MEDICATION GUIDE
JYNARQUE® (jin-AR-kew)
(tolvaptan)
Tablets

What is the most important information I should know about JYNARQUE?

JYNARQUE can cause serious side effects, including:

- **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

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**

It is important to stay under the care of your healthcare provider during treatment with JYNARQUE.

Because of the risk of serious liver problems JYNARQUE is only available through a restricted distribution program called the Tolvaptan for ADPKD Shared System REMS.

- Before you start treatment with JYNARQUE, you must enroll in the Tolvaptan for ADPKD Shared System REMS. Talk to your healthcare provider about how to enroll in the program.
- JYNARQUE can only be dispensed by a certified pharmacy that participates in the Tolvaptan for ADPKD Shared System REMS. Your healthcare provider can give you information on how to find a certified pharmacy.

What is JYNARQUE?

JYNARQUE is a prescription medicine used to slow kidney function decline in adults who are at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

It is not known if JYNARQUE is safe and effective in children.

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. See the end of this Medication Guide for a complete list of ingredients in JYNARQUE.
- are unable to urinate.

Before taking JYNARQUE, tell your healthcare provider about all your medical conditions, including if you:

- have a history of sodium 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 breast-feeding or plan to breastfeed. It is not known if tolvaptan passes into your breast milk. Do not breastfeed during 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.
- Keep a list of your medicines to show your healthcare provider and pharmacist.

How should I take JYNARQUE?

- Take JYNARQUE exactly as your healthcare provider tells you to.
- Take JYNARQUE orally two times each day. Take the first dose of JYNARQUE when you wake up and take the second dose 8 hours later.
- 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.
- If you take too much JYNARQUE, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I 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.

What are the possible side effects of JYNARQUE?

JYNARQUE may cause serious side effects, including:

See "What is the most important information I should know about JYNARQUE?"

- **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
  - feel confused or weak

The **most common side effects** of JYNARQUE include:

- thirst and drinking more fluid than normal
- making large amounts of urine, urinating often and urinating at night

These are not all the possible side effects of JYNARQUE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store JYNARQUE?

JYNARQUE comes in a child-resistant package. Store JYNARQUE between 68°F to 77°F (20°C to 25°C).

Keep JYNARQUE and all medicines out of the reach of children.

General information about the safe and effective use of JYNARQUE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use JYNARQUE for a condition for which it was not prescribed. Do not give JYNARQUE to other people, even if they have the same symptoms you have. It may harm them.

What are the ingredients in JYNARQUE?

Active ingredient: tolvaptan

Inactive ingredients: corn starch, hydroxypropyl cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose, and FD&C Blue no. 2 Aluminum Lake as colorant.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan
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For more information about JYNARQUE, go to www.TolvaptanADPKDSharedREMS.com or call 1-866-244-9446.

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