

Are you and your doctor considering JYNARQUE[®] (tolvaptan)?

Learn the basics

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

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

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

What can JYNARQUE® (tolvaptan) do?



JYNARQUE may help change the course of your disease

JYNARQUE is the first-and-only FDA-approved treatment proven to slow kidney function decline in adults who are at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

In a clinical study of ADPKD patients with chronic kidney disease (CKD) stages 2-4,

the speed of decline was slowed by

35%

with JYNARQUE vs placebo

In a clinical study of ADPKD patients with CKD stages 1-3,

the speed of decline was slowed by

26%

with JYNARQUE vs placebo

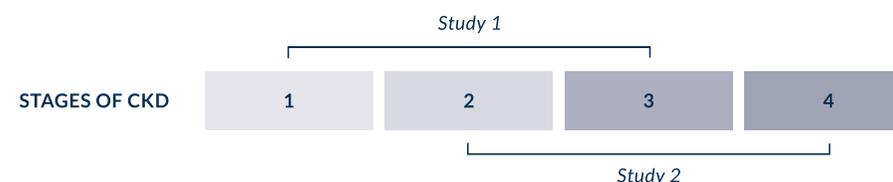


Patients taking JYNARQUE had less kidney pain

36% fewer pain events in a clinical trial of ADPKD patients with CKD stages 1-3.

JYNARQUE works at different stages of the disease

JYNARQUE is appropriate for adults with ADPKD at stages 1-4 of CKD who are at risk of rapidly progressing disease. Whether your glomerular filtration rate (GFR) is 90 or 30, JYNARQUE may help.



Visit [JYNARQUE.com](https://www.jynarque.com) to get more detailed information about what JYNARQUE does.

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 18-19.

What is “fast-progressing ADPKD”?



ADPKD causes cyst growth in the kidneys that gets worse as time goes on



ADPKD gets worse at different rates in different people

People with fast-progressing or rapidly progressing ADPKD will reach end-stage renal disease (ESRD) at a younger age than other patients with ADPKD.

With fast-progressing ADPKD, kidney function gets worse and cysts grow more quickly, leading to earlier kidney failure

Larger kidneys can lead to earlier high blood pressure, more pain, earlier kidney damage, and early kidney failure.

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

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.

You may be at greater risk for fast-progressing ADPKD if you:

- Have high blood pressure before age 35
- Have blood in the urine before age 35
- Have a family history of kidney failure before age 58
- Experience a fast drop in GFR
- Are male
- Have certain types of inherited genetic mutations
- Have kidneys that are larger than normal for a person your age with ADPKD

TIP:

Work with your doctor to learn more about how your kidneys look and how fast your disease is progressing.

This could include your doctor using magnetic resonance imaging (MRI) to get a more detailed picture of your kidneys.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

How does JYNARQUE® (tolvaptan) work?

JYNARQUE works by blocking vasopressin

For people with ADPKD, JYNARQUE targets the mechanisms that may lead cysts to grow.

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

This is necessary for proper cell function.

People with ADPKD have **too much** vasopressin, which causes cyst growth.

JYNARQUE works by blocking vasopressin. This makes it harder for cysts to grow.

For illustration purposes only.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

What other effects does this have?

Other effects of blocking vasopressin on the body

In normal kidneys, vasopressin helps control the amount of water in your body. When vasopressin is blocked by JYNARQUE, your body holds on to less water. This could make you thirstier and cause you to urinate more.

If you experience thirst and urination, it is a sign of JYNARQUE acting in the kidneys. Learn more on [page 12](#).

JYNARQUE may cause other side effects, including serious ones such as liver injury, too much sodium in your blood (hyponatremia), and loss of too much body fluid (dehydration). **Read the next few pages for more details about these serious side effects.**

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

What would be required to get JYNARQUE® (tolvaptan)?

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

Because JYNARQUE can cause serious and potentially fatal liver injury, the JYNARQUE Risk Evaluation and Mitigation Strategy (REMS) Program was set up to help reduce this risk for people taking JYNARQUE.

You and your doctor will need to join a safety program to reduce your risk of liver injury. Also, JYNARQUE is only available from REMS-certified pharmacies.

In clinical trials:



5% of people taking JYNARQUE experienced signs of liver injury

1% of people taking placebo experienced signs of liver injury



After JYNARQUE was stopped, signs of liver injury typically reversed within 1 to 4 months

