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# Risk Factors Checklist and Tips

TO PUSH BACK THE PROGRESSION OF YOUR ADPKD

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JYNARQUE® (tolvaptan) is proven to slow kidney function decline for adults at risk of rapidly progressing ADPKD.

USE THE CHECKLIST INSIDE  
TO SEE IF JYNARQUE IS RIGHT FOR YOU

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**.

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

# ADPKD risk factors **CHECKLIST**

If you have ADPKD and are over the age of 18, check all that apply to see if you are at risk for rapid progression:



I have experienced a fast drop in kidney function (measured by higher creatinine levels or a lower eGFR)



I have a high total kidney volume (kidneys that are larger than normal for a person my age with ADPKD)



I have certain types of genetic mutations\*



I have family members with ADPKD and a history of kidney failure, such as the need for dialysis or a kidney transplant, before age 58



I have high blood pressure that started before age 35



I have experienced blood in my urine (hematuria), cyst infections, or flank pain related to cysts, before age 35



I am overweight with a body mass index  $\geq 25$  kg/m<sup>2</sup>



I have protein and albumin in my urine (proteinuria and albuminuria)

If you checked one or more of the above, you may be at risk for rapidly progressing ADPKD, and you could be a candidate for treatment with JYNARQUE® (tolvaptan).

**Use your answers from the checklist above to start a conversation with your nephrologist to determine the best next steps for you in helping to manage your ADPKD.**

## **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

Please read **IMPORTANT SAFETY INFORMATION** on pages 4-5.

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## Tips for partnering with your **NEPHROLOGIST**

If you have been identified as an appropriate candidate for **JYNARQUE® (tolvaptan)**, it is important to build a strong relationship with your nephrologist and to have a thorough conversation about your treatment plan and your expectations for managing ADPKD.



Talk to your nephrologist about the right way to take your medication



Make sure that your healthcare team, including your healthcare providers and pharmacists, is aware of all the medicines you are taking

### KNOW YOUR DISEASE PROGRESSION

Kidney size is an important indicator of the risk for rapidly progressing ADPKD. Work with a nephrologist to learn more about how your kidneys look and how rapidly your disease could be progressing. This could include your nephrologist using an MRI or CT scan to get a more detailed picture of your kidneys.

CT=computed tomography; eGFR=estimated glomerular filtration rate; MRI=magnetic resonance imaging.

\*Certain types of genetic mutations are associated with the risk of rapid ADPKD progression. Talk to your doctor to learn more.

Please read **IMPORTANT SAFETY INFORMATION** on pages 4-5.

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# INDICATION and IMPORTANT SAFETY INFORMATION for **JYNARQUE**<sup>®</sup> (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 |
| -loss of appetite                                 | -fever    | part of the eye (jaundice)       |
| -nausea   | -rash     | -dark urine                      |
| -right upper stomach (abdomen) pain or tenderness | -itching  |                                  |

**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 Tolvaptan for ADPKD Shared System Risk Evaluation and Mitigation Strategy (REMS).**

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

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

### **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](http://www.fda.gov/medwatch)).

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



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## Still have **QUESTIONS** about rapidly progressing ADPKD and **JYNARQUE®** (tolvaptan)?

The JYNARQUE community at Otsuka is here to help

**Otsuka Connect Representatives are here to help support you.**

To speak with a representative, call Otsuka Connect at **1-833-468-7852**, Monday through Friday, 8 AM to 8 PM eastern time, excluding holidays.

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

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