SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

SOFTACORT 3.35 mg/ml eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml eye drops, solution contains 3.35 mg of hydrocortisone sodium phosphate.

One drop contains approximately 0.12 mg of hydrocortisone sodium phosphate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container.

The solution is a practically clear, colourless to slightly yellow solution, practically free from particles.

pH: 6.9 - 7.5

Osmolality: 280-320 mosmol/kg

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of mild non-infectious allergic or inflammatory conjunctival diseases.

4.2 Posology and method of administration

Posology

The recommended dosage is 2 drops 2 to 4 times daily in the affected eye.

The duration of this dosing regimen will generally vary from a few days to a maximum of 14 days. Gradual tapering off up to one administration every other day may be recommended in order to avoid a relapse.

In case of insufficient response, a more potent corticosteroid should be used.

Paediatric population

The safety and efficacy have not been established in the paediatric population. See section 4.4.

Elderly

No dose adjustment is necessary in elderly patients.

Method of administration

Ocular use.

A single-dose container contains enough solution to treat both eyes.

For single use only.

This medicinal product is a sterile solution that does not contain a preservative. The solution from one individual single-dose container is to be used immediately after opening for administration to the affected eye(s) (see section 6.3).

Patients should be instructed:

- to avoid contact between the dropper tip and the eye or eyelids,
- to use the eye drops, solution immediately after first opening of the single-dose container and to discard the single-dose container after use.

Nasolacrimal occlusion by compression of lacrimal ducts for one minute may reduce systemic absorption.

In case of concomitant treatment with other eye drops, solution, instillations should be spaced out by 5 minutes.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
- Known glucocorticosteroid-induced ocular hypertension and other forms of ocular hypertension;
- Acute herpes simplex virus infection and most of the other corneal viral infections at the acute stage of ulceration (except when combined with specific chemiotherapeutic agents for herpes virus); conjunctivitis with ulcerative keratitis even at the initial stage (positive fluorescein test);
- Ocular tuberculosis;
- Ocular mycosis;

- Acute ocular purulent infection, purulent conjunctivitis and purulent blepharitis, stye and herpes infection that may be masked or aggravated by anti-inflammatory drugs.

4.4 Special warnings and precautions for use

Topical steroids should never be given for an undiagnosed red eye.

Use of this medicinal product is not recommended for the treatment of viral herpes keratitis, but it may be used if required only with a combined antiviral treatment and under close supervision of an ophthalmologist.

Thinning of the cornea and sclera (caused by diseases) may increase the risk of perforations with the use of topical steroids.

Any fungal infection should be suspected in cases of corneal ulceration where a steroid has or had been used for a long period.

Patients should be monitored at frequent intervals during treatment with hydrocortisone eye drops. Prolonged use of corticosteroid treatment has shown to cause ocular hypertension/glaucoma especially for patients with previous IOP increase induced by steroids or with pre-existing high IOP or glaucoma, (see sections 4.3 and 4.8) and also cataract formation, especially in children and elderly population.

The use of corticosteroids may also result in opportunistic ocular infections due to the suppression of host response or to the delay of their healing. In addition, topical ocular corticosteroids may promote, aggravate or mask signs and symptoms of opportunistic eye infections.

Wearing of contact lenses during treatment with corticosteroid eye drops should be avoided.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

This medicine contains 0.227 mg phosphates in each drop (see also section 4.8).

Paediatric population
In children, long-term continuous corticosteroid therapy may produce adrenal suppression (see section 4.2).
The ocular hypertensive response to topical corticosteroids in children occurs more frequently, more severely, and more rapidly than that reported in adults.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited data from the use of SOFTACORT in pregnant women. Corticosteroids cross the placenta. Studies in animals have shown reproductive toxicity including formation of cleft palates (see section 5.3). The clinical relevance of this observation is unknown. After systemic administration of higher doses of corticosteroids, effects on the unborn/neonate (intra-uterine growth inhibition, inhibition of the function of the adrenal cortex) have been reported. However, these effects have not been observed after ocular use.

SOFTACORT is not recommended during pregnancy, unless clearly necessary.

Breastfeeding

Systemically administered glucocorticoids are excreted in breast milk and may cause suppression of growth or of endogenous corticosteroid production or may have other undesirable effects.

It is unknown whether SOFTACORT is excreted in human milk.

A risk to the newborns/infants cannot be excluded.

