



Not an actual patient.

# Starting **JYNARQUE®** (tolvaptan)

What you need to know  
for your treatment journey

Visit [JYNARQUE.com](https://www.jynarque.com) to learn more

## **INDICATION and SELECT IMPORTANT SAFETY INFORMATION:**

### **What is JYNARQUE?**

JYNARQUE is a prescription medicine used to slow kidney function decline in adults who are at risk for rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). It is not known if JYNARQUE is safe and effective in children.

**Serious liver problems.** JYNARQUE can cause serious liver problems that can lead to the need for a liver transplant or can lead to death. Stop taking JYNARQUE and call your healthcare provider right away if you get 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.

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

 **JYNARQUE®**  
(tolvaptan)  
15, 30, 45, 60, 90 mg tablets



# **Congratulations**

on deciding to push back the  
progression of your ADPKD  
with **JYNARQUE®** (tolvaptan)

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**In this brochure, you'll find what you need to know  
about starting JYNARQUE.**

**You can visit [JYNARQUE.com](https://www.jynarque.com) for more information  
and to sign up for email updates.**

ADPKD=autosomal dominant polycystic kidney disease.

**Take the next step!**

Please read **IMPORTANT SAFETY  
INFORMATION** on pages 14-15.

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## INDICATION:

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  - feeling tired
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  - rash
  - itching
  - yellowing of the skin and white part of the eye (jaundice)
  - dark urine

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# Get **JYNARQUE**® (tolvaptan) through a Specialty Pharmacy

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## **JYNARQUE is available exclusively through 3 REMS-certified pharmacies**

Your experience with a Specialty Pharmacy will be different than it is at a traditional pharmacy. Unlike a traditional pharmacy, a Specialty Pharmacy delivers your treatment to you in a timely manner each month, so there's no need to pick up JYNARQUE.

Many Specialty Pharmacies also offer clinical and educational support, help with taking JYNARQUE, and reminders about lab tests and refills.



[alliancexwp.com](http://alliancexwp.com)

**(800) 480-9052**



[optum.com](http://optum.com)

**(877) 719-6330**



[pantherxrare.com](http://pantherxrare.com)

**(833) 599-2245**

If you don't know which pharmacy you'll be using, ask your nephrologist.

REMS=Risk Evaluation and Mitigation Strategy.

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.





**The process for getting JYNARQUE® (tolvaptan) will include a few conversations with your Specialty Pharmacy to discuss your treatment:**

Soon after you are prescribed JYNARQUE, your Specialty Pharmacy will reach out to you. The pharmacy will ask how you prefer to be contacted and will lay out a plan to help you begin treatment with JYNARQUE when it is sent to you.

**Don't forget to ask your nephrologist and your pharmacy about your eligibility for copay assistance**

After your first prescription arrives, your pharmacy will reach out to you once a month to arrange refills. Save your pharmacy's phone number so you don't miss any of their calls and can easily reach them when you have questions. Pharmacies are open 24/7 and translators are available upon request.

**REMINDER**

Before you can get your first prescription, it is required that you get a blood test

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.

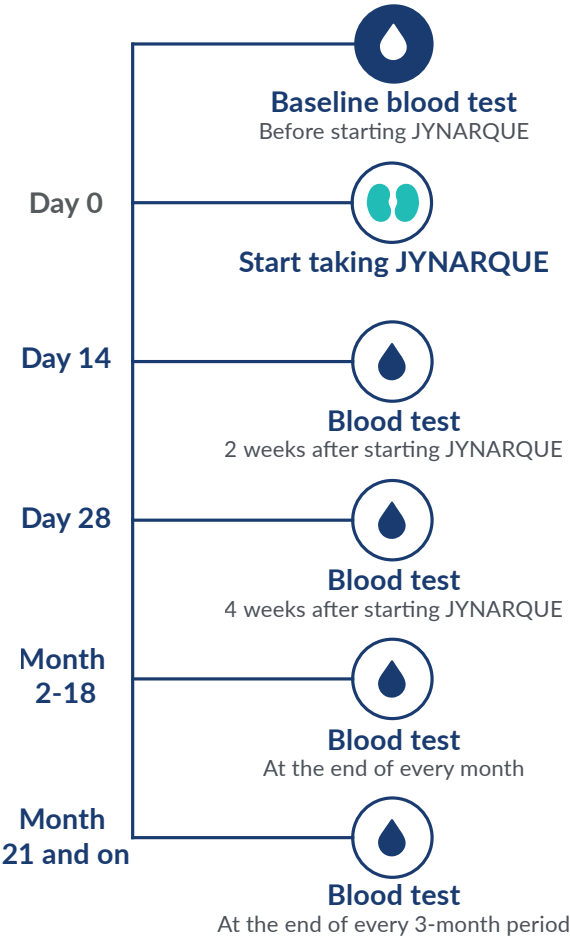
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**Get JYNARQUE® (tolvaptan) through  
a Specialty Pharmacy (cont'd)**

