Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet
1. What Softacort is and what it is used for
2. What you need to know before you use Softacort
3. How to use Softacort
4. Possible side effects
5. How to store Softacort
6. Contents of the pack and other information

1. What Softacort is and what it is used for

This medicine is an eye drops solution in single-dose containers, which contains a substance called hydrocortisone. This substance is a corticosteroid which reduces inflammatory symptoms.

It is used to treat mild allergic or inflammation conditions that affect the clear lining that covers the whites of your eye(s) and the insides of your eyelids (your conjunctiva).

The eye should not be infected (see Do not use Softacort).

2. What you need to know before you use Softacort

Do not use Softacort:
- If you are allergic to the active substance (hydrocortisone) or any of the other ingredients of this medicine (listed in section 6).
- If you have high pressure inside the eye (ocular hypertension), known to be due to glucocorticoids (family of corticosteroid medicines) or to other causes.
- If you have an eye infection caused by viruses (acute herpetic or other viruses while there are ulcers, unless the infection is being treated with an anti-infective treatment for herpes virus).
- If you have conjunctivitis with inflammation and ulcers on the clear cornea surface of the eye (keratitis) even if it is at an early stage.
- If you have an eye infection caused by bacteria (acute purulent infection, conjunctivitis, blepharitis, stye).
- If you have an eye infection caused by fungus (ocular mycosis).
- If you have a bacterial infection called tuberculosis which affects your eye (ocular tuberculosis).

Warnings and precautions
- Talk to your doctor, pharmacist or nurse before using this medicine.
- If you have a red eye that has not been diagnosed, do not use this medicine.
- If you have a viral eye infection (herpes), only use this medicine if the infection is being treated with an anti-infective treatment and close monitoring of your eyes is required.
- If you have a disease that causes thinning of the outer part of your eye (cornea and sclera), there can be a higher risk of perforation when topical corticosteroids are applied to the eye.
- If you have used or have been using a corticosteroid medicine for a long time and have an eye wound (corneal ulcer), a fungal infection may be suspected.
- Close regular monitoring of your eyes is required during your treatment. Prolonged use of corticosteroids has shown to cause an increase of the pressure inside the eye and the start of glaucoma, especially in patients who already suffer from high pressure inside the eye, or if you are known to be at risk of developing this condition with local steroid treatment (see Possible side effects), and to cause a clouding of the lens in the eye (cataract), in particular in children and older people.
- The use of corticosteroids can cause eye infections that may not normally happen (opportunistic eye infections). In addition, corticosteroids given to the eye may increase, make worse or hide signs and symptoms of these eye infections.
- You should avoid wearing contact lenses during treatment with this medicine.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children

There are no data on safety and effectiveness in children.
Continuous long-term treatment with corticosteroids in children may produce adrenal suppression.

The increase of the eye pressure in children occurs more frequently, more severely, and more quickly than in adults.

Other medicines and Softacort

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines including medicines you have without a prescription. Some medicines may increase the effects of Softacort and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as ritonavir or cobicistat).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- The use of this medicine during pregnancy is not recommended except when judged necessary by your doctor and under strict supervision.
- It is not known whether this medicine passes into breast milk. Your doctor will decide if you can use this medicine during breast-feeding or not.

Driving and using machines

Temporary blurred vision or other sight problems may affect the ability to drive or use machines. Do not drive or use machines until normal vision has returned.

Softacort contains phosphates

This medicine contains 0.227 mg phosphates in each drop.

3. How to use Softacort

Dose

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 2 drops in the affected eye(s), 2 to 4 times a day, depending on the prescription. Gradually reducing the dose is recommended in order to avoid relapse. The treatment usually varies from a few days to a maximum of 14 days.

The same dose is used for both adults and the elderly.

Use in children

The effectiveness and the safety in children have not been established for this medicine.

How to use the drops

This medicine is to be used in the eye.

Please follow these instructions to use the drops:
1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 10 single-dose containers. Write down the date of first opening on the sachet.
3. Break off one single-dose container from the strip.

To use the drops:

- Gently pull down your lower eyelid to make a small pocket.
- Place one drop of Softacort in the pocket.
- Close your eye gently to prevent the medicine from dripping out.
- Do not use the other eye.
- Do not use a dropper to put the drops in the eye, as this may contaminate the drops.
- If you accidentally put the drops in the wrong eye, wash it with warm water and see your doctor straight away.
- If you use more drops than prescribed, contact your doctor or pharmacist.

If you forget a dose:

- Do not use extra drops to make up for the dose you missed.
- Use the drops as soon as you remember, unless it is almost time for your next dose.
- Do not double up the next dose.

What to do if you get too much:

- Do not wash your eye with water.
- Wash your hands and see your doctor.

Stopping your treatment:

- Do not stop using your medicine without telling your doctor or pharmacist.
- Your doctor or pharmacist will advise you on how long your treatment should last.
- If you stop your treatment, the eye may become sensitive to light (photophobia).
- The symptoms of a relapse may become worse if you stop treatment too quickly.

If you have any further questions on using this medicine, please consult your doctor or pharmacist.
If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Softacort**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

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

Write down the date of first opening on the sachet.

**After first opening of the single-dose container:** use immediately and throw away the single-dose container after use.

After the individual single-dose container is opened, the solution inside cannot stay sterile, so you must throw away any solution remaining in the container after each use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. **Contents of the pack and other information**

**What Softacort contains**

- The active substance is hydrocortisone sodium phosphate.
- 1 ml eye drops, solution contains 3.35 mg of hydrocortisone sodium phosphate.
- The other ingredients are disodium phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride, disodium edetate, hydrochloric acid (for pH adjustment), water for injections.

**What Softacort looks like and contents of the pack**

This medicine is an eye drops solution in single-dose containers. The solution is practically clear, colourless to slightly yellow, practically free from particles, packed in a sachet of 10 units, each single-dose container holding 0.4 ml of product.

The pack size contains 10 (1 x 10), 20 (2 x 10), 30 (3 x 10) or 60 (6 x 10) single-dose containers. Not all pack sizes may be marketed.

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This leaflet was last revised in July 2018.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number 0345 521 1290.