

# Today marks an important step in your journey

Read on for a reminder of what you need to know about beginning treatment with JYNARQUE® (tolvaptan).

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).

## **SELECT 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, fever, loss of appetite, rash, nausea, itching, right upper stomach (abdomen) pain or tenderness, yellowing of the skin and white part of the eye (jaundice), vomiting, dark urine.

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



# Getting ready to begin JYNARQUE® (tolvaptan)

The choice to begin treatment with JYNARQUE is a choice to be proactive in your journey with ADPKD. And while moving forward is an exciting time, it's normal to have questions.

Inside, you will find key information you will need to help manage your treatment—from required lab work, to working with a specialty pharmacy, to understanding what to expect from treatment. Take your time as you familiarize yourself. Because knowing what's ahead can help you move forward with confidence.

ADPKD=autosomal dominant polycystic kidney disease.

## **SELECT IMPORTANT SAFETY INFORMATION:**

**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.**

# Why JYNARQUE® (tolvaptan)?

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

Your doctor prescribed JYNARQUE for you due to your risk of rapidly progressing ADPKD. JYNARQUE may change the course of your disease by slowing kidney function decline as it works over a period of years. As you begin treatment with JYNARQUE, remember that it is a long-term treatment and can take time to make a difference.

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

## How JYNARQUE works



JYNARQUE works by blocking vasopressin, a hormone that can cause cysts to grow. People with ADPKD have too much vasopressin in their systems. JYNARQUE blocks the binding of vasopressin in the kidneys, making it harder for cysts to grow.

# Risk Evaluation and Mitigation Strategy (REMS) Program

**You and your doctor are a part of a safety program that helps to keep you safe by reducing your risk of liver injury.**

The JYNARQUE® (tolvaptan) REMS Program was set up for your safety because JYNARQUE can cause serious and potentially fatal liver injury. This program ensures your doctor monitors your liver function.

- In clinical trials, evidence of serious liver injury occurred in 0.2% of tolvaptan-treated patients compared to 0% of placebo-treated patients. In time, after JYNARQUE was stopped, there were no longer any signs of liver injury

## **SELECT IMPORTANT SAFETY INFORMATION:**

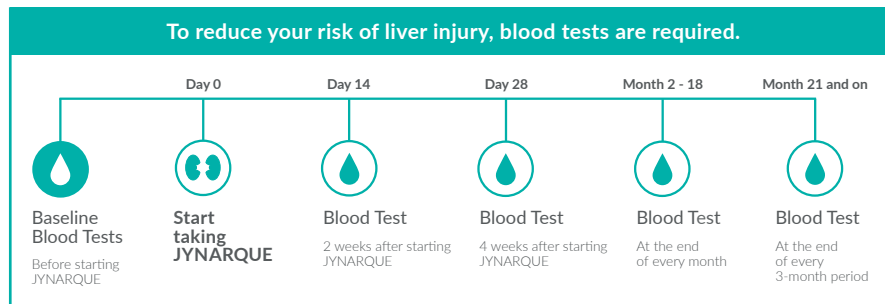
**Do not take JYNARQUE if you:**

- 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

# Scheduling your required blood tests

To reduce your risk of liver injury while taking JYNARQUE® (tolvaptan), it is required that you have a blood test before you start, and then 2 weeks and 4 weeks after you start.

After that, for the first 18 months of treatment with JYNARQUE, you will need to have a blood test every month. When that is done, you will only need to have a blood test every 3 months to be able to continue on JYNARQUE.



Download the **JYNARQUE REMS** calendar that contains your blood test dates at [jynarque.com/downloadable-resources#calendar](https://jynarque.com/downloadable-resources#calendar) or scan the QR code



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

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

## Serious side effects: what to watch out for

- Learn more about these side effects, serious liver problems, and the **JYNARQUE REMS Safety Program** on pages 4-5
- **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
  - fainting
  - weight loss
  - a change in the way your heart beats
  - feeling confused or weak

Call your healthcare provider right away if you experience any of the symptoms listed above.

## Three tips to help manage the most common side effects of JYNARQUE® (tolvaptan)



Bring a bottle of water wherever you go

Take your first dose as soon as you wake up, and the second dose exactly 8 hours later



Find out where restrooms are located ahead of time

Scan the QR code or visit [jynarque.com/online-resources](https://jynarque.com/online-resources) to check out apps that can help you locate a nearby bathroom



## Most common side effects: what to expect

Because of the way JYNARQUE works in the kidneys, it is common to experience excessive thirst and urination.

