precautions
- Corticosteroids may mask, activate or exacerbate eye infections.
- In general, caution is required when administering corticosteroids to infants under 2 years of age.
- Chloramphenicol should not be used for more than 10 days.
- If there is no improvement after 7–8 days of treatment, other therapeutic measures should be considered.
- Therapy with Spersadex comp. involves the potential risk of aplastic anaemia or other blood dyscrasias. A careful assessment of the risk-benefit ratio must therefore be made in each case. Spersadex comp. should only be used if other active substances are ineffective and/or contraindicated.

Note for contact lens wearers
Contact-lens wearers should not use the eye drops while wearing contact lenses because the preservative (benzalkonium chloride) accumulates in soft contact lenses and may discolour them. In general, however, contact lenses should not be worn during treatment because of the risk of spreading the infection.

Interactions
Spersadex comp. should not be used concurrently with bactericidal substances (penicillins, cephalosporins, gentamicin, tetracyclines, polymyxin B, vancomycin, sulfadiazine) because bacteriostatic antibiotics can inhibit those with a bactericidal action. In addition, as a precaution, Spersadex comp. should not be used in patients undergoing systemic treatment with drugs that suppress haematopoiesis, such as sulphonylureas, coumarin derivatives, hydantoins or methotrexate.

Pregnancy and Lactation
- Studies with chloramphenicol in animals have shown adverse effects on the fetus. There have been no controlled studies in pregnant women.
- Spersadex comp. should not be used during pregnancy.
- In addition, Spersadex comp. should not be used by women who are breastfeeding.

Effects on ability to drive and use machines
Temporary blurring – or other impairment – of vision may adversely affect the patient's ability to drive or use machines. Patients should not carry out these activities until such disturbances have subsided.

Adverse effects
Adverse ocular effects
A mild burning sensation may briefly occur after instillation.
There have been isolated reports of cataracts and corneal melt following long-term treatment with steroids. With use over several weeks, a reversible increase in intraocular pressure may occur in predisposed patients. Regular monitoring of intraocular pressure is indicated.
Adverse oral effects
The patient may experience a bitter taste shortly after application.
Systemic adverse effects
There have been isolated reports of occasionally **irreversible** blood dyscrasias (aplastic anaemia, pancytopenia, leucopenia, thrombocytopenia and agranulocytosis) following use of ophthalmic formulations containing chloramphenicol. The degree of severity and time of onset of the occasionally irreversible and lethal disorders did not correlate with the dosage.
Systemic adverse reactions may also occur during long-term topical treatment with corticosteroids (especially in children).

Overdose
There have been no known cases of overdosage involving topical use. Measures should be taken to delay absorption in case of inadvertent oral ingestion. There is no specific antidote.

Properties and Actions
ATC code: S01CA01
The anti-inflammatory effect of dexamethasone is about 25 times greater than that of hydrocortisone. Like all anti-inflammatory glucocorticoids, dexamethasone also inhibits phospholipase A2, the first step in prostaglandin synthesis. In addition, dexamethasone inhibits the chemotactic migration of neutrophils into the focus of inflammation.
Chloramphenicol, a low-molecular-weight and predominantly lipophilic antibiotic, is active against Gram-positive and Gram-negative bacteria as well as spirochaetes, salmonellae, rickettsiae and chlamydiae (trachoma).
Selective inhibition of bacterial protein synthesis has been shown to be the mechanism of action. Chloramphenicol is moderately effective against Proteus (20–50% resistant), Serratia (30–70%), Klebsiella (60–70%), Enterobacter (20–50%) and E. coli (20%). Chloramphenicol is ineffective against Pseudomonas, fungi and protozoa. Resistance within the spectrum of sensitive organisms has not significantly increased over the last few years.

Pharmacokinetics
Peak concentrations of 15 µg/g in the cornea and 1 µg/g in the aqueous humour were measured after a single 50 µl application of a 0.1% radioactively labelled 14C-dexamethasone phosphate solution in the rabbit eye.
Chloramphenicol penetrates the cornea effectively, and therapeutically active concentrations of 3–6 µg/ml can be found in the aqueous humour 15–30 minutes after topical application. The half-life is 3–5 hours. A considerably shorter retention time can be expected in the inflamed eye.

Preclinical data
Teratogenic and embryotoxic effects have been reported in reproductive toxicity studies with both chloramphenicol and corticosteroids.

Other information
Shelf-life
Unused and unopened packs of Spersadex comp. eye drops may be used until the expiry date (= EXP) printed on the pack. After opening, do not use for more than 1 month. At the end of treatment, any of the remaining medicinal product should be discarded.
Special precautions for storage
Store eye drops in a refrigerator (2–8°C).
Instructions for use and handling
Close the bottle immediately after use and always keep it tightly closed. The dropper tip must not touch either the hands or the eyes.

Pack sizes
5 ml dropper bottle

Manufacturer
See folding box.

Information last revised
June 2005
Approval date (text)
20 January 2006

® = registered trademark

Novartis Pharma AG, Basle, Switzerland
This is a medicament
– A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
– The doctor and the pharmacist are experts in medicine, its benefits and risks.
– Do not by yourself interrupt the period of treatment prescribed for you.
– Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists