



JYNARQUE®
(tolvaptan) tablets

Getting ready to start treatment with JYNARQUE® (tolvaptan)

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).

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 16 and 17.

Not an actual patient.



An important step in managing your ADPKD



Not an actual doctor or patient.

The choice to begin treatment with JYNARQUE® (tolvaptan) marks a new step in your journey with ADPKD. With JYNARQUE, you can help slow kidney function decline.

You may have some questions about treating your ADPKD with JYNARQUE, and about how to manage the effects of your new treatment. This brochure will help answer some of those questions.

As always, your doctor should be your main source of information about JYNARQUE. If you have any additional questions, please talk to your doctor, pharmacist, or another member of your treatment team.

ADPKD=autosomal dominant polycystic kidney disease.

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

Please read **IMPORTANT SAFETY INFORMATION** on pages 16 and 17.

Before you receive your medication, keep in mind:



It may take 2-3 weeks to process your prescription once your doctor has sent it to the pharmacy.



When your prescription is ready, you'll receive a welcome call from your specialty pharmacy.

- In the future, expect a monthly call from your specialty pharmacy regarding your prescription refill
- Save your specialty pharmacy number so you don't miss their calls



There may be a copay support program to reduce your out-of-pocket costs. Be sure to ask your specialty pharmacy if you are eligible.



After your prescription is approved for shipment, you will receive your medication and a welcome kit of resources.



The Patient Experience Program is designed to support you on your treatment journey. You will have access to multiple programs and services from Otsuka, such as:

- Personal support
- Communications and resources
- Copay assistance

To enroll in the Patient Experience Program, scan the QR code or visit PatientExperienceProgram.com.



Patient Experience Liaisons (PELs), licensed healthcare professionals, are available in-person and via phone and email to support you through your treatment journey.

They can help you with:

- The REMS (Risk Evaluation and Mitigation Strategy) Program
- Treatment access steps
- Insurance questions and support
- Specialty Pharmacy Process

You can contact a PEL or arrange a meeting by calling Otsuka Connect at **1-833-468-7852**. PELs are available from 9AM to 5PM.



For more information, visit otsukapatientssupport.com or call **1-833-468-7852**.

What to expect

Knowing what to expect as you're preparing to take JYNARQUE® (tolvaptan) will help you stay motivated and stay on track.

Here is a brief, weekly overview of your first 5 weeks on treatment.

Week 1

- Try to start your first dose on a non-workday or on the weekend so you have flexibility to adjust your routine
- Tell your doctor when you start your first dose so your doctor's office can order your first blood test
- Talk to your family about how your schedule and lifestyle will be affected after starting JYNARQUE. For example, you'll be drinking a lot of water and will need to use the restroom more frequently

Week 2

- Schedule your first blood test for 14 days after starting JYNARQUE. Please refer to [page 7](#) for more details about when to schedule your blood test
- Allow some time to adjust to your new routine and reach out to your family, friends, and PEL for support

Weeks 3 and 4

- Schedule your second blood test for 28 days after starting JYNARQUE
- More than 95% of people adjust to JYNARQUE within the first weeks of treatment

Week 5

- By week 5, you may still be adjusting to treatment and your new routine
- You'll be switching to monthly blood tests for the following 18 months, and then every 3 months thereafter

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 16 and 17.

Specialty pharmacies

JYNARQUE® (tolvaptan) is available exclusively through 3 REMS-certified pharmacies. Unlike other medications that can be picked up at a traditional pharmacy, when prescribed JYNARQUE, your prescription will be sent to a specialty pharmacy and delivered directly to you. And what really makes these pharmacies special is that they also offer clinical and educational support, including help with taking JYNARQUE, and reminders about lab tests and refills.

Save your pharmacy's phone number so you don't miss any of their calls and have it easily accessible when you have questions. Pharmacists are available 24/7, and translators are available upon request.