**To reduce your risk of liver injury, it is required that  
you have a blood test before you start JYNARQUE,  
and then 2 weeks and 4 weeks after you start**

For the next 18 months of treatment with JYNARQUE,  
you will need to have a blood test every month.

Following that period, you will only need to have a blood test  
every 3 months to be able to continue on JYNARQUE.



Please read **IMPORTANT SAFETY  
INFORMATION** on pages 14-15.





## Your nephrologist will need to monitor your liver health while you are taking JYNARQUE® (tolvaptan)

When you are prescribed JYNARQUE, you will be enrolled in the **REMS Program**, a special safety program that will have your blood work monitored by your nephrologist, to reduce your risk of liver injury. JYNARQUE can cause serious and potentially fatal liver injury. Your nephrologist will monitor your liver function throughout your scheduled blood tests.

### IN CLINICAL TRIALS,

**5%** of people taking JYNARQUE experienced signs of liver injury vs **1%** of people taking placebo

**After JYNARQUE was stopped, signs of liver injury typically resolved within 1 to 4 months**



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

**Evidence of serious liver injury occurred in 3 out of 1487 (0.2% of) tolvaptan-treated patients**

**Your Specialty Pharmacy will only send your prescription if you and your nephrologist continue monitoring your liver health. Your blood tests must be completed regularly in order to get JYNARQUE**

### REMINDER

Work with your nephrologist's office to enroll in the REMS Program and continue blood work over the course of treatment

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.

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# How does **JYNARQUE®** (tolvaptan) arrive?

**Once you have completed your REMS Program enrollment, and have confirmed delivery with your Specialty Pharmacy, your JYNARQUE Welcome Kit should be on its way!**

The Welcome Kit is a box that contains all of the supporting materials you'll need to help manage your treatment journey. The kit includes a patient brochure, a tips and tricks card, and a 32-oz water bottle.



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# How to take **JYNARQUE®** (tolvaptan)

**Together, you and your nephrologist will work to find the JYNARQUE dosage that is right for you**

The starting dose of JYNARQUE is 60 mg/day.



JYNARQUE comes in 3 dosage combinations: 60 mg per day, 90 mg per day, and 120 mg per day.

## SOME HELPFUL TIPS FOR TAKING JYNARQUE



- Take JYNARQUE twice a day, unless advised otherwise by your nephrologist. Take the first dose upon waking; take the second dose 8 hours later. Taking your second dose 8 hours after the first can help reduce the need to wake up at night to urinate
  - Your nephrologist might increase your dose of JYNARQUE to make sure that it's doing the most it can



- It is important to take both JYNARQUE doses as prescribed to make sure that it's working all day long



- JYNARQUE may be taken with or without meals



- Do not drink grapefruit juice during treatment with JYNARQUE. This could cause you to have too much tolvaptan in your blood



- If you miss a dose of JYNARQUE, do not double up. Take the next dose when you normally would

