

Your guide to



(tolvaptan)

15, 30, 45, 60, 90 mg tablets



Not an actual patient.

Push back the progression of your **ADPKD**

ADPKD=autosomal dominant polycystic kidney disease.

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**.

ADPKD and
Progression

JYNARQUE
and ADPKD

How JYNARQUE
Works

Side
Effects

How to Get
JYNARQUE

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Program

Taking
JYNARQUE

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Understanding **ADPKD**



The truth about ADPKD progression is that it looks different for everyone—even within the same family

- A parent with ADPKD has a 50% chance of passing it on to each child
- It is important to know that ADPKD disease progression and symptoms vary amongst patients



With rapidly progressing ADPKD, kidney function worsens and cysts grow more quickly, leading to early kidney failure

- According to the Mayo Clinic ADPKD study, out of 538 patients, ~2/3 of this group was at risk for rapid progression

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.

Rapidly progressing **ADPKD** vs being at risk for rapidly progressing **ADPKD**

Is my ADPKD already rapidly progressing?

- A person with ADPKD is considered to be already **rapidly progressing** when their eGFR (a test result that measures how well the kidneys work) declines quickly. eGFR is declining quickly when it drops:
 - ≥ 5 mL/min/1.73 m² within 1 year
 - OR
 - ≥ 2.5 mL/min/1.73 m² per year over a 5-year period

Am I at risk of rapidly progressing ADPKD?

There are a number of factors that may put someone already living with ADPKD at **risk of rapid ADPKD progression**. These may include:

- Kidneys that are bigger than normal for a person's age with ADPKD (high total kidney volume)
- Certain kinds of genetic mutations
- A family history of kidney failure, for instance having relatives who needed dialysis or a kidney transplant before age 58
- High blood pressure before age 35
- Blood in the urine before age 35
- Being overweight (BMI ≥ 25 kg/m²)
- Protein and albumin in your urine (proteinuria and albuminuria)

BE PROACTIVE

Wherever you are in your ADPKD journey, it's important to talk with your nephrologist to develop an appropriate treatment plan for your individual situation.

The sooner you start, the sooner you can help take control of your ADPKD and may start to experience the benefits of slowing down your disease progression. Don't wait, take the first step today. Make a plan to have a discussion about what you can do to help manage your ADPKD at your next appointment

BMI=body mass index; CT=computed tomography; eGFR=estimated glomerular filtration rate; MRI=magnetic resonance imaging.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.



JYNARQUE® (tolvaptan) may help push back the progression of your ADPKD



For adults who are at risk for rapidly progressing ADPKD,

JYNARQUE is the only FDA-approved treatment that works to slow the decline of kidney function.

REPRISE: a 1-year clinical study of patients with CKD stages 2 to 4

TEMPO 3:4: a 3-year clinical study of patients with CKD stages 1 to 3

JYNARQUE slowed the decline of kidney function by

35%

Treatment effect is 1.3 mL/min/1.73 m²/year (95% CI: 0.86 to 1.68, P<.0001)

vs placebo*

-2.3 mL/min/1.73 m²/year with JYNARQUE vs -3.6 mL/min/1.73 m²/year with placebo

26%

Treatment effect: 1.0 mL/min/1.73 m²/year (95% CI: 0.6-1.4, P<.001)

vs placebo*

-2.7 mL/min/1.73 m²/year with JYNARQUE vs -3.7 mL/min/1.73 m²/year with placebo

CKD=chronic kidney disease; eGFR=estimated glomerular filtration rate; FDA=Food and Drug Administration.

*Kidney function was measured by the change in the average eGFR over time.

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

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.



With JYNARQUE® (tolvaptan), you may be able to slow the progression of your disease—across CKD stages.

JYNARQUE is appropriate for people who are at risk for rapidly progressing ADPKD, throughout CKD stages 1 to 4.

STAGES OF CKD



JYNARQUE has been studied in over 3000 people with ADPKD

As you take JYNARQUE, remember that, because it's a long-term treatment, it may take time to see a difference.



Patients taking JYNARQUE experienced less kidney pain

In a clinical trial of patients with ADPKD, at CKD stages 1 to 3, those taking JYNARQUE were likely to experience **36% fewer pain events** requiring medication or treatment vs those taking placebo (HR=0.64; 95% CI: 0.47-0.89, P=.007). Treatment was defined as prescribed leave, surgery, and radiologic treatment.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.



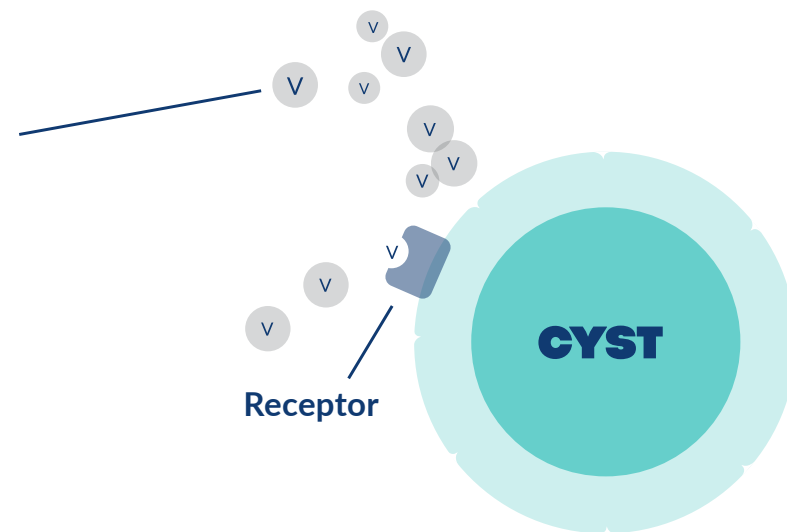


Not an actual patient.

How does **JYNARQUE**[®] (tolvaptan) work?

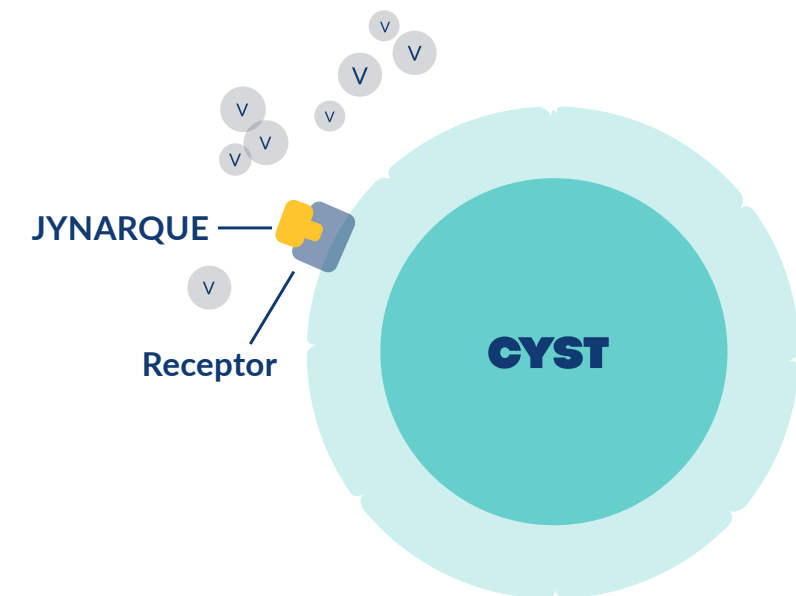
Vasopressin is a hormone that maintains the volume of water in the fluid space surrounding the cells in your body.

People with ADPKD have **too much** vasopressin, causing kidney cysts to grow.



JYNARQUE works by preventing vasopressin from binding in the kidneys, making it harder for cysts to grow.

For illustration purposes only.



Visit [HowJYNARQUEworks.com](https://www.howjynarqueworks.com) to see JYNARQUE in action

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.

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JYNARQUE[®]
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What are the possible serious side effects of **JYNARQUE**[®] (tolvaptan)?

Serious side effects may include:



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



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

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 20-21.

What are the most common side effects of **JYNARQUE**[®] (tolvaptan)?

The most common side effects caused by JYNARQUE include *excessive thirst and increased urination*.

IN CLINICAL STUDIES,

About **2 in 3** people (**64%**) felt thirsty while taking JYNARQUE vs about **1 in 4** people (**23%**) taking placebo

About **3 in 4** people (**70%**) had increased urination, including the need to wake up at night to urinate, urinating greater amounts, and urinating more often during the day vs about **1 in 4** people (**28%**) taking placebo

These side effects are related to how JYNARQUE works in the kidneys

In a clinical trial of patients with CKD stages 2 to 4, most people (95.8%) adjusted to taking JYNARQUE and were able to continue treatment

- Most people (95.8%) who continued in the study past the first 5 weeks with JYNARQUE stayed with it for at least 1 year
- Side effects may vary

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.