Walgreens
Specialty Pharmacy
walgreensspecialtyrx.com
Phone: [\(800\) 480-9052](tel:8004809052)

Optum
Specialty.OptumRx.com
Phone: [\(877\) 719-6330](tel:8777196330)


PANTHER
RAREX
pantherxrare.com
Phone: [\(833\) 599-2245](tel:8335992245)

Most people adjust to JYNARQUE after the first few weeks of treatment. Below are some reminders that will help make starting treatment easier and more manageable.



Before you first start JYNARQUE, think about when to take your first dose. Try to schedule it on a day when you don't have work, or on the weekend, when you have more time.



You may experience excessive thirst and frequent urination while taking JYNARQUE, but there are practical steps you can take. See [page 13](#) for ways to help you stay on track.



Talking to your family and researching together about how your lifestyle will change after starting JYNARQUE will help educate them about ADPKD and help them learn how to better support you as you adjust your day-to-day routine.



There are several support resources available to you—online resources, apps, etc. Learn more about the tools available to you, like bathroom finder apps, on [page 15](#).



If you have any questions, especially if they are health related, reach out to your doctor first. For additional support, contact your PEL.

You and your doctor have joined a safety program to help reduce your risk of liver injury

Your doctor will need to monitor your liver health while you are taking JYNARQUE. JYNARQUE can cause serious and potentially fatal liver injury.



The Tolvaptan for ADPKD Shared System REMS was set up to help reduce this risk of serious liver injury for people taking JYNARQUE.

- In time, after JYNARQUE was stopped, there was no longer any sign of liver injury

SELECT IMPORTANT SAFETY INFORMATION:

Tell your healthcare provider about all your medical conditions, including if you:

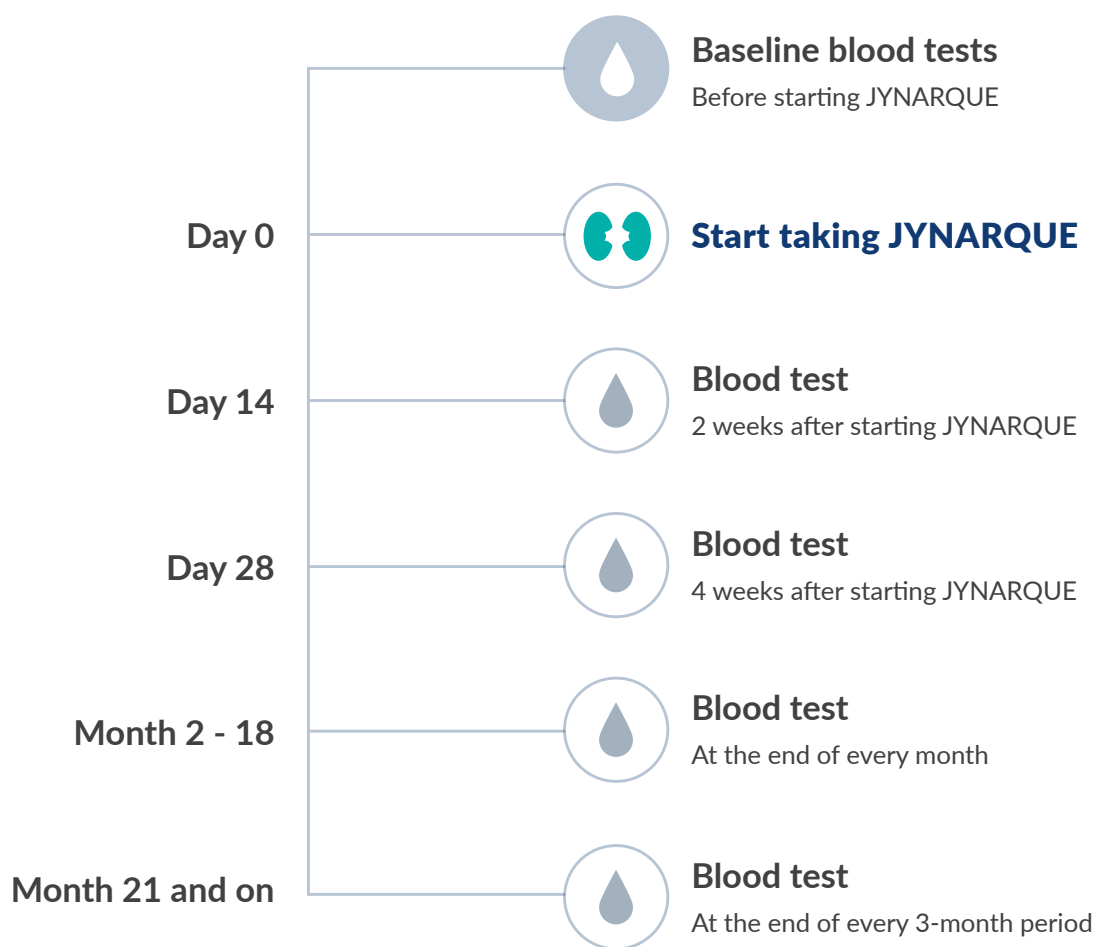
- have a history of sodium (salt) levels that are too low
- are pregnant or plan to become pregnant. It is not known if tolvaptan will harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant
- are breastfeeding or plan to breastfeed. It is not known 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 16 and 17.