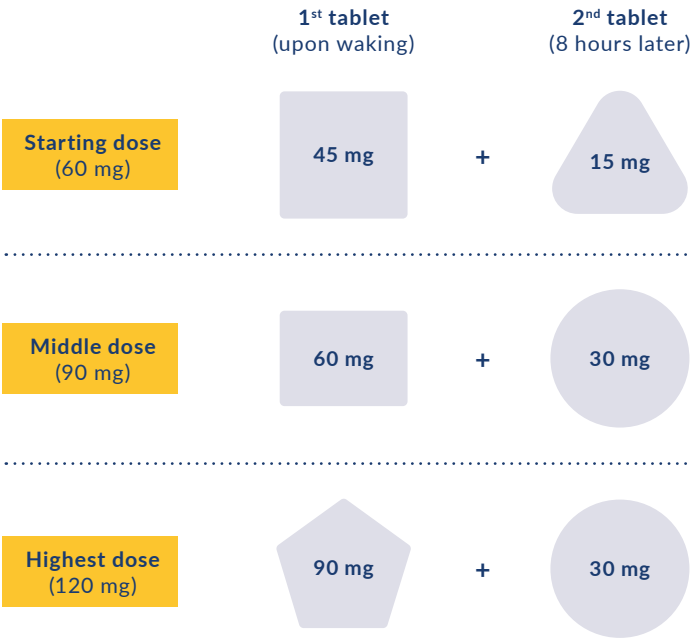
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**How to take JYNARQUE® (tolvaptan) (cont'd)**

**JYNARQUE comes in weekly blister packs, labeled with the days of the week. The morning and afternoon doses are clearly labeled with “AM” and “PM”**

**3 dosage combinations of JYNARQUE are available\*:**



\*Tablets are not shown at actual size.

**REMINDER**

Taking your second dose 8 hours after the first can help reduce the need to wake up at night to urinate

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.



# Who should not take **JYNARQUE®** (tolvaptan)?

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## **JYNARQUE is not for people who**

- have a history of liver problems or have signs or symptoms of liver problems, excluding polycystic liver disease
- cannot feel if they are thirsty or cannot replace fluids by drinking
- have been told that the amount of sodium (salt) in their blood is too high or too low
- are dehydrated
- are allergic to tolvaptan or any of the ingredients in JYNARQUE
- are unable to urinate

# What should I do if I can't manage the side effects of **JYNARQUE®** (tolvaptan)?

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Managing side effects can be challenging. If you have been taking JYNARQUE but are having trouble with side effects, talk to your nephrologist, nurse, or pharmacist, to see if they have any ideas that can help. You can also visit [JYNARQUE.com](https://www.jynarque.com) for some helpful resources.

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.



# The **JYNARQUE**® (tolvaptan) community at Otsuka is ready to help

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Otsuka is committed to being a helpful partner on your journey with JYNARQUE. Whether you are just starting on treatment or need help staying on track, there is a range of information and services available to support you every step of the way.

## **Otsuka Patient Support can also help with**

- No-cost medication if there are delays with your insurance coverage
- Laboratory testing support



## **Blood draw support with the Otsuka Laboratory Support Program**

- You can receive free blood work at Labcorp or Quest Diagnostics. Obtain an Otsuka Laboratory Support Requisition Form from your nephrologist. If you don't live near a lab, we will send a phlebotomist to your home to collect a blood sample. Call today to schedule your home collection appointment: (888) 302-7652, Monday-Friday between 10:30AM and 8PM ET
- It is important that you ask your nephrologist to help you enroll in the Otsuka Patient Support Program to get you access to free lab tests\*

Please read **IMPORTANT SAFETY INFORMATION** on pages 14-15.





## Connect with a Peer Mentor

- Speak with a Peer Mentor to hear about their experiences taking JYNARQUE® (tolvaptan)
- To talk with a Peer Mentor, call (855) 415-7459 or visit [www.adpkdpeermentorprogram.com](http://www.adpkdpeermentorprogram.com)

## Talk with a Patient Education Liaison (PEL)

- A PEL is a licensed healthcare professional who can provide education on the REMS Program, review treatment access steps, provide guidance on navigating helpful resources, and offer support for questions about insurance
- The PELs are available from 9AM to 5PM at the Otsuka Patient Support Center: (855) 242-7787

### REMINDER

Call (855) 242-7787 to contact the Otsuka Patient Support Center to learn more about medication, patient access, and assistance with navigating your treatment journey

