Tolvaptan for ADPKD Shared System REMS (RISK EVALUATION AND MITIGATION STRATEGY) PATIENT GUIDE

Patients: Your healthcare provider will go over this patient guide with you. It is important to ask any questions you may have. Keep this guide for important safety information about the serious risks of tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD).

Healthcare Providers: Review this patient guide with your patient, and provide your patient a copy to take home.

WHAT IS TOLVAPTAN?

Tolvaptan is a prescription medicine used to slow kidney function decline in adults who are at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

Tolvaptan is also used to help increase low sodium levels in the blood, in adults with conditions such as heart failure, and certain hormone imbalances.

It is not known if tolvaptan for ADPKD is safe and effective in children.

Please also read the Medication Guide that comes with your medicine for more information about how to take tolvaptan for ADPKD.

WHAT IS THE MOST SERIOUS RISK OF TOLVAPTAN FOR ADPKD?

- Tolvaptan for ADPKD can cause serious liver problems that can lead to the need for a liver transplant or can lead to death

WHAT IS THE TOLVAPTAN FOR ADPKD SHARED SYSTEM REMS?

- This Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage the risk of serious and potentially fatal liver injury associated with use of tolvaptan for ADPKD and is required by the Food and Drug Administration (FDA) to ensure the benefits of tolvaptan outweighs its risks
- This REMS applies to tolvaptan products indicated for the treatment of ADPKD. This REMS does not apply to tolvaptan products that are indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone
- Because of the risk of serious and potentially fatal liver injury, tolvaptan for ADPKD is only available through a restricted distribution program called the Tolvaptan for ADPKD Shared System REMS
- The REMS educates patients and healthcare providers about these risks associated with tolvaptan for ADPKD
- Requirements of the Tolvaptan for ADPKD Shared System REMS include the following:
  - You and your healthcare provider must be enrolled in the REMS to receive and prescribe tolvaptan for ADPKD
  - Tolvaptan for ADPKD is only available from pharmacies that participate in the REMS
- Your healthcare provider will do blood tests to check your liver before you start using tolvaptan for ADPKD and regularly while you are being treated with tolvaptan for ADPKD

WHAT DO I NEED TO DO BEFORE I START TREATMENT WITH TOLVAPTAN FOR ADPKD?

- Talk with your healthcare provider about:
  - The risk of serious liver problems that can lead to the need for a liver transplant or can lead to death
  - The required blood testing before your first dose and regularly during treatment
  - Signs or symptoms of liver injury
- Receive and read the **Patient Guide**
- Agree to have important blood tests before you start, and regularly while you are taking tolvaptan for ADPKD to monitor your liver health
- Complete a **Patient Enrollment Form** with your healthcare provider to enroll in the Tolvaptan for ADPKD Shared System REMS

HOW WILL I RECEIVE TOLVAPTAN FOR ADPKD?

After you are enrolled in the REMS, the pharmacy will call you to schedule a shipment of tolvaptan for ADPKD that will come right to your home.

- Tolvaptan for ADPKD is only available from pharmacies that participate in the REMS
- The pharmacy will only dispense a one-month supply at a time

WHAT DO I NEED TO DO WHILE I AM BEING TREATED WITH TOLVAPTAN FOR ADPKD?

- Get a blood test:
  - Before my treatment begins
  - At 2 weeks after my treatment begins
  - At 4 weeks after my treatment begins, and then
  - Every month after that for the first 18 months, and then
  - Every 3 months from then on
- Contact my healthcare provider if I have any side effects, reactions, or symptoms after receiving tolvaptan for ADPKD (See **"What are the signs and symptoms of serious liver injury?"** below)
- Notify the Tolvaptan for ADPKD Shared System REMS Coordinating Center if you change your tolvaptan for ADPKD healthcare provider, if your contact information changes, or if you stop treatment with tolvaptan for ADPKD

TOLVAPTAN FOR ADPKD LIVER BLOOD TESTING TIMELINE

While taking tolvaptan for ADPKD, you should stay in touch with your healthcare provider. You or your family members should tell your healthcare provider right away if you have any of the symptoms listed on the next page any time during treatment with tolvaptan for ADPKD. Also, tell your healthcare provider about any other new symptoms you notice while taking tolvaptan for ADPKD.

WHAT ARE THE SIGNS AND SYMPTOMS OF SERIOUS LIVER INJURY?

You should stop taking tolvaptan and you or your family member should contact your healthcare provider if you have any of the following symptoms.

- feeling tired
- loss of appetite
- nausea
- right upper stomach (abdomen) pain or tenderness
- vomiting
- fever
- rash
- itching
- yellowing of the skin and white part of the eye (jaundice)
- dark urine

Your healthcare provider should also report your symptoms to the Tolvaptan for ADPKD SS REMS Coordinating Center.

WHERE CAN I FIND MORE INFORMATION ABOUT THE TOLVAPTAN FOR ADPKD SHARED SYSTEM REMS?

In addition to this guide, you will receive a Medication Guide that has important information about your prescription. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider for information about tolvaptan for ADPKD that is written for healthcare providers.

If you have questions about the REMS, you can call the Tolvaptan for ADPKD Shared System REMS Coordinating Center.

Phone: 1-866-244-9446
Hours of Operation: 8 am-8 pm Eastern

IF YOU HAVE ANY QUESTIONS ABOUT YOUR HEALTH OR MEDICINES, TALK TO YOUR HEALTHCARE PROVIDER.

To report negative side effects, contact the FDA at **1-800-FDA-1088 or (www.fda.gov/medwatch).**

Please see the PRESCRIBING INFORMATION, including **BOXED WARNING**, and MEDICATION GUIDE.

Phone: 1-866-244-9446 | www.TolvaptanADPKDSharedREMS.com | Fax: 1-866-750-6820

Healthcare providers must report cases of liver injury to the REMS Coordinating Center.

Tolvaptan for ADPKD
Shared System REMS

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