

Keep your doses on schedule

Take JYNARQUE[®] (tolvaptan) on time

Take JYNARQUE when you first wake up. It's important to take your second dose of JYNARQUE 8 hours after the first one. The first dose of JYNARQUE is higher and the second is lower. JYNARQUE is taken in these split doses to make sure you have the best balance of it in your body and to help you avoid waking up to urinate. Take JYNARQUE exactly as your doctor tells you to.

Be sure to drink enough water so that you will not get thirsty or become dehydrated. If you miss a dose of JYNARQUE, take the next dose at your regular time.

JYNARQUE is proven to slow kidney function decline in adults who are at risk for rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

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.

This chart can help you remember when to take your second daily dose.

Higher dose tablet (<i>upon waking</i>)	Lower dose tablet (<i>8 hours later</i>)
5 AM	1 PM
6 AM	2 PM
7 AM	3 PM
8 AM	4 PM
9 AM	5 PM
10 AM	6 PM
11 AM	7 PM
12 PM (noon)	8 PM
1 PM	9 PM
2 PM	10 PM
3 PM	11 PM
4 PM	12 AM (midnight)
5 PM	1 AM
6 PM	2 AM
7 PM	3 AM
8 PM	4 AM
9 PM	5 AM
10 PM	6 AM
11 PM	7 AM
12 AM (midnight)	8 AM
1 AM	9 AM
2 AM	10 AM
3 AM	11 AM
4 AM	12 PM (noon)

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

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](#).