Scheduling your required blood tests

To reduce the risk of liver injury while taking JYNARQUE® (tolvaptan), blood tests are required at initiation, and again 2 weeks and 4 weeks after starting treatment.

- Then, for the following 18 months of treatment with JYNARQUE, blood tests will be needed monthly
- When that is done, you will only need to have a blood test every 3 months to be able to continue on JYNARQUE



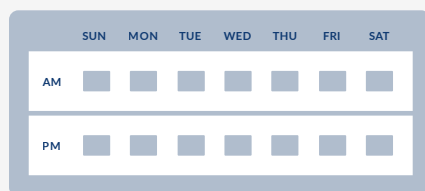
Use the **REMS calendar** to keep track of **when** you should schedule your blood tests.
Download the calendar at jynarque.com/downloadable-resources#calendar or scan the QR code.

You and your doctor will work together to find the JYNARQUE dosage that is right for you

Take JYNARQUE twice a day, unless advised otherwise by your doctor.

- Your doctor might increase your dose of JYNARQUE during your treatment journey
- It is important to take both JYNARQUE doses as prescribed
- 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

JYNARQUE comes in weekly blister packs, labeled with the days of the week. The morning and afternoon doses are clearly labeled “AM” and “PM.”



Take the first dose upon waking; take the second dose 8 hours later. Taking your second dose 8 hours after the first can help reduce the need to wake up to urinate.

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

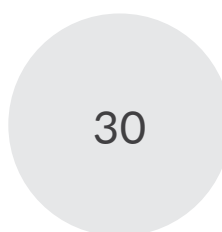
Please read **IMPORTANT SAFETY INFORMATION** on pages 16 and 17.

Dosage for JYNARQUE® (tolvaptan)

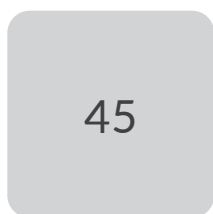
JYNARQUE comes in 5 dose strengths*



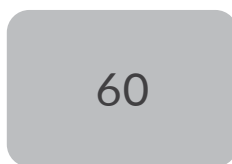
15-mg tablet
Triangular



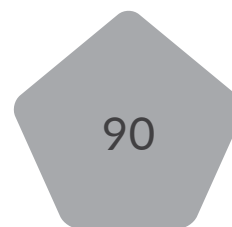
30-mg tablet
Round



45-mg tablet
Square



60-mg tablet
Rectangular



90-mg tablet
Pentagonal

Your doctor will determine which combination is right for you.

*Not actual size.

ADPKD is an inherited disease

You may want to talk about JYNARQUE with your family members



Not actual patients.

