PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SPERSADEX® 0,1 %, dexamethasone disodium phosphate 1mg/mL, sterile eye drops

Dexamethasone disodium phosphate

Read all of this leaflet carefully before you start using SPERSADEX® 0,1 %

- 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® 0,1 % 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® 0,1 % is and what it is used for

2. What you need to know before you use SPERSADEX® 0,1 %

3. How to use SPERSADEX® 0,1 %

4. Possible side effects

5. How to store SPERSADEX® 0,1 %

6. Contents of the pack and other information

1. What SPERSADEX® 0,1 % is and what it is used for

SPERSADEX® 0,1 % belongs to a group of medicines known as corticosteroids.

It is used to treat inflammation of the eye surface and the front portion inside the eye (anterior

segment). It helps to relieve the symptoms of inflammation such as redness, soreness and swelling.

2. What you need to know before you use SPERSADEX® 0,1 %

Do not use SPERSADEX® 0,1 %:

- if you are hypersensitive (allergic) to dexamethasone or any of the other ingredients of SPERSADEX® 0,1 % (listed in section 6).
- if you have injuries or sores of the cornea, in particular those of bacterial or viral origin (herpes simplex and herpes zoster).
- if you have an infection with a discharge from the thin membrane covering the front of your eye (conjunctiva) or eye lids.
- if you have tuberculosis of the eye.
- if you have a fungal eye infection.
- if you have glaucoma (high pressure in your eye that can damage sight).

Warnings and precautions

Take special care with SPERSADEX® 0,1 %:

- Only use SPERSADEX® 0,1 % in your eye(s).
- SPERSADEX® 0,1 % should not be used for more than one week, unless advised by your doctor. Use of SPERSADEX® 0,1 % for long periods of time, may cause:
    - Increased pressure in your eye(s). You should have your eye pressure checked regularly while using SPERSADEX® 0,1 %, particularly if you have a history of glaucoma. Ask your doctor for advice. This is especially important in paediatric patients, as the risk of corticosteroid-induced increased pressure in the eye may be greater in children and may occur earlier than in adults. The risk of increase in eye pressure and/or cataract formation is higher in susceptible patients (e.g. patients with diabetes) using steroids.
    - The development of cataracts. You should see your doctor regularly if using SPERSADEX® 0,1 % on a long-term basis.

- Use of SPERSADEX® 0,1 % may make eye infections worse and delay healing of an eye wound. If you have an infection, your doctor will prescribe another medicine to treat it. Topical NSAIDs (Non-steroidal anti-inflammatory medicines) are also known to slow or delay healing. Simultaneous use of topical NSAIDs and SPERSADEX® 0,1 % may increase the potential for healing problems.
- If you have a disorder causing a thinning of the eye tissues. SPERSADEX® 0,1 % may cause further thinning and possible perforation.
- 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 long-term or intensive treatment with SPERSADEX® 0,1 %. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a medicine called ritonavir or cobicistat.
- Contact your doctor if you experience blurred vision or other visual disturbances.

If any of these apply, you may still be able to use SPERSADEX® 0,1 %, but discuss it with your doctor first.

Children

There is no evidence of safety in use in children under two years of age.

Other medicines and SPERSADEX® 0,1 %

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

Tell your doctor if you are using topical NSAIDs (Non-steroidal anti-inflammatory medicines). Simultaneous use of SPERSADEX® 0,1 % and topical NSAIDs may increase healing problems in your eye(s).

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

Tell your doctor if you are diabetic and you are taking, have recently taken or might take medicines to treat diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide, as SPERSADEX® 0,1 % may decrease the blood glucose lowering effect of these medicines.

If you are using more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

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® 0,1 %.

Driving and using machines

It is not always possible to predict to what extent SPERSADEX® 0,1 % 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® 0,1 % affects you.

SPERSADEX® 0,1 % may cause your vision to be blurred for some time after use. Do not drive or use machines unless your vision is clear.

Important information if you wear contact lenses

Wearing contact lenses is not recommended while your eyes is inflamed. If you continue to wear your lenses, remove them before using SPERSADEX® 0,1 % and wait at least 15 minutes before putting your lenses back in.

There is a preservative in SPERSADEX® 0,1 % (benzalkonium chloride) that may cause eye irritation and is also known to discolour soft contact lenses.

3. How to use SPERSADEX® 0,1 %

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

Always use SPERSADEX® 0,1 % 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 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. Shake the bottle well.
3. Twist off the bottle cap.
4. Pull your lower eyelid down gently with a finger, until there is a 'pocket' between your eyelid and eye. The drop will go in there.
5. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
6. Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.
7. Gently press on the base of the bottle to release one drop at a time.
8. Do not squeeze the bottle, only a gentle press on the bottom is needed.
9. After using SPERSADEX® 0,1 %, it is advisable to gently press on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat.
10. If you use drops in both eyes, repeat steps 1 – 9 for your other eye. Put the bottle cap firmly back on immediately after use.

If a drop misses your eye, try again.

Your doctor will tell you how long your treatment with SPERSADEX® 0,1 % will last. If you have the impression that the effect of SPERSADEX® 0,1 % is too strong or too weak, tell your doctor or

pharmacist.

If you use more SPERSADEX® 0,1 % 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® 0,1 %

If you forget to use SPERSADEX® 0,1 %, just use it as soon as possible. Do not use/receive a double dose to make up for forgotten individual doses.

If you stop using SPERSADEX® 0,1 %

Do not stop using SPERSADEX® 0,1 % without consulting your doctor.

4. Possible side effects

SPERSADEX® 0,1 % can have side effects.

Not all side effects reported for SPERSADEX® 0,1 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SPERSADEX® 0,1 %, please consult your healthcare provider for advice.

If any of the following happens, stop using SPERSADEX® 0,1 % 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® 0,1 %. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- discomfort in your eye(s)

Less frequent side effects:

- persistent, unpleasant, abnormal or altered taste sensation
- swelling, dry eyes, corneal staining, sensitivity to light, blurred vision, abnormal sensation, increased tear production, eyelid crusting, itching, irritation or redness

Side effects with unknown frequency:

- allergy
- dizziness, headache
- glaucoma, corneal ulcer, increased pressure in your eye(s), reduced vision, corneal disorder, drooping of eyelid, pain or increase in pupil size
- 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")

Steroids, such as contained in SPERSADEX® 0,1 %, may be associated with an increase of blood glucose levels and diabetes.

In very rare cases, some 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.

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® 0,1 %.

5. How to store SPERSADEX® 0,1 %

Store in a cool place below 25 °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® 0,1 % contains

The active ingredient is dexamethasone disodium phosphate 1 mg/mL.

The other ingredients are benzalkonium chloride 0,01 % *m/v* (preservative), hydroxypropyl methylcellulose 2 mg and sterile water.

What SPERSADEX® 0,1 % looks like and contents of the pack

SPERSADEX® 0,1 % is a colourless solution.

SPERSADEX® 0,1 % is packed in a 5 mL transparent LDPE bottle, LLDPE dropper insert and a white screw HDPE cap.

Holder of Certificate of Registration

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