PRACTICAL STEPS:



Being patient with yourself, and with the adjustments in your lifestyle, will help you stay focused on slowing the decline of your kidney function

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 **JYNARQUE**[®]
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Get **JYNARQUE**[®] (tolvaptan) through a Specialty Pharmacy

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.

allianceRx
Walgreens Pharmacy

alliancerxwp.com
Phone: (800) 480-9052

Optum

Specialty.OptumRx.com
Phone: (877) 719-6330

**PANTHER**
RAREx

pantherxrare.com
Phone: (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 20-21.



Real patient living with ADPKD. He and his care partner have been compensated by Otsuka America Pharmaceutical, Inc. for their time. His image reflects his health status at the time the photo was taken.

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 20-21.

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Monitor your liver health while taking **JYNARQUE**[®] (tolvaptan)

Your nephrologist will need to monitor your liver health while you are taking JYNARQUE

When you are prescribed JYNARQUE, you will be enrolled in the **Risk Evaluation and Mitigation Strategy (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** compared to none of the placebo 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

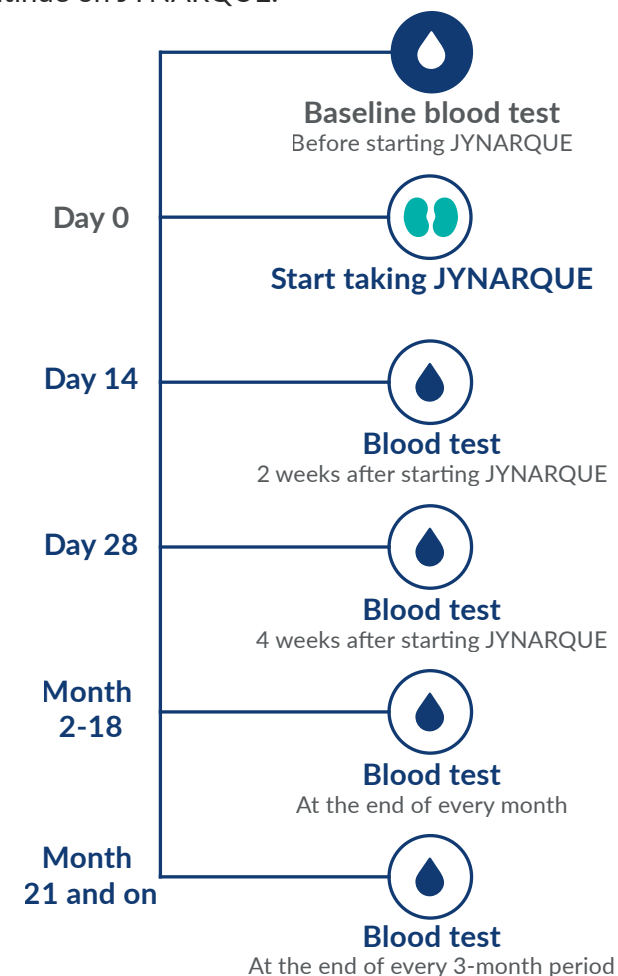
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Real patients living with ADPKD. They have been compensated by Otsuka America Pharmaceutical, Inc. for their time. Their images reflect their health status at the time the photo was taken.

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 20-21.



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 water bottle.



Please read **IMPORTANT SAFETY INFORMATION** on pages 20-21.