Fertility

There are no data on potential effects of hydrocortisone sodium phosphate 3.35 mg/ml on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

4.8 Undesirable effects

List of adverse reactions:

Adverse events are categorised by frequency as follows: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (frequency cannot be estimated from available data).

Hydrocortisone
Eye disorders:
- Not known:
Burning*, stinging*.

Corticoid class effects
The following adverse drug reactions have not been observed with hydrocortisone, but are known with other topical corticosteroids.
Eye disorders:
- Not known:
Allergic and hypersensitivity reactions, delayed wound healing, posterior capsular cataract*, opportunistic infections (herpes simplex infection, fungal infection, see Section 4.4), glaucoma*, mydriasis, ptosis, corticosteroid-induced uveitis, changes in corneal thickness*, crystalline keratopathy, blurred vision (see also section 4.4).

* *see section Description of selected adverse reactions*

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Description of selected adverse reactions
Burning and stinging may occur immediately after instillation. These events are usually mild and transient and have no consequences.

Prolonged use of corticosteroid treatment has shown to cause ocular hypertension/glaucoma (especially for patient with previous IOP increase induced by steroids or with pre-existing high IOP or glaucoma, or family history of high IOP or glaucoma) and also cataract formation. Children and elderly patients may be particularly susceptible to steroid-induced IOP rise (see section 4.4).
Increase of intra-ocular pressure induced by corticosteroid topical treatment has been generally observed within 2 weeks of treatment (see section 4.4.).

Diabetics are also more prone to develop subcapsular cataracts following topical steroid administration.

In diseases causing thinning of the cornea, topical use of steroids could lead to perforation in some cases (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the case of topical overdosage associated with prolonged eye irritation, the eye(s) should be rinsed with sterile water.

Prolonged overdosages could produce ocular hypertension. In this case, it is necessary to discontinue treatment.

The symptomatology due to accidental ingestion is not known. As with other corticosteroids however, the physician may consider gastric lavage or emesis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ANTIINFLAMMATORY AGENTS – Corticosteroids, plain, ATC code: S01BA02

Mechanism of action

Hydrocortisone or cortisol is a glucocorticoid secreted from the adrenal gland and equipped with anti-inflammatory activity capable of releasing and inducing the synthesis of the specific PLA2 inhibitor (lipocortin) therefore blocking the arachidonate cascade and the formation of phlogogenic factors, like prostaglandins, thromboxanes, (SRS-A) leukotrienes. Such a mechanism of action explains the anti-inflammatory and anti-allergic activity of hydrocortisone.

5.2 Pharmacokinetic properties

A pharmacokinetic study in rabbits performed with SOFTACORT has shown that after administration, hydrocortisone rapidly diffused in the aqueous humour, cornea and conjunctivae. The penetration of hydrocortisone was the highest in the cornea, followed by the conjunctivae, and is very low in the aqueous humour. A weak systemic passage of hydrocortisone was also observed (< 2% of applied dose).

5.3 Preclinical safety data

Prolonged repeated administration of hydrocortisone via the systemic route in animals reduced body weight gain, and increased neoglucogenesis and hyperglycaemia, thymolysis and ocular hypertension.

Reproductive toxicity

In mice, ocularly administered hydrocortisone has been shown to produce foetal resorptions and cleft palate. In rabbits, ocular use of hydrocortisone produced foetal resorptions and multiple abnormalities involving the head and abdomen.

In addition, intra-uterine growth inhibition and changes of functional development of the central nervous system have been reported after administration of corticosteroids to pregnant animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate,

sodium dihydrogen phosphate monohydrate,

sodium chloride,

disodium edetate,

hydrochloric acid (for pH adjustment),

water for injections.

6.2 Incompatibilities

Incompatibility with other drugs is not known.

6.3 Shelf life

2 years in the outer packaging.

After first opening of the sachet: use the single-dose containers within 1 month.

After first opening of the single-dose container: use immediately and discard the single-dose container after use.

Since sterility cannot be maintained after the individual single-dose container is opened, any remaining contents must be discarded immediately after administration.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the single-dose containers in the sachet, in order to protect from light.

For storage after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

10 single-dose containers (LDPE) containing 0.4 ml of eye drops, solution are overwrapped in a sachet composed of four layers made of paper/polyethylene/aluminium/ethylene copolymer.

A pack size contains 10 (1x10), 20 (2x10), 30 (3x10) or 60 (6 x 10) single-dose containers.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20162/0024

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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