

# Prescription Referral Form

Confidential - Protected Health Information

\*=required.

Please fax to preferred REMS-certified Specialty Pharmacy or visit [j-mypass.com/prescribe](http://j-mypass.com/prescribe) to fill out this form online.

## 1) Patient Demographic Information

First Name\* Last Name\* MI DOB\*

Address

City State: ZIP

Gender: M / F Preferred Language Email

Phone ( ) - Mobile ( ) -

Standard mobile carrier rates for voice and text messaging apply.

Check if there is a primary caregiver or an alternate contact. By completing the contact information on the right, the patient agrees that protected health information may be shared with the person named on the right and that the person named on the right agrees to be contacted by the Program in reference to the patient.

Caregiver/alternate Contact Name Relationship

Phone ( ) - Mobile ( ) -

Standard mobile carrier rates for voice and text messaging apply.

## 2) Patient Insurance Information

Check the box that applies:  Patient does not have insurance.  Patient has insurance coverage. **Copies of all medical and prescription insurance cards MUST be attached.**

## 3) Prescription Information

ICD-10 code:\*  Q61.2 (autosomal dominant polycystic kidney disease)  Other: \_\_\_\_\_

### Prescription:\*

Please note Specialty Pharmacy may dispense no more than 4 weekly blister packs at a time.

45-mg/15-mg JYNARQUE® (tolvaptan) tablets  
b.i.d., take one 45-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

4 weekly blister packs, 28-day supply, 56 tablets, Refill(s) \_\_\_\_\_

3 weekly blister packs, 21-day supply, 42 tablets, Refill(s) \_\_\_\_\_

2 weekly blister packs, 14-day supply, 28 tablets, Refill(s) \_\_\_\_\_

1 weekly blister pack, 7-day supply, 14 tablets, Refill(s) \_\_\_\_\_

60-mg/30-mg JYNARQUE® (tolvaptan) tablets  
b.i.d., take one 60-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

4 weekly blister packs, 28-day supply, 56 tablets, Refill(s) \_\_\_\_\_

3 weekly blister packs, 21-day supply, 42 tablets, Refill(s) \_\_\_\_\_

2 weekly blister packs, 14-day supply, 28 tablets, Refill(s) \_\_\_\_\_

1 weekly blister pack, 7-day supply, 14 tablets, Refill(s) \_\_\_\_\_

90-mg/30-mg JYNARQUE® (tolvaptan) tablets  
b.i.d., take one 90-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

4 weekly blister packs, 28-day supply, 56 tablets, Refill(s) \_\_\_\_\_

3 weekly blister packs, 21-day supply, 42 tablets, Refill(s) \_\_\_\_\_

2 weekly blister packs, 14-day supply, 28 tablets, Refill(s) \_\_\_\_\_

1 weekly blister pack, 7-day supply, 14 tablets, Refill(s) \_\_\_\_\_

Titration Directions (if needed)

Special Instructions

Known Food/ Drug Allergies

Rx Date\* NPI #\* Prescriber Name\*

Prescriber Signature\* Prescriber Signature\*

Brand Medically Necessary/Dispense as Written/Do Not Substitute

Prescriber's signature required (NO STAMPS).

May Substitute/Substitution Permissible

### Prescriber Authorization:

I certify that therapy with JYNARQUE® (tolvaptan) is medically necessary for this patient based on my best professional judgment, and I have reviewed the current Prescribing Information for the prescribed product. I certify that the information provided in this form is complete and accurate to the best of my knowledge and medical expertise. I understand that I may not delegate signature authority. I attest that I am not on the HHS/OIG list of Excluded Individuals and that I am presently authorized under State law to prescribe and dispense the requested medication.

Prescriber Signature\* Date\*

Prescriber's signature required (NO STAMPS).

