



## JYNARQUE® (tolvaptan) REMS Program

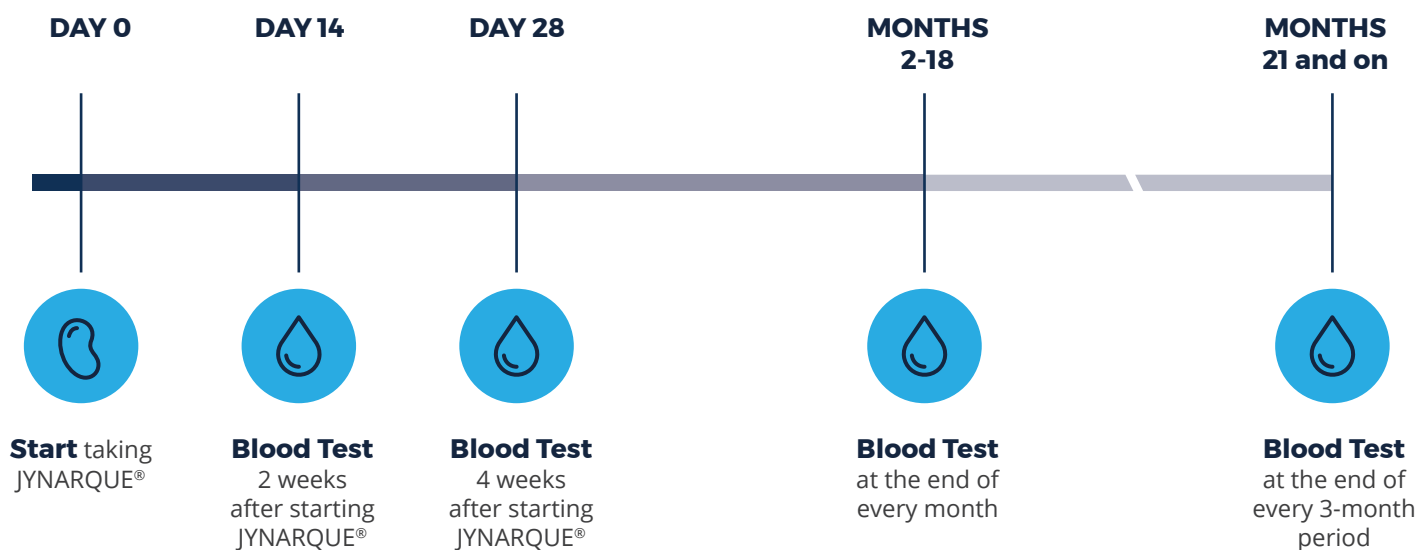
During your treatment with JYNARQUE®, your doctor will want to monitor your liver health. In clinical trials, only 5% of patients experienced signs of liver injury compared to 1% of patients who were not taking JYNARQUE®.<sup>1,2</sup>

JYNARQUE® is part of a Risk Evaluation and Mitigation Strategy, or REMS, program to ensure that you are closely monitored for signs of liver injury. The best way to monitor your liver health is by having your blood tested for any elevated levels of certain liver enzymes. The risk of liver injury is greatest at the start of therapy and reduces over time, but it can occur anytime during treatment.<sup>3</sup> Therefore, you need to receive blood tests more frequently at the start of treatment and less frequently later.



### The testing schedule is as follows:

- Before starting JYNARQUE®
- 2 weeks after starting JYNARQUE® therapy
- 4 weeks after starting JYNARQUE® therapy
- Every 30 days for 18 months
- Every 3 months, thereafter





You must receive these required blood tests to receive refills of JYNARQUE®. If you do not complete your blood test, we will not be able to ship you your medication. You may find it helpful to set reminders on your phone or mark your calendar to help you be mindful of upcoming test dates.

Patients in clinical trials that experienced signs of liver injury saw reversal within 1 to 4 months after pausing therapy.<sup>2</sup> Elevated liver enzymes may not always be caused by JYNARQUE® and some patients may return to treatment with JYNARQUE® once their labs are normal.

### **Some signs and symptoms of potential liver injury include:**

**Fatigue**

**Fever**

**Loss of appetite**

**Unexplained rash or itching**

**Pain in the upper right portion of the abdomen**

**Yellowing of the skin or whites of the eyes**

**Vomiting**

**Dark urine**



**If you experience any of these symptoms, contact your doctor immediately.**

*The information shared in this brochure is not intended to be a substitute for professional medical advice. We strongly recommend that your care and treatment decisions be made in consultation with your healthcare professional team.*

1. <https://www.jynarquehcp.com/clinical-information/safety-profile>
2. <https://www.jynarque.com/risks-and-rems#common-side-effects>
3. Chebib FT, Perrone RD, Chapman AB, et al. A Practical Guide for Treatment of Rapidly Progressive ADPKD with Tolvaptan. J Am Soc Nephrol. 2018;29(10):2458-2470. doi:10.1681/ASN.2018060590



**For additional resources, visit our website:**

**[www.pantherxrare.com/rare-disorders/jynarque-adpkd/](http://www.pantherxrare.com/rare-disorders/jynarque-adpkd/)**

**Contact PANTHERx Rare's JYNARQUE® RxARECARE® Team**

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