

EMERGENCY USE AUTHORIZATION OF MEROPENEM

FACT SHEET FOR RECIPIENTS

What You Need to Know about Meropenem For Treatment of Melioidosis and/or Glanders

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

You are being given a medicine called **meropenem** (sounds like MER-oh-PEN-em) because you have been infected by ***Burkholderia pseudomallei*** (*B. pseudomallei*) and/or ***Burkholderia mallei*** (*B. mallei*) bacteria and need treatment.

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 long as several decades after exposure.

What is Meropenem?

Meropenem 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 of infections caused by *B. pseudomallei* and/or *B. mallei*. However, FDA is allowing the emergency use of meropenem to treat melioidosis and/or glanders caused by *B. pseudomallei* and *B. mallei*, respectively.

Who should NOT be given Meropenem?

You should not receive meropenem if you have had a severe allergic reaction to it. Severe allergic reaction may include closing of the throat, trouble breathing, and/or swelling of your lips, tongue, or face. If you ever had a severe allergic reaction to other similar category of antibiotics called beta-lactams (examples: carbapenems, penicillins, and cephalosporins) then be sure to tell your healthcare provider.

How is Meropenem given?

Meropenem will be given to you through a needle in a vein in your arm (called intravenous [IV] route) by your healthcare provider. You will be given meropenem for at least 10 days, following the recommendation of your healthcare provider. You may also receive other medicines, including other antibiotics, to be taken by mouth, to help treat your illness after you finish receiving meropenem.

What are the Possible Serious Side Effects of Meropenem?

Serious side effects from meropenem are rare. Tell your healthcare provider IMMEDIATELY if you get any of these serious, but rare, side effects:

- swelling of the tongue, hands, or feet
- severe itching or rash, especially hives and wheals
- severe stomach cramps with high fever
- uncontrollable or bloody diarrhea
- closing of the throat or trouble breathing
- seizures
- unusual bleeding

Keep taking the medicine if you have any of these common side effects:

- mild nausea or vomiting
- upset stomach
- mild diarrhea
- constipation
- headache
- irritation at injection site

Common side effects may require treatments which are available over-the-counter or by prescription from your healthcare provider. However if these side effects either become bothersome or worsen, then tell your healthcare provider.

What are the Risks if I am Pregnant or Breastfeeding?

There is a lack of information on the use of meropenem in human pregnancy and during breastfeeding. High doses of meropenem have been tested in pregnant animals and no serious problems were detected in the unborn animals. Meropenem passes into breast milk, but use during breastfeeding is not expected to be dangerous to babies. Talk to your healthcare provider about the risks of meropenem during pregnancy and during breastfeeding.

What if I am Taking Other Medicines?

Meropenem may cause additional side effects when taken with some medicines or may change how much meropenem or your other medications you need. Talk to your healthcare provider if you are taking a medicine for gout called Probalan (probenecid) or medicine for seizures and bipolar disorder called Valproic or Depakote (valproic acid) and any other medication you are taking.

What Should you tell your Healthcare Provider Before Receiving Meropenem?

Tell your healthcare provider if you:

- have had a history of allergic reaction or other serious reaction to antibiotics
- any past or current medical conditions such as kidney disease
- are pregnant or breastfeeding

Risk-Benefit Statement

Although meropenem has some potential and serious adverse effects, the expected benefit of meropenem in helping treat disease and preventing death associated with *B. pseudomallei* and *B. mallei* outweigh these risks.

What Alternative Medicines Can I Take Instead of Meropenem?

There are no FDA-approved antibiotics or vaccines for the treatment of melioidosis and/or glanders caused by *B. pseudomallei* and *B. mallei*, respectively. However, you may benefit from supportive therapy (e.g. intravenous fluids, medicine to control fever or pain). You should discuss any questions you have and other choices you may have with your healthcare provider.

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, meropenem 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 drugs or vaccines. If you have been injured by meropenem used to treat melioidosis and/or glanders, you can learn more about this program by visiting <http://www.hrsa.gov/cicp> or by calling this toll-free number 1-855-266-2427.

How can I learn more

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