- If you are comfortable talking to your family members about your ADPKD treatment plan, this information might help them understand what you're going through
- Sharing your experiences with JYNARQUE may help your family members learn about the medication you're taking
- Since ADPKD is an inherited disease, this may affect other family members as well. It may be helpful for them to discuss their family's medical history of ADPKD with their doctor

JYNARQUE® (tolvaptan) may cause serious side effects

Serious side effects may include:

- **Liver injuries.** Learn more about liver injuries and the **Tolvaptan for ADPKD Shared System Risk Evaluation and Mitigation Strategy (REMS)** on [page 6](#)
- **Too much sodium in your blood (hyponatremia) and loss of too much body fluid (dehydration).** 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.

JYNARQUE has been studied in over 3000 patients with ADPKD



Not an actual doctor or patient.

The most common side effects of JYNARQUE® (tolvaptan) may take some lifestyle adjustments

JYNARQUE may cause side effects, including **excessive thirst and urination**. These side effects are related to how JYNARQUE works in the kidneys.



Why does this happen?

In normal kidney cells, a hormone called vasopressin helps to control the amount of water in your body. When you take JYNARQUE, vasopressin is blocked, causing your body to hold on to less water; this could make you feel thirsty and give you the urge to urinate.

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

Please read **IMPORTANT SAFETY INFORMATION** on pages 16 and 17.

Prepare for the most common side effects of JYNARQUE® (tolvaptan) with these practical steps

PRACTICAL STEPS



Try taking a water bottle with you everywhere you go, so you always have something to drink



Wherever you go, plan ahead by finding nearby restrooms.

For helpful tools, like **the bathroom finder app**, **scan the QR code** or visit jynarque.com/online-resources



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

Lifestyle tips

Taking JYNARQUE® (tolvaptan) may change the course of your disease. But it will likely mean lifestyle changes, too. Here are some tips that might help you get adjusted.



SPEAK UP

- Talk to your doctor to make sure you know exactly how to take JYNARQUE
- Tell your entire healthcare team and pharmacist that you are taking JYNARQUE
- If you feel comfortable, you may want to talk to people you know about your treatment, including the need for water and frequent bathroom visits



KEEP TO A SCHEDULE

- Set a recurring event in your calendar to remind you when lab testing and other appointments are scheduled
- Set alarms on your phone to help remind you when to take JYNARQUE
- Helpful resources that may help you keep to a schedule like the Lab Test Reminder Calendar or Healthy Living app are available at: jynarque.com/downloadable-resources or scan this QR code



MAKE A PLAN

- Download an app you can use to find nearby restrooms while traveling
- Keep extra water bottles handy—in the office, at home, and in the car
- Make sure to urinate before meetings, dinner time, movies, or other social events

SELECT IMPORTANT SAFETY INFORMATION:

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.

Please read **IMPORTANT SAFETY INFORMATION** on pages 16 and 17.

Helpful resources and links

JYNARQUE® (tolvaptan)

- [About JYNARQUE](#)
- [REMs Program](#)
- [Copay Assistance](#)

ORGANIZATIONS AND EDUCATION



pkdcure.org



NATIONAL KIDNEY
FOUNDATION®

kidney.org



American Kidney Fund®
FIGHTING ON ALL FRONTS

kidneyfund.org

SUPPORT AND MENTORING

- [PKD Foundation Peer Mentor Program](#)
- [NKF Peers](#)
- [American Association of Kidney Patients](#)
- [American Kidney Fund](#)

[Lifestyle Apps](#)

- [Flush: Toilet Finder & Map](#)
- [Toilet Finder](#)
- [H2O Overload: Fluid Control for Heart-Kidney](#)

This is not an exhaustive list.



Scan this QR code to find more
information on some [lifestyle tips](#) or visit
jynarque.com/tips-while-on-treatment

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 16 and 17.

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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 part |
| - loss of appetite | - fever | 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

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** continued on next page.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

- Taking JYNARQUE® (tolvaptan) 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).

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

For more information visit
JYNARQUE.com



Otsuka

Otsuka America Pharmaceutical, Inc.

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