SCHEDULING STATUS

S4

SIVEXTRO 200 mg powder for concentrate for solution for infusion

Active ingredient: Tedizolid phosphate

Read all of this leaflet carefully, before you are given SIVEXTRO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- Contains sugar (mannitol).

What is in this leaflet

1. What SIVEXTRO is and what it is used for

SIVEXTRO is an antibiotic that contains 200 mg of the active substance tedizolid phosphate. It belongs to a group of medicines called “oxazolidinones.”

It is used to treat adults with infections of the skin and tissues below the skin.

It works by stopping the growth of certain bacteria which can cause serious infections.

2. What you need to know before you are given SIVEXTRO

You should not be given SIVEXTRO if you:

- are allergic to tedizolid phosphate, or any of the other ingredients of SIVEXTRO (see section 6).
- If you are pregnant or breastfeeding.

Warnings and precautions

Before and while you take SIVEXTRO, tell your health care provider if you:

- Are suffering from diarrhoea or have suffered from diarrhoea while (or up to 2 months after) taking antibiotics in the past.
- Are allergic to other medicines belonging to the group “oxazolidinones” (e.g., linezolid, cycloserine).
- Are taking certain medicines to treat depression, known as tricyclics, SSRIs (selective serotonin reuptake inhibitors) or MAOIs (monoamine oxidase inhibitors). See Other medicines and SIVEXTRO for examples
- Are taking certain medicines to treat migraine known as “triptans”. See Other medicines and SIVEXTRO for examples.

Children

SIVEXTRO should not be used in children and adolescents (< 18 years of age). The safety of SIVEXTRO in these populations has not been established.

Other medicines and SIVEXTRO

Always tell your health care provider if you are taking other medicines. (This includes complementary or traditional medicines).

Know the medicines you take. Keep a list of them and show the list to your health care provider when you get a new medicine.

It is especially important to tell your doctor if you take any of the following:

- methotrexate (used to treat cancer or rheumatoid arthritis)
- topotecan (used to treat cancer)
- rosuvastatin (used to lower blood cholesterol)

SIVEXTRO can interfere with the effects of these medicines. Your doctor will explain more.

Pregnancy and Breastfeeding

You should not take SIVEXTRO if you are pregnant.

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 health care provider for advice before you are given SIVEXTRO.Your doctor will advise if you should receive SIVEXTRO during pregnancy.

It is not known if SIVEXTRO passes into breast milk and whether it could harm your baby. You should not breastfeed your baby while on treatment with SIVEXTRO.

Driving and using machinery

Do not drive or use machines if you feel dizzy or tired after taking this medicine.

3. How to take SIVEXTRO

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

Your doctor or other healthcare professional will administer SIVEXTRO injection.

Instructions for use

Your doctor will tell you how long your treatment with SIVEXTRO will last. Talk to your doctor if you feel worse after starting treatment. If you have the impression that the effect of SIVEXTRO is too strong or weak, tell your doctor or pharmacist.

SIVEXTRO powder for solution for infusion

The recommended dose is 200 mg by intravenous infusion over 1 hour once a day for 6 days.

If you take more SIVEXTRO than you should

Since a health care provider will administer SIVEXTRO, he/she will control the dosage. However, if you have any concerns, you should let your doctor or other health care provider know immediately.

As SIVEXTRO injection is given by a doctor or other healthcare professional, it is very unlikely that you will be given too much SIVEXTRO injection. However, if you have any concerns, you should let your doctor or other health care provider know immediately.

If you miss a dose of SIVEXTRO

SIVEXTRO Injection

Since a health care provider will administer SIVEXTRO, it is unlikely that the dose will be missed.

If you think you have not been given a dose of SIVEXTRO, tell your doctor or other health care provider immediately.

If you have any further questions on the use of this medicine, ask your doctor or other healthcare professional.

4. Possible side effects

SIVEXTRO can cause side effects, although not everybody gets them.

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

Contact your doctor immediately if you suffer from diarrhoea during or after your treatment.

Frequent medication-related undesirable effects in adults are nausea, vomiting, headache, itching all over the body, tiredness, dizziness and infusion site pain or swelling.

Less frequent reported medication-related undesirable effects in adults include:

- Fungal infections of skin , mouth and vagina (oral / vaginal thrush)
- Itching (including itching due to allergic reaction), hair loss, acne, red and/or itchy rash or hives, excessive sweating
- Decrease or loss of skin sensitivity, tingling/prickling skin sensation
- Hot flush or blushing/redness in the face, neck or upper chest
- Abscess (swollen, pus-filled lump)
- Vaginal infection, inflammation or itching
- Anxiety, irritability, Shaking or trembling
- Respiratory tract (sinuses, throat and chest) infection
- Dryness in the nose, congestion in the chest, cough
- Sleepiness, abnormal sleep pattern, difficulty sleeping, nightmares (unpleasant/disturbing dreams)
- Dry mouth, constipation, indigestion, pain/discomfort in the belly (abdomen), retching, dry heaving, bright red blood in the stool
- Acid reflux disease (heartburn, pain or difficulty swallowing), flatulence/passing wind
- Joint pain, muscle spasms, back pain, neck pain, pain/discomfort in limbs, decrease of grip strength
- Blurred vision, 'floaters' (small shapes seen floating in the field of vision)
- Swollen or enlarged lymph nodes
- Allergic reaction
- Dehydration
- Poor control of diabetes
- Abnormal sense of taste
- Slow heartbeat
- Fever
- Swelling in ankles and/or feet
- Abnormal smelling urine, abnormal blood tests
- Infusion reactions (chills, shaking or shivering with fever, muscle pain, swelling of the face, weakness, fainting, shortness of breath, chest tightness and angina pectoris).

Other reported medication-related undesirable effects that have occurred at an unknown frequency in adults include:

- Bleeding or bruising easily

Certain side effects on blood cells have been observed with SIVEXTRO or another member of the oxazolidinone class when administered over a duration exceeding that recommended for SIVEXTRO. Tell your doctor immediately if you suffer from bleeding or bruising while taking SIVEXTRO.
Other side effects may also occur rarely, and as with any prescription medicine, some side effects may be serious.
Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
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 or 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 SIVEXTRO.

How to store SIVEXTRO

SIVEXTRO for Injection should be stored at 20°C to 25°C.
Store all medicines out of the reach of children.
Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

SIVEXTRO contains a medicine called tedizolid phosphate as the active ingredient.
SIVEXTRO Powder for concentrate for solution for infusion contains 200 mg tedizolid per vial. In addition, SIVEXTRO powder for concentrate for solution for infusion contains the following inactive ingredients: Mannitol, Sodium hydroxide (for pH adjustment, Hydrochloric acid (for pH adjustment).

What SIVEXTRO looks like and the contents of the pack

SIVEXTRO powder for solution for infusion is supplied in single use vials containing 200 mg tedizolid phosphate as a sterile, lyophilized powder.
SIVEXTRO powder for solution for infusion is a clear 10 ml glass vial with stopper. Available in packs of 1 vial and 6 vials.

Holder of Certificate of Registration

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