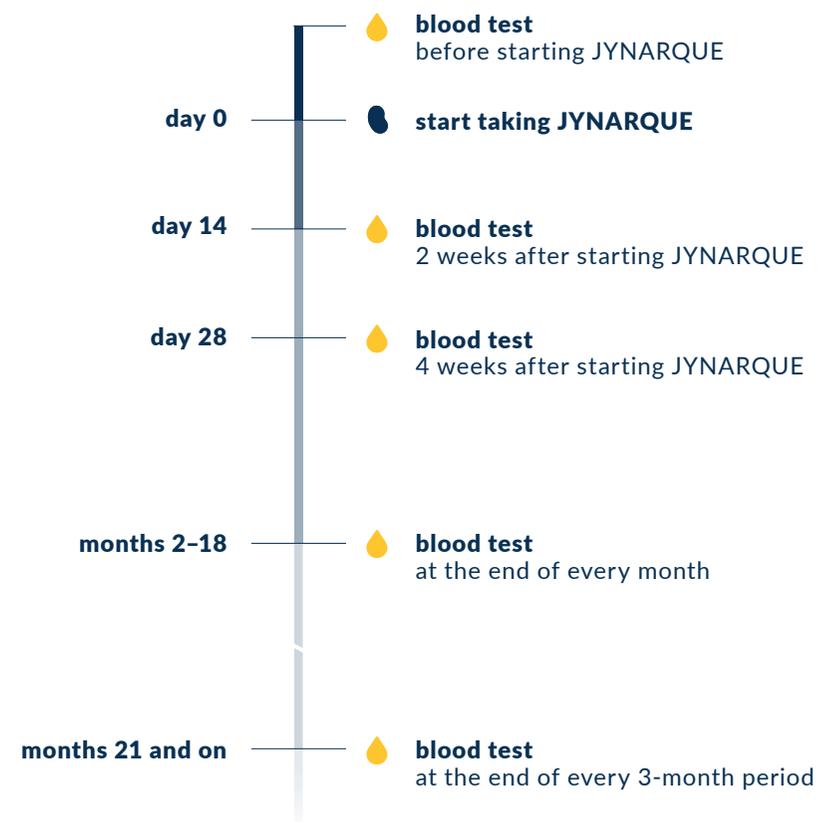
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 - feeling tired
 - loss of appetite
 - nausea
 - right upper stomach (abdomen) pain or tenderness
 - vomiting
 - fever
 - rash
 - itching
 - yellowing of the skin and white part of the eye (jaundice)
 - dark urine

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.

After the first 18 months, you will only need to do a blood test every 3 months to be able to continue on JYNARQUE.



Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

How do I enroll in the JYNARQUE® (tolvaptan) REMS Safety Program?

Only a REMS-certified doctor can enroll you in the program

There are 2 ways your doctor can do this:



Give your doctor's office your email address to sign up online.

- You will get 2 emails from jynarquerems@unitedbiosource.com. One will have a link and another will have a temporary password
- Click on the link and enter the password to access a secure site where you can add your signature using your finger or a computer mouse

The email address you provide will only be used for your REMS signup and no other purpose.



If you do not have an email address, you can sign a paper form in your doctor's office.

What are the possible side effects with JYNARQUE?

Serious side effects may include:

Liver injury. Learn more about liver injury and the JYNARQUE REMS Safety Program on page 8.

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

Call your healthcare provider right away if you have any of the above symptoms.

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 18-19.

What are the most common side effects with JYNARQUE® (tolvaptan)?

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

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

In a clinical study, most people adjusted to taking JYNARQUE and were able to continue treatment. For people who took JYNARQUE in clinical trials, the first 2-4 months were critical to seeing if they could adjust to these side effects.

- In a clinical study of patients with CKD stages 2-4, after the first 5 weeks, these side effects were reported less often

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.

SELECT IMPORTANT SAFETY INFORMATION:

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

In clinical studies,

About 2 in 3 people (64%) felt thirsty while taking JYNARQUE

About 3 in 4 people (70%) had increased urination, including needing to wake up from sleep to urinate, urinating greater amounts, and urinating more often during the day

Practical step:



Try taking a water bottle with you everywhere so you always have something to drink. Be sure to drink water to stay hydrated and not other drinks

Practical step:



Wherever you go, plan ahead by finding out where the restrooms are

Practical step:



Take your first JYNARQUE dose upon waking and the second dose exactly 8 hours later and you may be able to reduce the need to wake up to urinate

Do not drink grapefruit juice during treatment with JYNARQUE. This could cause you to have too much tolvaptan in your blood.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

Is JYNARQUE® (tolvaptan) covered by insurance?

Work with your doctor and your pharmacy to find out how your plan can cover JYNARQUE. There are a few ways you can check on your own:



Check your insurance company's website

There, you can see a list of what your plan covers.



Read your Summary of Benefits and Coverage

You can get this from your insurance company.



Call your insurance company

Make sure to have your information ready when you call.



Review your documents

This information may be included in documents mailed to you by your insurance company.



Know your code

What your insurance covers might depend on your ICD-10 code, which your doctor's office uses on your prescription.

Remember, JYNARQUE is only approved for adults with rapidly progressing ADPKD, so the correct ICD-10 code is the one that includes the adult designation.

Q61.2 Polycystic kidney, adult type = ADPKD*

If you are prescribed JYNARQUE, it will be delivered directly to your door by a REMS-certified specialty pharmacy

For more information on specialty pharmacies visit [JYNARQUE.com](https://www.jynarque.com).

**This resource is provided for informational purposes only and does not guarantee that billing codes will be appropriate or that coverage and reimbursement will result. Providers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended as legal advice or a substitute for a provider's independent professional judgment.*

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

Need help paying for JYNARQUE® (tolvaptan)?



Otsuka, the maker of JYNARQUE, is committed to helping people with ADPKD

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

Copay support

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

**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.*

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 18-19.

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 eligible patients taking JYNARQUE can get their monthly lab tests for free
- Ask your doctor to sign up for an Otsuka Patient Support program account to get you access to free lab tests†

†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.

SELECT IMPORTANT SAFETY INFORMATION:

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

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:

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- 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.

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- 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](#).

What's the next step with JYNARQUE® (tolvaptan)?

If you and your doctor decide JYNARQUE is right for you, your doctor will give you the **Getting JYNARQUE® (tolvaptan)** resource to explain how you'll receive your JYNARQUE. Also, you'll receive a **Welcome Kit** that goes into more detail about treatment with JYNARQUE, along with continued support from your specialty pharmacy.

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

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