JYNARQUE works in the kidneys to block the hormone vasopressin, which controls the amount of water in your body. With JYNARQUE treatment, your body holds on to less water, making you frequently thirsty and needing to urinate more.

### SELECT IMPORTANT SAFETY INFORMATION:

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

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

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



## Your specialty pharmacy

By now, you have received your first dose of JYNARQUE® (tolvaptan) through one of the three REMS-certified pharmacies. So you may already understand just how different a specialty pharmacy is from a traditional pharmacy.

Here are some things to keep in mind as you continue working with your specialty pharmacy:



After your first dose arrives, your pharmacy will reach out to you once a month to arrange refills.



When your prescriptions are ready, your specialty pharmacy will call to schedule delivery. So be sure to answer.

JYNARQUE will not ship without your confirmation.



Pharmacists are available 24/7 and translators are available upon request.



Your specialty pharmacy also offers:

- Clinical and educational support
- Help with taking JYNARQUE
- Reminders about lab tests and refills

### SELECT IMPORTANT SAFETY INFORMATION:

**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



# Know who to call



Save your pharmacy's phone number so you don't miss any of their calls and can easily reach them when you have questions.

**allianceRx**  
*TeleGreen's* Pharmacy

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

Phone: (800) 480-9052

**Optum**

[specialty.optumrx.com](http://specialty.optumrx.com)

Phone: (877) 719-6330



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

Phone: (833) 599-2245

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

 **JYNARQUE<sup>®</sup>**  
(tolvaptan)  
15, 30, 45, 60, 90 mg tablets

## 3 dose combinations of JYNARQUE are available\*:



Starting dose (60 mg)



45-mg tablet  
Square

+



15-mg tablet  
Triangular



Middle dose (90 mg)



60-mg tablet  
Rectangular

+



30-mg tablet  
Round



Highest dose (120 mg)



90-mg tablet  
Pentagonal

+



30-mg tablet  
Round

\*Not actual size. Not all dose strengths are packaged together.

## Your JYNARQUE® (tolvaptan) dose

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

The starting dose for JYNARQUE is 60 mg/day. Your doctor may increase your dosage to make sure your treatment is doing the most it can.

### SELECT IMPORTANT SAFETY INFORMATION:

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
- fainting
- weight loss
- a change in the way your heart beats
- feeling confused or weak

# Taking JYNARQUE® (tolvaptan)

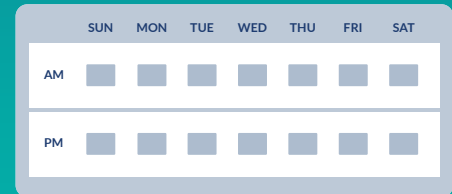
Take JYNARQUE twice a day, unless advised otherwise by your doctor.

- It is important to take both JYNARQUE doses as prescribed, to make sure it is 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 JYNARQUE in your blood
- If you miss a dose of JYNARQUE, do not double up. Take the next dose when you normally would

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

Use the labels on  
your blister pack to help you  
stay on track

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



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 to use the bathroom at night.

# You're starting an important journey; know you're not alone

As you begin your treatment, take comfort in the real-life stories of people living at risk of rapidly progressing ADPKD. May their stories inspire you, motivate you, and provide support along the way.

Hear from these real patients at:

[jynarque.com/patient-stories](https://jynarque.com/patient-stories)

or scan the QR code



*Jim*

*Evelynn*

*Zack*

*Deidre*



*Cari*

*Will*

*Anthony*

*Lauren*

*Nancy*

“Just knowing that there's a treatment—it's huge. It changes your whole perspective.”

— Nancy

These are real patients, living with ADPKD, who have been compensated by Otsuka America Pharmaceutical, Inc. for their time.

Their images reflect their health status at the time of production.

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

 **JYNARQUE<sup>®</sup>**  
(tolvaptan)  
15, 30, 45, 60, 90 mg tablets

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

### INDICATION:

#### 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.

### 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
- 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 (hypernatremia) 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
  - fainting
  - weight loss
  - a change in the way your heart beats
  - feeling confused or weak

### **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](tel:1-800-438-9927) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

Please read [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**, and [MEDICATION GUIDE](#).



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

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



Otsuka  
Otsuka America Pharmaceutical, Inc.