\*Assumes one 28-day supply prescription per month. If more than one prescription is filled in a calendar month, patient may pay more than \$10 in that month. Offer is not transferable. Patients are not eligible if they are under 18 years of age, or are covered in whole or in part by any state program or federal healthcare program, including, but not limited to, Medicare or Medicaid (including Medicaid managed care), Medigap, VA, DOD, or TRICARE. Only valid in US and Puerto Rico. Offer void where prohibited by law, taxed, or restricted. Other restrictions may apply. This program is not health insurance. Otsuka America Pharmaceutical, Inc. has the right to rescind, revoke, or amend this program at any time without notice. Your participation in this program confirms that this offer is consistent with your insurance coverage and that you will report the value received if required by your insurance provider. When you use this program, you are certifying that you understand and will comply with the program rules, terms, and conditions.

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# INDICATION and IMPORTANT SAFETY INFORMATION for **JYNARQUE**® (tolvaptan)

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## INDICATION:

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## IMPORTANT SAFETY INFORMATION:

• **Serious liver problems.** JYNARQUE can cause serious liver problems that can lead to the need for a liver transplant or can lead to death. Stop taking JYNARQUE and call your healthcare provider right away if you get 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

**It is important that you have a blood test before you start JYNARQUE to help reduce your risk of liver problems. Your healthcare provider will do a blood test to check your liver:**

- **before you start taking JYNARQUE**
- **at 2 weeks and 4 weeks after you start treatment with JYNARQUE**
- **then monthly for 18 months during treatment with JYNARQUE**
- **and every 3 months from then on**

**Because of the risk of serious liver problems, JYNARQUE is only available through a restricted distribution program called the JYNARQUE Risk Evaluation and Mitigation Strategy (REMS) Program.**

**Do not take JYNARQUE if you:**

- have a history of liver problems or have signs or symptoms of liver problems, excluding polycystic liver disease
- cannot feel if you are thirsty or cannot replace fluids by drinking
- have been told that the amount of sodium (salt) in your blood is too high or too low
- are dehydrated
- are allergic to tolvaptan or any of the ingredients in JYNARQUE
- are unable to urinate

**Tell your healthcare provider about all your medical conditions, including if you:**

- have a history of sodium (salt) levels that are too low

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

## **INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan) (cont'd)**

- are pregnant or plan to become pregnant. It is not known if tolvaptan will harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant
- are breastfeeding or plan to breastfeed. It is not known if tolvaptan passes into your breast milk. Do not breastfeed during your treatment with JYNARQUE. Talk to your healthcare provider about the best way to feed your baby during this time

**Tell your healthcare provider about all the medicines you take,** including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

- Taking JYNARQUE with certain medicines could cause you to have too much tolvaptan in your blood. JYNARQUE should not be taken with certain medications. Your healthcare provider can tell you if it is safe to take JYNARQUE with other medicines
- Do not start taking a new medicine without talking to your healthcare provider

**JYNARQUE may cause serious side effects, including:**

- **Too much sodium in your blood (hyponatremia) and loss of too much body fluid (dehydration).** In some cases, dehydration can lead to extreme loss of body fluid called hypovolemia. You should drink water when you are thirsty and throughout the day and night. Stop taking JYNARQUE and call your healthcare provider if you cannot drink enough water for any reason, such as not having access to water, or vomiting or diarrhea. Tell your healthcare provider if you get any of the following symptoms:
  - dizziness
  - a change in the way your heart beats
  - fainting
  - feeling confused or weak
  - weight loss

**What should you avoid while taking JYNARQUE?**

Do not drink grapefruit juice during treatment with JYNARQUE. This could cause you to have too much tolvaptan in your blood.

The **most common side effects** of JYNARQUE are:

- thirst and increased fluid intake
- making large amounts of urine, urinating often, and urinating at night

These are not all the possible side effects of JYNARQUE. Talk to your healthcare provider about any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist.

**If you have any questions about your health or medicines, talk to your healthcare professional.**

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

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





# Have additional questions about starting **JYNARQUE<sup>®</sup>** (tolvaptan)?

**JYNARQUE is proven to slow kidney function decline in adults who are at risk for rapidly progressing ADPKD**

Learn more at [JYNARQUE.com](https://www.jynarque.com)

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

LIKE AND FOLLOW JYNARQUE



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Otsuka

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