## 4) Prescriber Information

Specialty:  Nephrology  Internal Medicine  Other: \_\_\_\_\_

Site Type:  Hospital/Institution  Clinical/Private Practice  Other: \_\_\_\_\_

Name\* Last Name\* MI

State License #\* DEA #

Site Name and Address

City\* State\* ZIP\*

Phone\* ( ) - Fax ( ) -

Office Contact Name (and contact information if different from above)

Please see **IMPORTANT SAFETY INFORMATION** on page 2.

For additional assistance, please contact 1-833-J-MYPASS.

September 2018

10US18EBP0271

# INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

## INDICATION:

JYNARQUE is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

## IMPORTANT SAFETY INFORMATION:

### WARNING: RISK OF SERIOUS LIVER INJURY

- **JYNARQUE (tolvaptan) can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported**
- **Measure transaminases (ALT, AST) and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months and every 3 months thereafter. Prompt action in response to laboratory abnormalities, signs, or symptoms indicative of hepatic injury can mitigate, but not eliminate, the risk of serious hepatotoxicity.**
- **Because of the risks of serious liver injury, JYNARQUE is available only through a Risk Evaluation and Mitigation Strategy program called the JYNARQUE REMS Program**

## CONTRAINDICATIONS:

- History, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease
- Taking strong CYP3A inhibitors
- With uncorrected abnormal blood sodium concentrations
- Unable to sense or respond to thirst
- Hypovolemia
- Hypersensitivity (e.g., anaphylaxis, rash) to JYNARQUE or any component of the product
- Uncorrected urinary outflow obstruction
- Anuria

**Serious Liver Injury:** JYNARQUE can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. To reduce the risk of significant or irreversible liver injury, assess ALT, AST and bilirubin prior to initiating JYNARQUE, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter.

**Hypertremia, Dehydration and Hypovolemia:** JYNARQUE therapy increases free water clearance which can lead to dehydration, hypovolemia and hypertremia. Instruct patients to drink water when thirsty, and throughout the day and night if awake. Monitor for weight loss, tachycardia and hypotension because they may signal dehydration. Ensure abnormalities in sodium concentrations are corrected before initiating therapy. If serum sodium increases above normal or the patient becomes hypovolemic or dehydrated and fluid intake cannot be increased, suspend JYNARQUE until serum sodium, hydration status and volume status parameters are within the normal range.

**Inhibitors of CYP3A:** Concomitant use of JYNARQUE with drugs that are moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, and conivaptan) increases tolvaptan exposure. Use with strong CYP3A inhibitors is contraindicated; dose reduction of JYNARQUE is recommended for patients taking moderate CYP3A inhibitors. Patients should avoid grapefruit juice beverages while taking JYNARQUE.

**Adverse Reactions:** Most common observed adverse reactions with JYNARQUE (incidence >10% and at least twice that for placebo) were thirst, polyuria, nocturia, pollakiuria and polydipsia.

### Other Drug Interactions:

- **Strong CYP3A Inducers:** Co-administration with strong CYP3A inducers reduces exposure to JYNARQUE. Avoid concomitant use of JYNARQUE with strong CYP3A inducers
- **OATP1B1/3 and OAT3 Transporter Substrates:** Patients who take JYNARQUE should avoid concomitant use with OATP1B1/B3 and OAT3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide), as the plasma concentrations of these substrates may be increased
- **BCRP Transporter Substrates:** Tolvaptan is an inhibitor of BCRP. Patients who take JYNARQUE, should avoid concomitant use with BCRP substrates (e.g., rosuvastatin)
- **V<sub>2</sub>-Receptor Agonist:** Tolvaptan interferes with the V<sub>2</sub>-agonist activity of desmopressin (dDAVP). Avoid concomitant use of JYNARQUE with a V<sub>2</sub>-agonist.

**Pregnancy and Lactation:** Based on animal data, JYNARQUE may cause fetal harm. In general, JYNARQUE should be discontinued during pregnancy. Advise women not to breastfeed during treatment with JYNARQUE.

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](http://www.fda.gov/medwatch)).

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.



Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.  
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA.  
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