

JYNARQUE®
(tolvaptan) tablets

JYNARQUE 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 JYNARQUE.

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

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

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

WHAT IS JYNARQUE?

JYNARQUE 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).

It is not known if JYNARQUE is safe and effective in children.

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

WHAT IS THE MOST SERIOUS RISK OF JYNARQUE?

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

WHAT IS THE JYNARQUE 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 JYNARQUE and is required by the Food and Drug Administration (FDA) to ensure the benefits of JYNARQUE outweighs its risks
- Because of the risk of serious and potentially fatal liver injury, JYNARQUE is only available through a restricted distribution program called the JYNARQUE REMS
- The REMS educates patients and healthcare providers about these risks associated with JYNARQUE
- Requirements of the JYNARQUE REMS include the following:
 - You and your healthcare provider must be enrolled in the JYNARQUE REMS to receive and prescribe JYNARQUE
 - JYNARQUE 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 JYNARQUE and regularly while you are being treated with JYNARQUE

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WHAT DO I NEED TO DO BEFORE I START TREATMENT WITH JYNARQUE?

- 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 JYNARQUE - to monitor your liver health
- Complete a **Patient Enrollment Form** with your healthcare provider to enroll in the JYNARQUE REMS

HOW WILL I RECEIVE JYNARQUE?

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

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

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WHAT DO I NEED TO DO WHILE I AM BEING TREATED WITH JYNARQUE?

- 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 JYNARQUE (See **“What are the signs and symptoms of serious liver injury?”** below)
- Notify the JYNARQUE REMS Program Coordinating Center if you change your JYNARQUE healthcare provider, if your contact information changes, or if you stop treatment with JYNARQUE

JYNARQUE LIVER BLOOD TESTING TIMELINE



While taking JYNARQUE, 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 JYNARQUE. Also, tell your healthcare provider about any other new symptoms you notice while taking JYNARQUE.

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WHAT ARE THE SIGNS AND SYMPTOMS OF SERIOUS LIVER INJURY?

You or your family member should contact your healthcare provider right away 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

WHERE CAN I FIND MORE INFORMATION ABOUT THE JYNARQUE 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 JYNARQUE that is written for healthcare providers.

If you have questions about the REMS, you can call the JYNARQUE REMS Program Coordinating Center.

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Hours of Operation: 8 am-8 pm Eastern

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

To report negative side effects, contact Otsuka America Pharmaceutical, Inc. at **1-800-438-9927** or FDA at **1-800-FDA-1088** (www.fda.gov/medwatch).

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

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Otsuka
Otsuka America Pharmaceutical, Inc.

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