

**EMERGENCY USE AUTHORIZATION OF
SULFAMETHOXAZOLE AND TRIMETHOPRIM (SMZ-TMP)
FACT SHEET FOR RECIPIENTS**

**What You Need to Know about SMZ-TMP
For Treatment or Prevention of Melioidosis and/or Glanders**

The FDA has issued this Emergency use Authorization (EUA) to allow the use of SMZ-TMP during this emergency.

You are being given a medicine called **Sulfamethoxazole (sul-fa-meth-OX-a-zole) and Trimethoprim (trye-METH-oh-prim) or SMZ-TMP** because you either:

- 1) **Have been infected** by *Burkholderia pseudomallei* (*B. pseudomallei*) and/or *Burkholderia mallei* (*B. mallei*) bacteria and need treatment; or
- 2) **Have been exposed** to *B. pseudomallei* and/or *B. mallei* and need a prevention measure.

What is *Burkholderia pseudomallei* and *Burkholderia mallei*?

B. pseudomallei and *B. mallei* can cause serious diseases that can be **deadly**. Melioidosis and glanders are two diseases caused by these bacteria, respectively. You can get sick if you breathe in the *B. pseudomallei* and/or *B. mallei* bacteria. You can also get sick by eating/drinking contaminated foods/water or through a cut or scratch on your skin.

Melioidosis and glanders have similar symptoms:

- The first signs or symptoms may seem like a cold or the flu (such as a runny nose, swollen lymph nodes, feeling tired, and/or having fever and chills).
- Other signs or symptoms may be a cough, chest discomfort, muscle tightness, headache, joint or bone pains.
- You may get ulcers on your skin if you had an open wound that was exposed to *B. pseudomallei* and/or *B. mallei*.

Symptoms generally appear approximately one to two weeks after coming in contact with *B. pseudomallei* and/or *B. mallei* but may appear as soon as 1 day or as late as several decades after exposure.

What is SMZ-TMP?

SMZ-TMP is a prescription antibiotic (medicine that fights against bacteria) that is approved by the Food and Drug Administration (FDA) to treat various bacterial infections, but is not FDA-approved for the treatment or prevention of melioidosis and/or glanders. During this declared public health emergency however, FDA is allowing the emergency use of SMZ-TMP to be used to treat or prevent melioidosis and/or glanders. Other brand or generic names for SMZ-TMP include Bactrim, Bactrim DS, Septra, Septra DS, Sulfatrim, co-trimoxazole, SMX-TMP, TMP-SMX, TMP-SMZ, and trimethoprim and sulfamethoxazole.

Who should NOT take SMZ-TMP?

Do **NOT** take SMZ-TMP if you have or ever had an allergic reaction to sulfonamide (sulfa) or trimethoprim drugs, have had a history of low platelet counts after taking sulfonamides or trimethoprim, have had megaloblastic anemia (abnormal red blood cells) caused by low folate levels in your body, or have severe kidney and/or liver disease that is not checked regularly by a doctor. Infants less than 2 months old cannot take SMZ-TMP.

How is SMZ-TMP given?

Usually SMZ-TMP will be given, as oral tablets to be taken by mouth twice a day. The dose will depend on your weight. SMZ-TMP tablets are supplied either as Double-strength (DS) tablets which contains 800 milligrams (mg) of sulfamethoxazole [SMZ] and 160 mg of trimethoprim [TMP] OR Single-strength (SS) tablets 400 mg of SMZ and 80 mg of TMP.

How do I take SMZ-TMP?

For patients weighing more than 132 pounds (> 60 kilograms):

- Take 2 DS tablets (800 mg SMZ/160 mg TMP) OR 4 SS tablets (400 mg of SMZ/80 mg of TMP) in the **morning** and
- Take 2 DS tablets (800 mg SMZ/160 mg TMP) OR 4 SS tablets (400 mg of SMZ/80 mg of TMP) in the **evening**.

For patients weighing between 88 to 132 pounds (40 to 60 kilograms):

- Take 1.5 DS tablets (800 mg SMZ/160mg TMP) OR 3 SS tablets (400 mg of SMZ/80 mg of TMP) in the **morning** and
- Take 1.5 DS tablets (800 mg SMZ/160 mg TMP) OR 3 SS tablets (400 mg of SMZ/80 mg of TMP) in the **evening**.

For patients weighing less than 88 pounds (< 40 kilograms):

- You will be given instructions on the amount of SMZ-TMP to take in a day (usually in the amount of 30 mg of SMZ and 6 mg of TMP per kilogram of your body weight every 12 hours).

Your morning and evening doses should be taken 12 hours apart each day, for as long as directed and each dose should be taken with a full glass of water (with or without food).

If you **cannot swallow tablets or if you are a child under 12 years old and weight less than 88 pounds (40 kilograms)**, then you may receive oral suspension of SMZ-TMP and the dose to take if it is available, or you should receive other directions on how best to take SMZ-TMP tablets.

