Package leaflet: Information for the patient

Sivextro® 200 mg film-coated tablets
tedizolid phosphate

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sivextro is and what it is used for

Sivextro is an antibiotic that contains the active substance tedizolid phosphate. It belongs to a group of medicines called "oxazolidinones".

It is used to treat adults and adolescents 12 years of age and older 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 take Sivextro

Do not take Sivextro
- if you are allergic to tedizolid phosphate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Your doctor will have decided if Sivextro is suitable to treat your infection.

Talk to your doctor or nurse before taking Sivextro if any of the following apply to you:
- are suffering from diarrhoea, or have suffered from diarrhoea whilst (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).
- have a history of bleeding or easy bruising (which may be a sign of low numbers of platelets, the small cells involved in clotting in your blood).
- have kidney problems.
- are taking certain medicines to treat depression, known as tricyclics, SSRIs (selective serotonin reuptake inhibitors), opioids or MAOIs (monoamine oxidase inhibitors). The use of these medicines together with tedizolid phosphate can lead to serotonin syndrome, a potentially life-threatening condition (with symptoms such as feeling disorientated, difficulty

concentrating, high temperature, increased reflexes, difficulty to coordinate muscle movements). See Other medicines and Sivextro for examples.
- are taking certain medicines to treat migraine known as "triptans". See Other medicines and Sivextro for examples.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

Diarrhoea
Contact your doctor straight away if you suffer from diarrhoea during or after your treatment. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Resistance to antibiotics
Bacteria can become resistant to treatment with antibiotics over time. This is when antibiotics cannot stop the growth of bacteria and treat your infection. Your doctor will decide if you should be given Sivextro to treat your infection.

Possible side effects
Certain side effects 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 straight away if you suffer from any of the following while taking Sivextro:
- a low white blood cell count
- anaemia (low red blood cells)
- bleeding or bruising easily
- loss of sensitivity in your hands or feet (such as numbness, prickling/tingling, or sharp pains)
- any problems with your eyesight such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

Children
This medicine should not be used in children under 12 years of age as it has not been studied enough in this population.

Other medicines and Sivextro
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important that you tell your doctor if you are also taking:
- amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, isocarboxazid, lofepramine, moclobemide, paroxetine, phenelzine, selegiline, sertraline, duloxetine and venlafaxine (used to treat depression). There is a risk that tedizolid phosphate could interact with certain medicines, including those mentioned, to cause side effects such as changes in blood pressure or temperature.
- sumatriptan, zolmitriptan (used to treat migraine)
- opioids (such as fentanyl)
- imatinib, lapatinib (used to treat cancer)
- methotrexate (used to treat cancer, rheumatoid arthritis or psoriasis)
- sulfasalazine (used to treat inflammatory bowel diseases)
- topotecan (used to treat cancer)
- statins such as pitavastatin, rosuvastatin (used to lower blood cholesterol)

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

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.

It is not known if Sivextro passes into breast milk in humans. Ask your doctor for advice before breast-feeding your baby.

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

3. How to take Sivextro

Always take 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 one 200 mg tablet once a day for 6 days. The tablets are swallowed whole and can be taken with or without food or drink.
Talk to a doctor if you do not feel better, or if you feel worse after 6 days.

If you take more Sivextro than you should
Contact your doctor, pharmacist or nearest hospital casualty department as soon as possible if you have taken more tablets than you should, and take your medicine with you.

If you forget to take Sivextro
If you forget to take your medicine, take the dose as soon as possible anytime up to 8 hours prior to the next scheduled dose. If less than 8 hours remains before the next dose, then wait until the next scheduled dose. Do not take a double dose to make up for a forgotten dose. If in any doubt, contact your pharmacist for advice.

You should take all 6 tablets to complete your course of treatment, even if you have missed a dose.

If you stop taking Sivextro
If you stop taking Sivextro without the advice of your doctor, your symptoms may get worse. Talk to your doctor or pharmacist before you stop taking your medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Other side effects may include:
Common side effects (may affect up to 1 in 10 people)
- Nausea
- Vomiting
- Headache
- Itching all over the body
- Tiredness
- Dizziness

Uncommon side effects (may affect up to 1 in 100 people)
- 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

Frequency not known (frequency cannot be estimated from the available data)
- Bleeding or bruising easily (due to low numbers of platelets, the small cells involved in clotting in your blood)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Sivextro

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 or blister label after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Sivextro contains
- The active substance is tedizolid phosphate. Each film-coated tablet contains 200 mg of tedizolid phosphate.
- The other ingredients are microcrystalline cellulose, mannitol, povidone, crospovidone and magnesium stearate within the tablet core. The film coat of the tablet contains polyvinyl alcohol, titanium dioxide (E171), macrogol, talc and yellow iron oxide (E172).

What Sivextro looks like and contents of the pack
Sivextro is an oval, yellow film-coated tablet imprinted with 'TZD' on one side and '200' on the other side.

It is available in 6 × 1 tablets in perforated unit-dose blisters.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, United Kingdom.

Manufacturer:
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

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