

Getting JYNARQUE[®] (tolvaptan)

What you need to know

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

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



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.

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 14-15.

Congratulations

on taking a new step in
managing your ADPKD with
JYNARQUE[®] (tolvaptan)

In this brochure, you'll find what you need to know about getting JYNARQUE. You can visit JYNARQUE.com for more information and to sign up for JYNARQUE email updates.

Let's get started!

How will I get my JYNARQUE[®] (tolvaptan)?

JYNARQUE will be delivered directly to your door by a REMS-certified specialty pharmacy.

A specialty pharmacy is different from a regular pharmacy. Your specialty pharmacy will deliver your medication directly to you wherever you are in the United States. They also offer clinical and educational support tailored to your needs, including help taking JYNARQUE and reminders about your lab tests and refills.



1-800-480-9052



1-877-719-6330



1-833-599-2245

If you don't know which pharmacy you'll be using, ask your doctor.

REMS=Risk Evaluation and Mitigation Strategy.

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

The process for getting JYNARQUE will include a few conversations with your pharmacy to discuss your treatment:

Soon after you are prescribed JYNARQUE, your pharmacy will reach out to you. So, answer the phone if you get a call from a number you don't recognize. It might be the pharmacy trying to reach you.

The pharmacy will discuss how you prefer to be contacted and lay out a plan to help you begin JYNARQUE when it is sent to you.

After your first prescription, your pharmacy will reach out to you once a month to arrange refills. To make sure you get their calls, you may want to add the number to your contacts.

TIP:

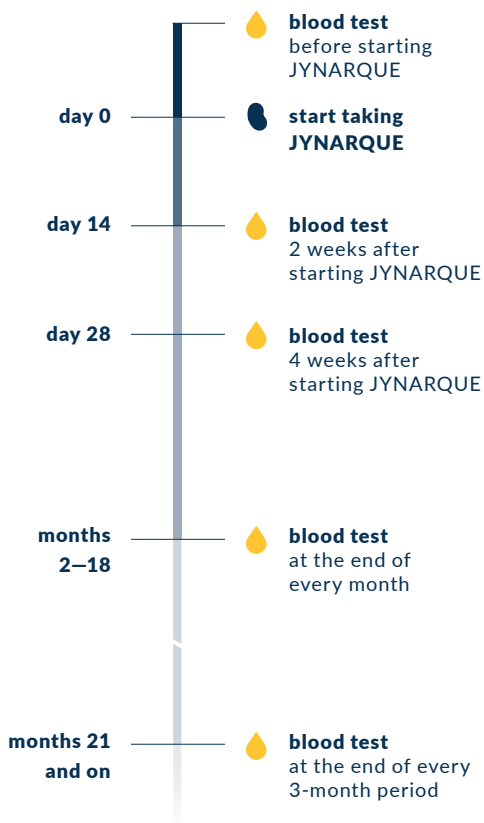
Work with your doctor and your pharmacy to find out how your insurance plan can cover JYNARQUE. This may take more than one try to complete.

How will I get my JYNARQUE® (tolvaptan)? (cont'd)

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 do a blood test every 3 months to be able to continue on JYNARQUE.



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

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

By now, you and your doctor should have joined the JYNARQUE REMS Safety Program to help reduce your risk of liver injury when taking JYNARQUE.

In clinical trials, about 5% of people taking JYNARQUE and 1% of people taking placebo experienced signs of liver injury.

Within 1 to 4 months after JYNARQUE was stopped, there was no longer any sign of liver injury.

Your specialty pharmacy will only send your JYNARQUE if you and your doctor are monitoring your liver health. Your blood tests must be completed regularly to get JYNARQUE.

TIP:

Talk to your doctor's office about setting up your blood tests before you leave!

What can Otsuka Patient Support help with?



Otsuka Patient Support is a program dedicated to helping people with ADPKD throughout their treatment with JYNARQUE® (tolvaptan).

Eligible patients pay no more than \$10 per month for JYNARQUE.*

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

**Assumes one 28-day supply prescription per month. If more than one prescription is filled in a calendar month, you may pay more than \$10 in that month. 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.*

Otsuka Patient Support can also help with:

- no-cost medication if there are delays with your insurance coverage
- laboratory testing support

Lab testing support

- You will need to get regular lab testing done while taking JYNARQUE. Otsuka Patient Support has partnered with the 2 largest national laboratories to help make sure patients taking JYNARQUE can get their monthly lab tests for free
- It is important that you ask your doctor to sign up for an Otsuka Patient Support program account to get you access to free lab tests[†]

TIP:

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

Call 1-855-727-6274 or visit otsukapatientassistance.com to learn more.

[†]**ELIGIBILITY CRITERIA:** Only patients treated with JYNARQUE are eligible for this program. Patients must be enrolled in the JYNARQUE REMS Program to be eligible for this program. 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 14-15.

How does JYNARQUE® (tolvaptan) arrive?

Once you have completed your REMS enrollment and confirmed delivery with your specialty pharmacy, your JYNARQUE Welcome Kit should be on its way!

The Welcome Kit is a box of materials created especially for ADPKD patients. In it will be your first shipment of JYNARQUE.



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

How do I take JYNARQUE?

**You and your doctor will work to find the
JYNARQUE dose that is right for you.**

The starting dose of JYNARQUE is 60 mg/day



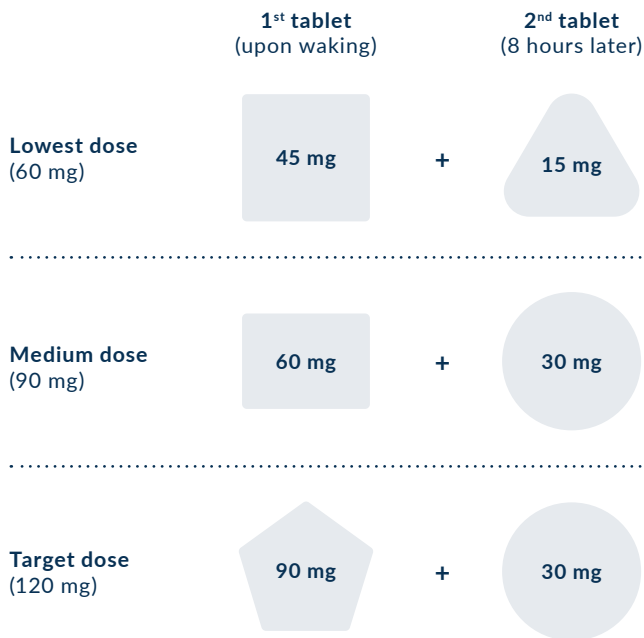
*JYNARQUE comes in 3 dose combinations: 60 mg per day,
90 mg per day, and 120 mg per day*

- Take JYNARQUE twice a day, unless advised otherwise by your doctor
- Your doctor might increase your dose of JYNARQUE to make sure it's doing the most it can
- It is important to take both JYNARQUE doses 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

How do I 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 dose combinations of JYNARQUE are available*:



*Tablets are not shown at actual size.

TIP:

Taking your second dose 8 hours after the first can help reduce the need to wake up to urinate.

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

Who should not take JYNARQUE?

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?

If you have been taking JYNARQUE but are having trouble with side effects, talk to your doctor, nurse, or pharmacist to see if they have ideas that can help. You can also visit [JYNARQUE.com](https://www.jynarque.com) for some helpful resources.

INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

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 - 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

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IMPORTANT SAFETY INFORMATION (cont'd)

- 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
 - 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.

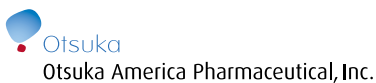
To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

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Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.
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