- Do not skip doses. However, if you miss a dose, **do NOT take 2 doses at once**. Take the next dose as scheduled.
- If you get a mild upset stomach after you take the medicine, then take it with food.
- Keep SMZ-TMP tablets dry. Store them at room temperature (between 68–77°F or 20 - 25°C).
- Keep additional SMZ-TMP away from children and pets. Call the poison control center if children or pets ingest the medicine by accident (1-800-222-1222).
- While you are taking SMZ-TMP, you should to take an additional folic acid supplements (from 0.1 mg/kg to 5 mg) by mouth every day as well.

How long do I take SMZ-TMP?

- **For treatment:**
 - You will begin taking this antibiotic in the hospital when your healthcare provider tells you to
 - Take the prescribed amount of SMZ-TMP by mouth twice a day for a minimum of **90** days (for example: once in the morning and once in the evening) until you have finished ALL of the antibiotic.
 - If you are released from the hospital while still taking this medication, be sure to continue taking it until you have finished the entire treatment course.
- **For prevention:**
 - You will begin taking this antibiotic at home
 - Take the prescribed amount of SMZ-TMP by mouth twice a day for **21** days (for example: once in the morning and once in the evening) until you have finished ALL of the antibiotic.
 - Take SMZ-TMP until you finish all of the antibiotic, even if you feel better. Do not stop taking SMZ-TMP without talking with your healthcare provider.

Important: If you stop taking SMZ-TMP too soon or skip doses, then you may not be completely treated and the bacteria may become resistant to this antibiotic.

If you are taking SMZ-TMP as directed and begin to feel sick or feel worse than before, notify your healthcare provider right away.

What should you tell your healthcare provider before receiving SMZ-TMP?

Tell your healthcare provider if you:

- have had a history of allergic reaction or other serious reaction to sulfonamide (sulfa) or trimethoprim drugs
- any past or current medical conditions such as kidney disease as you may need a dose adjustment
- any past or current medical conditions such as liver disease
- any specific blood disorders and/or medical conditions that can cause your body to have low folate levels
- are taking these medications that may increase your chances of having side effects such as thiazides, warfarin, phenytoin, methotrexate, cyclosporine, digoxin, indomethacin, pyrimethamine, amantadine, angiotensin, tricyclics, diabetes medications, dofetilide, methenamine, potassium p-aminobenzoate, leucovorin, or procaine

- are pregnant or breastfeeding. SMZ-TMP has been used in pregnant and nursing women to treat and prevent other bacterial infections even though it can cross the placenta and be found in breastmilk but in very small amounts. Discuss this and any potential risks with your healthcare provider.

STOP taking the SMZ-TMP if you get any of these serious, but rare, side effects. Notify your healthcare provider, or if you are at home, go to the Emergency Room or call 911 to get medical help right away:

- swelling of the tongue, hands, or feet
- closing of the throat or trouble breathing/shortness of breath
- severe itching or rash, especially hives and wheals
- severe stomach cramps with high fever or bloody diarrhea

Are there other possible side effects?

During the first few days of taking SMZ-TMP you might have: mild upset stomach, diarrhea, nausea, vomiting, loss of appetite, or mild muscle aches. If these symptoms continue or become very bad, let your healthcare provider know. If you have questions about any side effects, contact your healthcare provider. For a complete list of all side effects, please see the package insert [*placeholder for manufacturer's package insert*].

Risk-Benefit Statement

Although SMZ-TMP may have some potential and serious adverse effects, the expected benefit of taking SMZ-TMP in helping treat or prevent disease and death caused by *B. pseudomallei* and/or *B. mallei*, outweigh these risks. Many other countries have been successful in treating patients with melioidosis and/or glanders and preventing serious illness when taken as directed. Taking SMZ-TMP is your choice.

What alternative medicine can I take instead of SMZ-TMP?

There are no FDA-approved drugs for the treatment or prevention of melioidosis and/or glanders. Amoxicillin-clavulanate (Augmentin) may be another alternative antibiotic for the treatment and prevention of melioidosis and/or glanders, if available and FDA must authorize its use during this emergency. Doxycycline may be another alternative drug that may be available to prevent melioidosis and/or glanders after exposure to *B. pseudomallei* and/or *B. mallei*. However, doxycycline use will also require FDA to authorize its use during an emergency. Your healthcare provider can discuss these alternatives with you.

How do I report side effects or medication errors?

Tell your healthcare provider right away and report side effects or medication errors to **FDA MedWatch** at www.fda.gov/medwatch or 1-800-FDA-1088.

On rare occasions, SMZ-TMP can cause a serious problem. A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. If you have been injured by SMZ-TMP used to treat melioidosis and/or glanders during this declared public health emergency, you can learn more about this program by visiting www.hrsa.gov/cicp, emailing cicp@hrsa.gov, or calling 1-855-266-2427 (toll-free)

How can I learn more?

Contact your state/local public health department or your healthcare provider. You can also visit www.cdc.gov or www.fda.gov.