

Disclosure and Consent  
Drug Therapy for Treatment of Tuberculosis Disease

The information in this consent form is given so you can know more about your treatment. After you are sure that you understand this information, sign this form to show that you do understand and agree to take the treatment.

I have been told I need drug treatment because of: **CIRCLE ONE**

1. Tuberculosis, current disease    2. Tuberculosis is suspected    3. Other mycobacterial disease

The following drugs have been prescribed: **CIRCLE ALL THAT APPLY**

- |                       |                       |                                    |                  |
|-----------------------|-----------------------|------------------------------------|------------------|
| 1. Isoniazid (INH)    | 6. Amikacin (AK)      | 11. Levofloxacin (LFX)             | 16. Other: _____ |
| 2. Rifampin (RIF)     | 7. Bedaquiline (BDQ)  | 12. Moxifloxacin (MFX)             | _____            |
| 3. Rifabutin (RBT)    | 8. Clofazimine (CFZ)  | 13. Linezolid (LZD)                | _____            |
| 4. Pyrazinamide (PZA) | 9. Cycloserine (CS)   | 14. Para-Aminosalicylic Acid (PAS) |                  |
| 5. Ethambutol (EMB)   | 10. Ethionamide (ETA) | 15. Pretomanid (Pa)                |                  |

Some people who take these drugs may experience one or more of the following shown below:

<input type="checkbox"/> Isoniazid	Decreased appetite, nausea, vomiting, abdominal discomfort/bloating, dark urine (tea or coffee color), yellow skin/eyes, rash, pale colored stools, tiredness, weakness, numbness or tingling of fingers or toes, vision changes (rare but possible: pain to eye, vision loss, loss of color vision, flashing lights, red/green color blindness). <b>Caution:</b> Avoid drinking alcohol. Limit use of acetaminophen products (i.e. Tylenol). May cause serotonin syndrome; avoid foods containing tyramine to include but not limited to: aged cheeses, processed meats, fermented foods, and chocolate.
<input type="checkbox"/> Rifampin	Orange body fluids (tears, urine, sweat). May stain soft contact lenses or clothing. Flu-like symptoms, joint pain, tiredness, weakness, nausea, vomiting, stomach pain or cramps, heartburn, loss of appetite, yellow skin and/or eyes, itching, rash, bleeding from nose or gums or around your teeth, dizziness, musculoskeletal pain, fever or chills, light colored stools (poop), brown urine, bruises, or red or purple spots on your skin that you cannot explain, shortness of breath. <b>Caution:</b> Avoid drinking alcohol. May reduce the effectiveness of birth control pills and other hormonal contraceptives. If birth control is desired, an alternative method should be considered. Interacts with many other medications.
<input type="checkbox"/> Rifabutin	Same as Rifampin. Also, vision changes (eye pain, vision changes, sensitivity to light), sore throat, sores in mouth. <b>Caution:</b> Same as with Rifampin.
<input type="checkbox"/> Pyrazinamide	Tiredness, decreased appetite, nausea, vomiting, abdominal discomfort/bloating, fever, joint pain or swelling, muscle aches, rash, dark urine (tea or coffee color), yellow skin/eyes, photosensitivity. <b>Caution:</b> Avoid drinking alcohol. Use sunscreen.
<input type="checkbox"/> Ethambutol	Vision changes (eye pain, vision loss, flashing lights, blurring, red/green color blindness), tiredness, decreased appetite, nausea, vomiting, abdominal discomfort/bloating, fever, headaches, dizziness, rash/hives, trouble breathing, swelling in face. <b>Caution:</b> Do not take antacids within 4 hours of taking this medication.
<input type="checkbox"/> Amikacin	Hearing loss, ringing in the ears, dizziness, loss in balance, rash or swelling around face or mouth, shortness of breath, muscle twitching or weakness, decrease urination. <b>Caution:</b> Avoid in pregnancy.
<input type="checkbox"/> Bedaquiline	Change in heart rhythm, chest pain, shortness of breath, fainting, seizures, decreased appetite, nausea, vomiting, abdominal discomfort/bloating, headaches, pain in joints, rash. <b>Caution:</b> Swallow pill whole. Take with food. Avoid drinking alcohol.

