

Getting Started on JYNARQUE[®] (tolvaptan)

Please read [IMPORTANT SAFETY INFORMATION.](#)

Preparing for JYNARQUE[®] (tolvaptan)

This resource can help with getting started if you and your doctor have decided that JYNARQUE, the **first-and-only** FDA-approved treatment to slow kidney function decline in adults who are at risk for rapidly progressing autosomal dominant polycystic kidney disease (ADPKD), is right for you.

Before you begin JYNARQUE, there are some things you need to know. Your doctor should tell you about the JYNARQUE **Risk Evaluation and Mitigation Strategy (REMS)** Program. The REMS Program was set up to help **reduce the risk of liver injury for people taking JYNARQUE**. Both you and your doctor are joining this safety program to help monitor your liver health together while you're taking JYNARQUE.

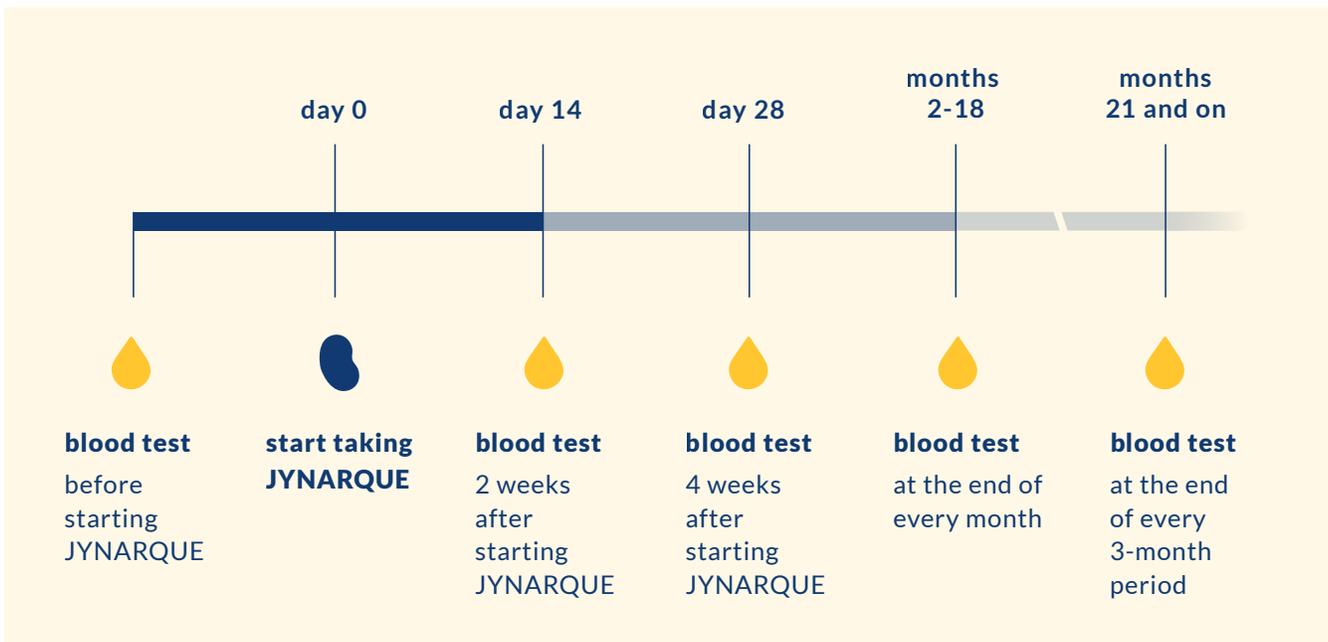
SELECT IMPORTANT SAFETY INFORMATION:

- **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

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Preparing for JYNARQUE[®] (tolvaptan)

- You and your doctor each sign a Patient Enrollment Form to enroll you in the REMS Program. You will need to complete this form to get JYNARQUE, so, if you haven't done it yet, talk to your doctor
- To reduce your risk of liver injury while taking JYNARQUE, it is required that you have a blood test before you start JYNARQUE, 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



To learn more about preparing for JYNARQUE, visit [JYNARQUE.com](https://www.jynarque.com)

Getting JYNARQUE[®] (tolvaptan)

- Once your doctor has enrolled you in the JYNARQUE REMS Program, he or she can write you a prescription for JYNARQUE
- Your doctor will send your prescription to a pharmacy that is REMS-certified to sell JYNARQUE. That pharmacy will deliver JYNARQUE right to your door

allianceRx
Wellness + PRIME

1-800-480-9052

Avella
Specialty Pharmacy

1-877-719-6330

PANTHER[®]
SPECIALTY PHARMACY

1-833-599-2245

- If you would like your doctor to send your prescription to a particular REMS-certified pharmacy, please let him or her know. If you're not sure which pharmacy will be delivering your JYNARQUE, remember to ask your doctor
- Your doctor may also ask you to sign a different form to make sure you have the opportunity to benefit from services that can support you as you take JYNARQUE

How JYNARQUE is packaged

JYNARQUE comes in weekly blister packs, labeled with the days of the week

The morning and afternoon doses are clearly labeled "AM" and "PM"

	SUN	MON	TUE	WED	THU	FRI	SAT
AM	<input type="checkbox"/>						
PM	<input type="checkbox"/>						

JYNARQUE comes in 3 dose combinations



Paying for JYNARQUE[®] (tolvaptan)

Otsuka, the maker of JYNARQUE, is committed to helping patients get access to the medication they need, and created MyPASS—My Personalized ADPKD Support Service™—just for patients like you.



With MyPASS, you will get more support from your REMS-certified pharmacy.

If you are a commercially insured patient without other coverage, you may pay no more than \$2.50 per week with the JYNARQUE Copay Savings Program.*

You can sign up for MyPASS using a form from your doctor or online at j-mypass.com or call 1-833-J-MYPASS.

Don't have insurance or need help affording your JYNARQUE tablets?

Call 1-855-727-6274 to learn more about your options.

Lab testing support*

Patients taking JYNARQUE can get their monthly lab tests for free. Talk to your doctor to find out more.

*For eligible commercially insured patients. Further conditions apply. 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.

Please read [IMPORTANT SAFETY INFORMATION](#).

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

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IMPORTANT SAFETY INFORMATION (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).

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