JYNARQUE® (tolvaptan) Prescription Form for VA Patients

Risk Evaluation and Mitigation Strategy (REMS)-certified specialty pharmacy for VA
Before the prescription can be processed, the prescriber must enroll and certify in the JYNARQUE REMS Program and the patient must also be enrolled.

AllianceRx | Phone: (800) 480-9052 | Fax: (866)-320-2531 | **DUNS Number 141815931** | Hours (EST): M-F: 8AM – 7PM, Sat: 9AM – 1PM, Sun: closed

Forward completed form to the VA Pharmacy.
VA Pharmacy will fax completed form to AllianceRx at 1-866-320-2531.

Confidential - Protected Health Information ***=required.**

1) Patient Information

First Name* Last Name* MI

Gender: ☐ M ☐ F Preferred Language DOB*

Shipping Address*

City* State* ZIP*

Phone* ( ) - Mobile ( ) -

Standard mobile carrier rates for voice and text messaging apply.

2) Shipping Information

Ship to: ☐ VA Pharmacy ☐ Patient Address

3) VA Pharmacy Information

VA Name* DEA #*

Address* Payment Method: ☐ Credit Card (call purchasing contact) ☐ E-invoice Tungsten Network

City* State* Zip* Purchase Order #*

Primary Purchasing Contact* Secondary Purchasing Contact*

Phone* Fax* Phone* Fax*

Email* Email*

Primary Clinical Contact* Secondary Clinical Contact*

Phone* Fax* Phone* Fax*

Email* Email*

4) Prescriber Information

Specialty: ☐ Nephrology ☐ Internal Medicine ☐ Other:

Prescriber Name* Hospital/Clinic Name*

Address*

City* State* ZIP*

Office Contact Phone* Fax*

NPI #* State License #

5) Prescription Information

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

Dosing

☐ **45-mg/15-mg JYNARQUE® (tolvaptan) tablets**
NDC (7-Day Blister Card): 59148-087-07
NDC (28-Day Carton): 59148-087-28
b.i.d., take one 45-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

☐ **60-mg/30-mg JYNARQUE® (tolvaptan) tablets**
NDC (7-Day Blister Card): 59148-088-07
NDC (28-Day Carton): 59148-088-28
b.i.d., take one 60-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

☐ **90-mg/30-mg JYNARQUE® (tolvaptan) tablets**
NDC (7-Day Blister Card): 59148-089-07
NDC (28-Day Carton): 59148-089-28
b.i.d., take one 90-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

Dose reduction of JYNARQUE is recommended for patients while taking moderate CYP3A inhibitors (see Dosage and Administration [2.4]).
Patients should avoid grapefruit juice beverages while taking JYNARQUE.

Other Doses Available

☐ **15-mg/15-mg JYNARQUE® (tolvaptan) tablets**
NDC (7-Day Blister Card): 59148-0079-07
NDC (28-Day Carton): 59148-0079-28
b.i.d., take one 15-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

☐ **30-mg/15-mg JYNARQUE® (tolvaptan) tablets**
NDC (7-Day Blister Card): 59148-0080-07
NDC (28-Day Carton): 59148-0080-28
b.i.d., take one 30-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

Quantity

☐ 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) Rx Date*

Known Food/Drug Allergies Rx Needed By Date

Prescriber Name* ***Prescriber's signature required (NO STAMPS).***

Prescriber Signature* Prescriber Signature*

Brand Medically Necessary/Dispense as Written/Do Not Substitute *May Substitute/Substitution Permissible*

6) Prescriber Signature

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* (no stamps) Date:

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

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.

Hypernatremia, Dehydration and Hypovolemia: JYNARQUE therapy increases free water clearance which can lead to dehydration, hypovolemia and hypernatremia. 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
- **V_2-Receptor Agonist:** Tolvaptan interferes with the V_2-agonist activity of desmopressin (dDAVP). Avoid concomitant use of JYNARQUE with a V_2-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).

Please see FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

Otsuka

Otsuka America Pharmaceutical, Inc.

June 2021 10US21EBP0171