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

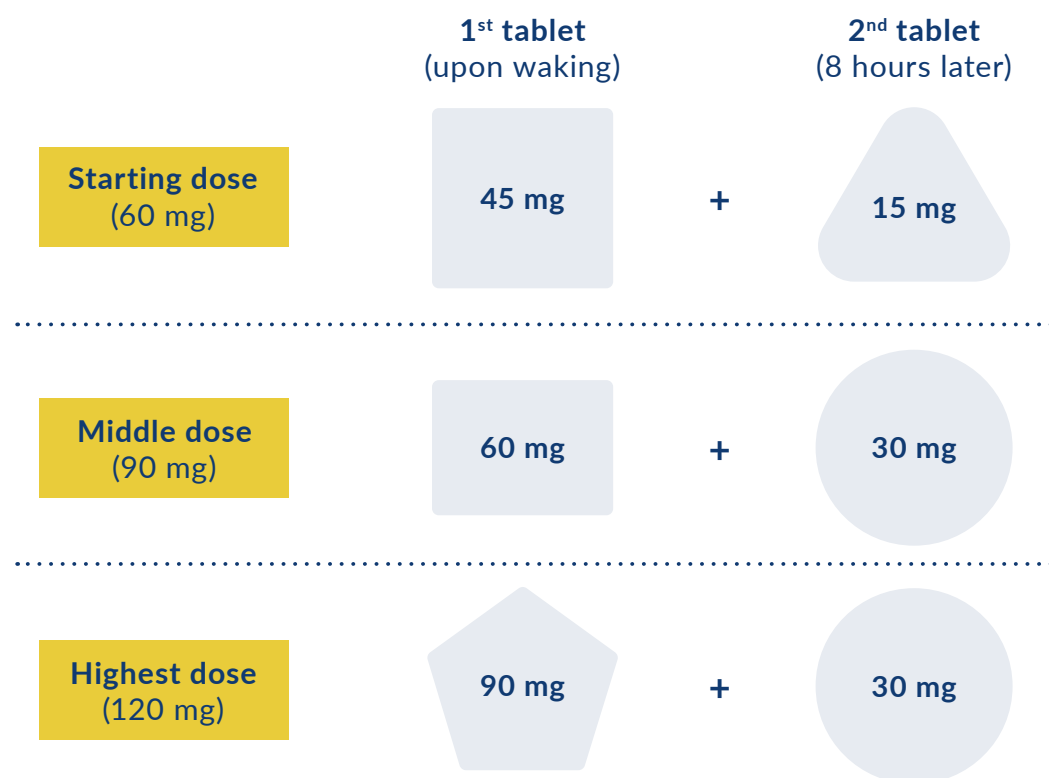
Please read **IMPORTANT SAFETY INFORMATION** on pages 20-21.



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 20-21.

Who should not take **JYNARQUE**[®] (tolvaptan)?

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**?

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 for some helpful resources.

Now that you know how **JYNARQUE** can slow down progression,
learn how you can get started

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

Otsuka is committed to being a helpful partner on your journey with JYNARQUE.

Talk with a Patient Experience 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 through Otsuka Connect at **1-833-468-7852**

Copay Program

- Eligible patients pay as little as \$10 per month for JYNARQUE*
 - 83% of patients with commercial insurance have coverage
 - 94% of all patients pay \$10 or less per month for JYNARQUE, regardless of coverage type[†]



Visit www.jynarque.com/copay-assistance or scan the QR code

Patient Stories

- Hear from the real patients at risk of rapidly progressing ADPKD talk about their experiences and treatment journeys



To watch their videos and read their stories visit jynarque.com/patient-stories or scan the QR code

*Assumes one 28-day supply prescription per month. If more than one prescription is filled in a calendar month, patients may pay more than \$10 in that month. Other terms and conditions may apply.

[†]Managed Markets Insight & Technology, LLC: Analytics website as of July 2023. Commercial lives exclude Health Insurance Exchanges Program (HIX) data.

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Real patients living with ADPKD. They have been compensated by Otsuka America Pharmaceutical, Inc. for their time. Their images reflect their health status at the time the photo was taken.

SIGN UP FOR MORE INFORMATION

Receive helpful texts and emails with information to support conversations with your nephrologist and healthcare team.

Visit jynarque.com/sign-up-more-info or scan the QR code.



TALK WITH A PEER MENTOR

Speak one-on-one with a Peer Mentor living with rapidly progressing ADPKD and taking JYNARQUE.

Call 1-855-415-7459, visit jynarque.com/adpkd-peer-mentor-program, or scan the QR code



JOIN AN ONLINE ADPKD COMMUNITY

Sign up for an ADPKD Peer Conversations webinar to talk with people living with ADPKD.

To join or learn more, visit jynarque.com/adpkd-peer-conversations, or scan the QR code.



Call Otsuka Connect at 1-833-468-7852 to learn more about medication, patient access, and assistance with navigating your treatment journey

Please read **IMPORTANT SAFETY INFORMATION** on pages 20-21.



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

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 (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).

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





Start pushing back on ADPKD today with **JYNARQUE**[®] (tolvaptan)

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

If you are eligible to take JYNARQUE, the sooner you start treatment, the sooner you may experience the benefits.

Learn more about JYNARQUE.
Visit jynarque.com or scan the QR code



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, 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 [IMPORTANT SAFETY INFORMATION](#) on pages 20-21.

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