Package leaflet: Information for the patient

Sivextro® 200 mg powder for concentrate for solution for infusion
tedizolid phosphate

Read all of this leaflet carefully before you start receiving 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 nurse.
- If you get any side effects, talk to your doctor or nurse. 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."

Sivextro is used in all age groups to treat infections of the skin and tissues below the skin.

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

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

Do not use 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 being given 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) being treated with 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, tingling/prickling, 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 is available as 200 mg tablets for adolescents and children weighing at least 35 kg.

Other medicines and Sivextro
Tell your doctor or nurse 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)

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 nurse for advice before using 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.

Sivextro contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How you will be given Sivextro

Sivextro will be given to you by a nurse or doctor.

It will be given to you through a drip directly into a vein (intravenously) over approximately 1 hour.

Adults, as well as adolescents and children weighing at least 35 kg
You will be given one 200 mg infusion of Sivextro once a day for 6 days.

Adolescents and children weighing less than 35 kg
Sivextro will be given twice a day for 6 days. The dose will be based on the body weight.

Talk to a doctor if you do not feel better, or if you feel worse after 6 days.

If you are given more Sivextro than you should
Tell your doctor or nurse immediately if you are concerned that you may have been given too much Sivextro.

If you miss a dose of Sivextro
Tell your doctor or nurse immediately if you are concerned that you may have missed a dose.

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

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
- Infusion site pain or swelling.

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
- Infusion reactions (chills, shaking or shivering with fever, muscle pain, swelling of the face, weakness, fainting, shortness of breath, chest tightness and angina pectoris).

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any particles or the solution is cloudy.

Once opened this medicine must be used immediately. If not, the reconstituted and diluted solution should be stored at room temperature or in a refrigerator at 2 °C to 8 °C, and administered within 24 hours after reconstitution.

Any unused medicine or waste material, including materials used for reconstitution, dilution and administration, should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Sivextro contains
- The active substance is tedizolid phosphate. Each vial of powder contains disodium tedizolid phosphate which is equal to 200 mg of tedizolid phosphate.

- The other ingredients are mannitol, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What Sivextro looks like and contents of the pack
Sivextro is a white to off-white powder for concentrate for solution for infusion in a glass vial. The powder will be reconstituted in the vial with 4 mL of water for injections. The reconstituted solution will be withdrawn from the vial and added to an infusion bag of 0.9% sodium chloride in the hospital.

It is available in packs containing 1 or 6 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer:
Patheon Italia S.p.A., 2° Trav. SX Via Morolense 5, 03013 Ferentino, Italy

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The following information is intended for healthcare professionals only:

Important: Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Patients who commence treatment on the parenteral formulation may be switched to the oral presentation when clinically indicated.

Sivextro must be reconstituted with water for injections and subsequently diluted in 250 mL of 0.9% sodium chloride for infusion.

Only limited data are available on the compatibility of Sivextro with other intravenous substances, therefore additives or other medicinal products should not be added to Sivextro single use vials or infused simultaneously. If the same intravenous line is used for sequential infusion of several different medicinal products, the line should be flushed before and after infusion with 0.9% sodium chloride. Do not use Lactated Ringer's Injection or Hartmann's Solution.

Reconstitution
Aseptic technique must be followed when preparing the infusion solution. Reconstitute the contents of the vial with 4 mL water for injections, and swirl gently until the powder has dissolved entirely. Avoid shaking or rapid movement as it may cause foaming.

Dilution
For administration, the reconstituted solution must be further diluted in 0.9% sodium chloride. Do not shake the bag. The resulting solution is a clear colourless or light-yellow solution.

Infusion
The reconstituted solution should be inspected visually for particulate matter prior to administration. Reconstituted solutions containing visible particles should be discarded.

Sivextro is administered intravenously over approximately 1 hour.

The reconstituted solution must be administered as an intravenous infusion only. It must not be administered as an intravenous bolus. Sivextro must not be mixed with other medicinal products.

Each vial is for single use only.

Preparation of doses

For preparation of the 200 mg Sivextro dose for once-daily infusion (adults, as well as adolescents and children weighing ≥35 kg):

1. Withdraw 4 mL of the reconstituted solution from the vial using a syringe and add to an infusion bag containing 250 mL of sodium chloride 0.9% for injection.

2. Infuse the entire bag over 1 hour.

For preparation of weight-based doses for twice-daily infusion (for adolescents and children weighing < 35 kg):

1. Preparing the stock solution (100 mL of 0.8 mg/mL tedizolid phosphate):
Withdraw 1.6 mL of the reconstituted solution from the vial using a syringe and add it to an infusion bag containing 98.4 mL of 0.9% sodium chloride for injection.

2. Preparing the required volume of stock solution for infusion:
    a. Determine the appropriate amount of Sivextro in mg by consulting the dosing table below.
    b. Transfer the appropriate volume of stock solution to an adequately sized infusion bag or infusion syringe. It may be necessary to round to the nearest graduation mark of an appropriately sized syringe for smaller volumes.

Table 1. Preparation of Sivextro for infusion for paediatric patients weighing < 35 kg body weight from the 100 mL stock solution of 0.8 mg/mL tedizolid phosphate

Body Weight (kg)	Amount (mg) of Sivextro per dose (given twice daily)	Volume (mL) of stock solution to administer to the patient
1 to less than 3	6	7.5
3 to less than 6	12	15
6 to less than 10	20	25
10 to less than 14	30	37.5
14 to less than 20	40	50
20 to less than 35	60	75

    c. Infuse over 1 hour via infusion or syringe pump
    d. This process is repeated for the second dose of the day

Note: Both doses should be used within the required duration of storage (see section 6.3 of the Summary of Product Characteristics).

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