

# Talking with your doctor about the future of your disease

You may be at risk for fast-progressing ADPKD, so now is a good time to talk to your doctor about your disease progression and whether JYNARQUE® (tolvaptan) is right for you. JYNARQUE is proven to slow kidney function decline in adults who are at risk for rapidly progressing ADPKD.

**Be sure to share the risk factors you have identified with your doctor so you can talk about next steps. Since you are male and 1 or more of these is true for you, you may be at risk for fast-progressing ADPKD.**

High blood pressure (hypertension) that started before age 35

Blood in your urine (hematuria) before age 35

A family history of kidney failure before age 58

If you have any family members who've reached kidney failure before age 58, list their name(s) and relationship to you here:

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A fast drop in your eGFR (kidney function) or increase in your creatinine levels

Kidneys larger than normal for a person your age with ADPKD (high total kidney volume)

Male (Men are at higher risk for fast-progressing ADPKD.)

**On the next page are some suggestions on what to discuss with your doctor.**

*ADPKD=autosomal dominant polycystic kidney disease. eGFR=estimated glomerular filtration rate, a measure of kidney function.*

## **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 4-5.



# Starting an empowered conversation

Sometimes, your doctor may not be as close to your disease as you are. Here are some ways you can get the most out of your appointment.



## Talking to your primary care doctor?

- Discuss your family history of kidney disease using the list on the previous page
- Talk about seeing a kidney specialist, like a nephrologist (*see below*)
- Let your doctor know there may be a treatment option available for you
  - Talk to a specialist to learn more
  - Find a doctor certified to prescribe JYNARQUE® (tolvaptan) at [JYNARQUE.com/doctor-search](https://www.jynarque.com/doctor-search)



## Talking to your nephrologist?

- Discuss your family history of kidney disease using the list on the previous page
- As you talk about the risk factors you have related to fast-progressing ADPKD, discuss whether you should have imaging done to find out more about the size of your kidneys (total kidney volume, also known as TKV)
- Talk about whether you should make an appointment with a radiologist, the doctor who conducts imaging tests

**Remember, you have a right to know everything about your healthcare. Never hesitate to ask about something you might not understand, or to voice any concerns you might have.**

Go to [About ADPKD](https://www.jynarque.com/about-adpkd) at JYNARQUE.com for more information on disease progression.

### **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 4-5.



## Notes

If you have any questions or concerns before talking with your doctor, you can list them here. Be sure to take as many notes as possible during your appointment. It can be helpful to bring a friend or family member with you so they can take notes while you speak with your doctor.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 4-5.



# 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

(continued on next page)

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

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
  - 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 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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Otsuka

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