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<input type="checkbox"/> Clofazimine	<i>Requires separate consent directly from the prescribing physician following an Institutional Review Board (IRB) approval for the use of this medication.</i>
<input type="checkbox"/> Cycloserine	Mood changes, headache, depression, inability to concentrate, lethargy, slurred speech, suicidal thoughts, sleep problems, shakiness, dizziness, memory loss, abnormal behavior, seizures, rash or hives. <b>Caution:</b> Avoid drinking alcohol.
<input type="checkbox"/> Ethionamide	Tiredness, decreased appetite, nausea, vomiting, abdominal discomfort/bloating, metallic taste, rash, depression, irritability, tingling of fingers or toes, dark urine (tea or coffee color), yellow skin/eyes, decreased energy, headaches, loss of concentration or memory, hair loss, skin changes, acne, irregular menses, enlarged or swelling of breast tissue in males.
<input type="checkbox"/> Levofloxacin, <input type="checkbox"/> Moxifloxacin	Decreased appetite, nausea, vomiting, abdominal discomfort/bloating, tiredness, fainting, fever, rash, increased gas, headache, sleep problems, agitation, depression, tingling of fingers or toes, achiness, joint pain or swelling, pain in tendons often at ankle, change in heart rate, photosensitivity, seizures. <b>Caution:</b> Do not take with milk-based products, antacids, multi-vitamins, mineral supplements (iron or magnesium) within 2 hours of medication; avoid caffeinated foods and beverages. Use sunscreen.
<input type="checkbox"/> Linezolid	Tingling of fingers or toes, vision changes (pain to eye, vision loss, flashing lights, red/green color blindness), unusual bleeding or bruising, black or tarry stools, change in urinary frequency, fatigue/weakness, fainting, headache, dizziness, confusion, shortness of breath, fever, chills, pale skin, lips or nail beds, rapid pulse, diarrhea, nausea, vomiting, abdominal discomfort. <b>Caution:</b> May interact with many other drugs and foods. May cause serotonin syndrome; avoid foods containing tyramine to include but not limited to: aged cheeses, processed meats, fermented foods, and chocolate.
<input type="checkbox"/> Para-Aminosalicylic Acid	Decreased appetite, nausea, vomiting, abdominal discomfort/bloating, dark urine, yellow skin/eyes, severe itching or hives, unusual bruising or bleeding, increased tiredness, hair loss, skin changes, trouble concentrating, irritability, depression, irregular menses, metallic taste, enlargement or swelling of breast tissue in males. <b>Caution:</b> Avoid drinking alcohol. Keep refrigerated. Do not chew granules.
Pretomanid <i>Used in combination with Bedaquiline and Linezolid (BPAL)</i>	The most common side effects with BPAL are peripheral neuropathy (numbness or tingling in fingers/toes), acne, anemia, nausea, vomiting, headache, indigestion, decreased appetite, rash, itching, abdominal pain, stabbing or burning pain in the chest when breathing/coughing/laughing, lower respiratory tract infection, liver problems, back pain, cough with/without blood, visual impairment, low blood sugar, abnormal loss of weight, and diarrhea. <i>Serious adverse reactions can occur with the combination of pretomanid, bedaquiline, and linezolid:</i> liver problems (decreased appetite, nausea, vomiting, abdominal discomfort/bloating, dark urine [tea or coffee color], yellow skin/eyes, rash, pale colored stools, tiredness), myelosuppression including anemia (pale and or cold skin and lips, feeling tired, dizziness, weakness, headaches, shortness of breath, rapid breathing), loss of vision or changes in vision, pain in the eyes, numbness/tingling to fingers/toes, and cardiac rhythm abnormalities. <b>Pretomanid Caution:</b> The potential effects on human male fertility are unknown. Counsel men of reproductive age. Avoid use in nursing or pregnant women whose baby is known to be male. Take with food. Swallow tablet whole with water. Do not drink alcohol or take medications that can affect the liver; tell your nurse or doctor about any herbal products you are taking.

**Allergic reactions including rashes and hives may be caused by any of the drugs. If severe immune reactions occur (including swelling of lips, breathing difficulty or wheezing), stop taking the drug and contact the nurse or physician immediately; or, to seek emergency medical help,**

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**dial 911 or visit the ER (Emergency Room) at a hospital.**

**For female patients:** *I have been informed that I should not become pregnant while taking Amikacin and Clofazimine. I agree to use an effective birth control method while I am taking these medications. If I am on birth control pills or taking another hormonal contraceptive, or using a hormonal contraceptive device, I will add a barrier method of contraception, such as a condom and spermicide while I am taking this medicine. I will inform the nurse or physician if I think I am pregnant.*

**For male patients:** *I have been informed that reproductive toxicities have not been adequately evaluated, including reduced or absent sperm counts, while taking Pretomanid.*

The risks are small and the health problems that may arise usually clear up completely. Sometimes the side effects may be bad, but very rarely may cause lasting damage or death. The Health Department will check me regularly for side effects. I will be responsible for telling my healthcare provider about any unusual symptoms and follow treatment recommendations and instructions. The Health Department believes that the benefits of drug treatment for tuberculosis disease are always much greater than the risks.

I have answered all the questions about my medical history and my present health condition fully and truthfully. I have told the doctor or other clinic staff about any conditions that might suggest I should not take the medication(s). I have had the chance to ask questions about this health condition, the benefits and risks of specific tuberculosis drugs, including how long side effects may last and how bad the side effects may be. I understand the risks of not taking treatment. I understand that no promises can be made about cure or side effects. Any blank spaces on this form have been filled in. **By signing below, I consent to the treatment for tuberculosis disease.**

**SECTION I:**

Patient's name: \_\_\_\_\_

Patient's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Person authorized to consent (if not patient): \_\_\_\_\_

Relationship: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**SECTION II:**

I certify that the person who has the power to consent cannot be contacted and has not previously objected to the service being requested.

Patient's name: \_\_\_\_\_

Name of person giving consent: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Relationship to patient: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

**SECTION III:**

Counselor's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Interpreter's Signature (If used): \_\_\_\_\_

Date: \_\_\_\_\_