

Patient Information
SIVEXTRO[®](sih-vex-tro)
(tedizolid phosphate)
tablets

What you need to know about SIVEXTRO

- Before you take this medicine, be sure you understand what it is for and how to take it safely.
- Keep this information.
- If you have questions about this medicine, ask your doctor or pharmacist.
- Every time you get a refill, look at the Patient Information sheet that comes with it. There may be new information.
- Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What is SIVEXTRO?

SIVEXTRO is a tablet for people 12 years of age and older who have a skin infection or an infection in the tissue below the skin. SIVEXTRO is an antibiotic that works by stopping the growth of certain bacteria.

Children

SIVEXTRO should not be used for people under 12 years old. It is not known if SIVEXTRO works or is safe for people under age 12.

What should I tell my doctor before taking SIVEXTRO?

Medical Conditions

Tell your doctor if you:

- have diarrhea or have ever had diarrhea while taking antibiotics. Tell your doctor, even if you had diarrhea that occurred up to 2 months after you took the antibiotic.
- are allergic to tedizolid phosphate or any of the ingredients in SIVEXTRO. See the end of this Patient Information for a complete list of ingredients in SIVEXTRO.
- are pregnant or plan to get pregnant, tell your doctor if you become pregnant while taking SIVEXTRO. It is not known if SIVEXTRO will harm your baby while you are pregnant. You and your doctor should decide together if you will take SIVEXTRO.
- are breastfeeding or plan to breastfeed, tell your doctor before you take SIVEXTRO. It is not known if SIVEXTRO passes into your breast milk. You and your doctor should decide together if you will take SIVEXTRO or breastfeed.

Are you taking other medicines?

- SIVEXTRO can affect the way other medicines work, and other medicines can affect how SIVEXTRO works. Some medicines cannot be taken with SIVEXTRO at all. Your doctor will tell you if it is safe to take SIVEXTRO with other medicines.
- It is especially important to tell your doctor if you take any of the following medicines:
 - Methotrexate (for cancer or rheumatoid arthritis)
 - Topotecan (for cancer)
 - Rosuvastatin (for cholesterol)

- **Tell your doctor about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal and dietary supplements.
- Know the medicines you take. Keep a list of them and show the list to your doctor and pharmacist when you get a new medicine.

How do I take SIVEXTRO?

- Take SIVEXTRO exactly how your doctor tells you to take it.
- **Take 1 SIVEXTRO tablet 1 time each day.**
- **Take SIVEXTRO for 6 days, at the same time every day.**
- Take SIVEXTRO by mouth, with or without food.

What if I forget to take SIVEXTRO?

- If you miss a dose, take the missed dose as soon as you remember. If it is less than 8 hours until your next dose, skip the missed dose and take the next tablet at the time you usually take it.
- Do not take 2 doses of SIVEXTRO at the same time to make up for a missed dose.
- If you are not sure how to take SIVEXTRO, call your doctor or pharmacist.
- Take all 6 tablets to finish your SIVEXTRO, even if you have missed a dose.

If you do not finish your medicine, SIVEXTRO may not work. You may get sick again and the remaining bacteria may be harder to treat.

What are the possible side effects of SIVEXTRO?

SIVEXTRO may cause serious side effects, including diarrhea from **C-diff (Clostridioides difficile) infection**. Call your healthcare provider right away if you get stomach cramps, fever, watery diarrhea, diarrhea that does not go away, or bloody stools. C-diff infection can happen 2 or more months after you have finished your antibacterial medicine.

1. C-diff is an infection of your intestines (bowels) that can happen with many antibiotics like SIVEXTRO and may cause mild diarrhea to life-threatening swelling of your intestines (colitis).

Common side effects of SIVEXTRO include:

- | | |
|-------------|---|
| ▪ nausea | ▪ diarrhea |
| ▪ headache | ▪ increased liver enzymes |
| ▪ dizziness | ▪ painful swelling or inflammation of veins (phlebitis) |
| ▪ vomiting | |

Some less common side effects are:

Problems with your skin

- itching, red or itchy rash, hives, acne
- hot flushes or feeling like you are blushing or your face, neck or chest is red
- not able to feel something as well
- a tingling or prickling sensation

Problems with your sleep

- hard time sleeping

Problems with your body

- numbness
- facial paralysis

Problems with infections

- vagina that is infected, inflamed, or itchy
- fungal infections of skin, mouth

Problems with your eyes

- eye strain
- blurred or impaired vision
- seeing dots or spots in your eyes

Problems with your heart

- Your heartbeat does not feel normal. It could feel like your heart is beating too fast or pumping harder than usual.

Problems with your vascular system

- high blood pressure

Problems with your blood work

Your doctor may tell you that you have the following while taking SIVEXTRO:

- a low white blood cell count
- anemia (low red blood cells)
- low platelet count, the small cells involved in clotting your blood

Side effects where the frequency is not known:

- bleeding or bruising easily

If you have any side effect that bothers you or does not go away, tell your doctor.

These are not all the possible side effects of SIVEXTRO. For information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SIVEXTRO?

- Store SIVEXTRO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SIVEXTRO and all medicines out of the reach of children.

General information about SIVEXTRO.

- Medicines are sometimes prescribed for purposes that are not mentioned here.
- Do not use SIVEXTRO for a condition for which it was not prescribed.

What if I have questions?

- Call your doctor.
- Call Merck, the company that makes SIVEXTRO, at 1-800-444-2080.
- Go to the website – www.SIVEXTRO.com.
- You can ask your doctor or pharmacist for information about SIVEXTRO that is written for health professionals.

What are the ingredients in SIVEXTRO?

- The active ingredient: tedizolid phosphate.
 - The inactive ingredients: crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, and povidone. Film coating: polyethylene glycol/macrogol, polyvinyl alcohol, talc, titanium dioxide, and yellow iron oxide.
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Manuf. for: Nabriva Therapeutics US, Inc.



Fort Washington, PA 19034

Sivextro tablets Manufactured by: Patheon Inc., Whitby, Ontario, L1N 5Z5 Canada

Sivextro for injection Manufactured by: Patheon Italia S.p.A., 03013, Ferentino, FR Italy

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This Patient Information has been approved by the U.S. Food and Drug Administration

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