

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
DISCLOSURE AND CONSENT
DRUG THERAPY FOR TREATMENT OF HANSEN'S 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 the treatment.

I have been told that I need drug therapy because of the following: **CHECK ALL THAT APPLY**

- Active Hansen's Disease**
- Complications Related to Hansen's Disease**
- Exposure to Hansen's Disease**

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

- | | | | |
|---|--|--|---|
| <input type="checkbox"/> Clofazimine | <input type="checkbox"/> Methotrexate | <input type="checkbox"/> Prednisone | <input type="checkbox"/> Thalidomide |
| <input type="checkbox"/> Dapsone | <input type="checkbox"/> Moxifloxacin | <input type="checkbox"/> Rifampin | <input type="checkbox"/> Other: |
| <input type="checkbox"/> Gabapentin | <input type="checkbox"/> Minocycline | <input type="checkbox"/> Rifabutin | <input type="checkbox"/> Other: |

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

Drug	Side Effects
Clofazimine	Darkens skin from pink to brownish-black, skin dryness, itching, rash, pain in abdomen, diarrhea, nausea and vomiting, dryness, burning and itching of eyes, red or brownish coloration of whites of eyes, sweat, tears, urine and feces. May cause dry, itchy skin. NOTE: Separate consent is required under the Institutional Review Board (IRB) with additional side effects listed.
Dapsone	Nausea, vomiting, loss of appetite, headaches, nervousness, inability to sleep, blurred vision, changes in mental state, neuritis, swelling of hands and feet. May cause you to sunburn more easily; use sunscreen or avoid sun exposure.
Gabapentin	Nausea, vomiting, diarrhea, dry mouth. Dizziness or drowsiness may occur; take care operating a vehicle until you know how this may affect you. Take with food. Swallow whole; do not crush. Take 2 hours before or after any antacid. Avoid drinking alcohol.
Methotrexate	Decreased appetite, hair loss, feeling dizzy/tired/weak, stomach pain. Avoid pregnancy during therapy and for 6 months after completion. Take on an empty stomach. Wash hands after touching tablets. Avoid drinking alcohol.
Moxifloxacin*	Decreased appetite, nausea, vomiting, diarrhea, 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. Caution: 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.

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Drug	Side Effects
Minocycline*	Diarrhea, upset stomach, vomiting, decreased appetite. Swallow whole with plenty of water, with or without food. May cause you to sunburn more easily; use sunscreen or avoid sun exposure. Take 2 hours before or after any antacid or vitamin.
Prednisone	Upset stomach, vomiting, restlessness, trouble sleeping, dizziness, headache. Take with food or milk. If only taking once per day, take dose in the morning.
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. Caution: Avoid drinking alcohol. May reduce the effectiveness of birth control pills and other hormonal contraceptives. If birth control is desired, an alternative method of birth control should be considered. Interacts with many other medications.
Rifabutin	Same as Rifampin. Also, vision changes (eye pain, vision changes, sensitivity to light), sore throat, sores in mouth. Caution: Same as with Rifampin.
Thalidomide	Drowsiness, serious birth defects to infants born to mothers who take it during pregnancy, swelling of hands and feet. Take with water at least one hour after the evening meal, preferably at bedtime. NOTE: Separate consent is required by the drug makers due to side effects.

**Rifampin, moxifloxacin, and minocycline are prescribed as a once-monthly regimen (the RMM regimen). RMM is highly recommended to be administered by direct observation only.*

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

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 Texas Department of State Health Services (DSHS) Hansen's Disease (HD) clinic 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 DSHS HD Clinic believes that the benefits of drug treatment for Hansen's Disease or HD problems 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 Hansen's Disease drugs, including how long

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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.

For patients prescribed the once-monthly Rifampin, Moxifloxacin, and Minocycline (RMM) regimen: *I understand that my Hansen's Disease physician is recommending that I take a regimen of rifampin, minocycline, and moxifloxacin as a combined treatment for my Hansen's Disease. I understand this treatment regimen is based on limited population studies. The benefits and risks of this regimen have been explained to me by my Hansen's Disease physician. I have had the opportunity to ask questions and have my questions answered.*

Instructions for the use of the drug(s) have been given to me as follow: Orally Written

(Check One) I have read the form or I have had the form read to me and it has been fully explained to me. Any blank spaces on this form have been filled in.

Based on the above, by signing below, I give this informed consent for treatment as recommended.

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: _____