

At a glance

Tips for managing the most common side effects of 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.

SELECT IMPORTANT SAFETY INFORMATION:

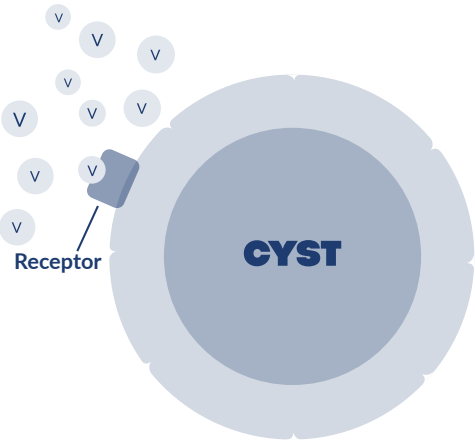
- **Serious liver problems.** JYNARQUE can cause serious liver problems that can lead to the need for a liver transplant or can lead to death. Stop taking JYNARQUE and call your healthcare provider right away if you get any of the following symptoms: feeling tired, fever, loss of appetite, rash, nausea, 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 page 4.

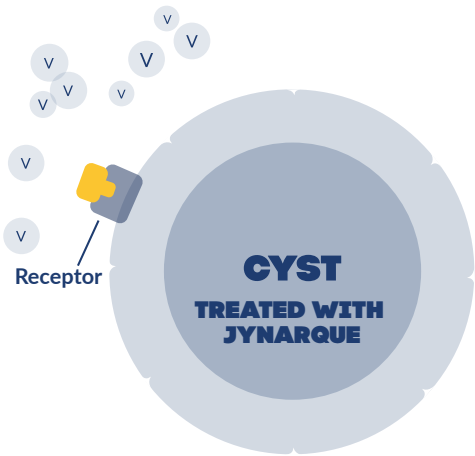


How JYNARQUE® (tolvaptan) works

- **Vasopressin** **V** is a hormone that helps the body retain water
- **People with ADPKD have too much vasopressin**, causing kidney cysts to grow



- **JYNARQUE** **T** prevents vasopressin from binding to the kidneys, slowing down cyst growth

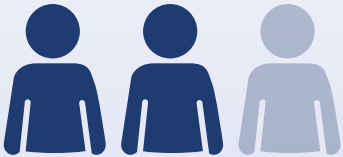


ADPKD=autosomal dominant polycystic kidney disease.

While on treatment, you may experience:

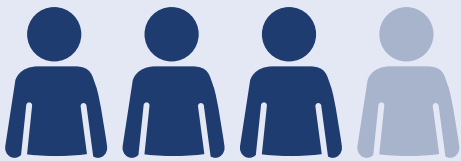
Excessive thirst and the need to increase your fluid intake.
This may affect almost:

2 out of 3 people (64%)



The need to urinate more frequently both day and night.
This may affect almost:

3 out of 4 people (70%)



A period of adjustment

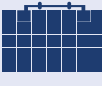
Most people **(95.8%)** adjust to JYNARQUE after the first few weeks.

Simple changes may help with increased thirst and urination

Time your doses



- Take JYNARQUE upon waking and the second dose exactly 8 hours later. This may reduce the need to urinate throughout the night



- Start treatment on a non-workday or weekend to help adjust



- Plan ahead! Find a restroom near where you'll be throughout the day. **Tip:** Download apps that can help you locate nearby restrooms while traveling. **Scan the QR code or visit www.jynarque.com/online-resources to learn more**



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 page 4.

Managing your fluids

JYNARQUE can cause you to feel thirsty and dehydrated—drink fluids when needed



To stay hydrated, drink when thirsty throughout the **day and night**



- Water is the best choice; avoid drinks with high sugar, fat, or caffeine content



It is very important that you discuss alcohol intake with your healthcare professional prior to starting JYNARQUE as alcohol is metabolized in the liver and is also dehydrating.

Making better food choices



- **Avoid extra salt and protein** in the diet as they may make you need to urinate more

- **Reduce your salt intake** to 2.3-3 grams per day

1 teaspoon of table salt



contains ~2.3 grams of sodium

- **Try to reduce the amount of protein you eat** to 0.8-1.0 gram per kilogram of your weight (1 kilogram is 2.2 pounds)
 - For a 150-pound adult (68 kilograms) that is 54-68 grams of protein daily

That's similar to having:



2 servings of salmon



or 4 blocks of firm tofu



or 2 cups of almonds

In general, each serving is about the size of a deck of cards



Tips while taking JYNARQUE



Set alarms or reminders for each dose



Download apps that can help you locate nearby restrooms while traveling



Carry a water bottle everywhere you go



Avoid sodas, fruit juices, and whole milk



Use less salt and high-sodium sauces in cooking. Use no-salt-added seasoning blends, fresh or dried herbs, and spices instead



Choose **plant-based proteins** over animal proteins, when possible. These include: beans, peas, lentils, nuts, nut butters, seeds, tofu, edamame and soy milk

Looking for more tips? Go to <https://www.jynarque.com/tips-while-on-treatment> for a deeper look into treatment side effects

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

INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

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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 of the eye (jaundice) |
| - loss of appetite | - fever | - dark urine |
| - nausea | - rash | |
| - 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
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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

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](tel:1-800-438-9927) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) (www.fda.gov/medwatch).

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

