PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SPERSADEX® COMP, dexamethasone disodium phosphate 1mg/mL and chloramphenicol 5mg/mL, sterile eye drops

Dexamethasone disodium phosphate, Chloramphenicol

Read all of this leaflet carefully before you start using SPERSADEX® COMP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- SPERSADEX® COMP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SPERSADEX® COMP is and what it is used for

SPERSADEX® COMP contains dexamethasone disodium phosphate, a corticosteroid and chloramphenicol, an antibiotic combined in sterile eye drops.

SPERSADEX® COMP Eye drops is used in acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature, infection of the anterior uvea (iritis, iridocyclitis), skleritis, episcleritis and

myositis, sympathic ophthalmia, post-operative management of cataract, glaucoma, and strabismus.

Your doctor will explain your condition.

2. What you need to know before you use SPERSADEX® COMP

Do not use SPERSADEX® COMP:

- if you are hypersensitive (allergic) to dexamethasone, chloramphenicol or any of the other ingredients of SPERSADEX® COMP (listed in section 6).
- if you suffer from Herpex simplex and other virus conditions
- if you suffer from injuries and ulcerous processes of the cornea
- if you suffer from mycoses
- if you suffer from glaucoma
- if you suffer from severe blood disorders due to bone marrow depression and hepatic dysfunction
- if you have a family history of bone marrow depression
- in newborn infants (0 to 27 days old).

Warnings and precautions

Take special care with SPERSADEX® COMP:

- Avoid repeated courses because the local use of the cortisone as contained in SPERSADEX® COMP over a long period may lead to secondary glaucoma and the development of complicated cataract.
- Avoid situations in which bruising or injury may occur.
- If you use SPERSADEX® COMP over a long period of time the pressure in your eye should be monitored regularly.
- Do not wear contact lenses during the treatment for eye infection.
- If the eye infection is very severe, your doctor may give you antibiotic tablets as well as this eye drops.
- If you experience a condition in which the bone marrow is unable to produce blood cells and you experience symptoms such as weakness, fatigue, and weight loss.
- Call your doctor if you experience signs of infection.

- If you experience swelling and weight gain around the trunk and in the face

  as these are usually the first manifestations of a syndrome called Cushing's syndrome.
- Suppression of the adrenal gland function may develop after stopping a longterm or intensive treatment.
- If you experience blurred vision or other visual disturbances, contact your doctor.

Children

Use with caution in infants under 2 years of age.

Other medicines and SPERSADEX® COMP

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not administer with medicines such as penicillins, cephalosporins, gentamicin, tetracyclines, polymyxin B, vancomycin or sulphadiazine.

Do not give systemic therapy concomitantly with medicines that impair haematopoiesis, sulphonylureas, or methotrexate (precautionary measure).

SPERSADEX® COMP can increase the effects of:

- medicine used to treat epilepsy (barbiturates)
- medicine to treat tuberculosis (rifampicin)

SPERSADEX® COMP can decrease the effects of:

- medicines such as anticholinesterases (indicated for reduced intestinal movement and for myasthenia gravis (a muscle weakening disease)
- medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning).

Tell your doctor if you are using ritonavir, as this may increase the amount of dexamethasone in the blood.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of SPERSADEX® COMP on contact lenses. Therefore, do not wear contact lenses until the effects of the drops have completely worn off.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using SPERSADEX® COMP.

Driving and using machines

It is not always possible to predict to what extent SPERSADEX® COMP may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which SPERSADEX® COMP affects you.

SPERSADEX® COMP may cause blurring of vision on installation.

SPERSADEX® COMP contains phosphate

SPERSADEX® COMP contains 0,16 mg phosphates in each drop which is the equivalent of 3,95 mg/mL. If you suffer from severe damage to the clear layer at the front (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use SPERSADEX® COMP

Do not share medicines prescribed for you with any other person.

Always use SPERSADEX® COMP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop one to 4 times daily into the lower eyelid.

Method of administration

If you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.

2. Use a mirror, this will help you to see what you are doing.

3. Carefully dry your eyes using a tissue.

4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.

Make sure the dropper does not touch any parts of your eye.

5. Close your eye and blink a few times to make sure your eye is covered by the liquid.

It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.

7. Repeat steps 4, 5 and 6 for the other eye if necessary and close the bottle immediately after use.

If your eyes get worse or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist. SPERSADEX® COMP should not be used for long term and frequent use without talking to your doctor or pharmacist.

Your doctor will tell you how long your treatment with SPERSADEX® COMP will last. If you have the impression that the effect of SPERSADEX® COMP is too strong or too weak, tell your doctor or pharmacist.

If you use more SPERSADEX® COMP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SPERSADEX® COMP

Do not take / receive a double dose to make up for forgotten individual doses.

If you stop using SPERSADEX® COMP

Do not stop using SPERSADEX® COMP without consulting your doctor.

4. Possible side effects

SPERSADEX® COMP can have side effects.

Not all side effects reported for SPERSADEX® COMP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SPERSADEX® COMP, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using SPERSADEX® COMP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to SPERSADEX® COMP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- aplastic anaemia (condition in which the bone marrow is unable to produce blood cells)
- bone marrow depression, pale skin, weakness, increased heart rate, out of breath, headache, pain, fever, infection, bruises may be a sign a severe blood disorder
- hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions")

- patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment
- long term, frequent use of corticosteroids can lead to clouding of the lens in the eye (cataract) or to an increase of the pressure inside the eye
- burning, stinging, itching or rash with swelling of skin (rash could be puffy (swollen) or blotchy or blister-like appearance) and skin irritation (including dermatitis) around the area it has been used on. These effects are not permanent.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SPERSADEX® COMP.

5. How to store SPERSADEX® COMP

Store at 2 – 8 °C.

Discard 30 days after opening.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label / carton / bottle

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SPERSADEX® COMP contains

The active ingredients are dexamethasone disodium phosphate 1 mg/mL and chloramphenicol 5,5 mg/mL.

The other ingredients are hydroxypropyl methylcellulose 2 mg, thiomersal (preservative) 0,002 % m/v and sterile water.

What SPERSADEX® COMP looks like and contents of the pack

SPERSADEX® COMP is a cloudy solution which is no more than pale yellowish and has a characteristic odour.

SPERSADEX COMP® is packed in a 5 mL white LDPE plastic dropper bottle with a LLDPE dropper insert and a white HDPE screw cap.

Holder of Certificate of Registration

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This leaflet was last revised in

16/02/2022

Registration number

H1 278 (Act 101/1965)