JYNARQUE® (tolvaptan) REMS PATIENT ENROLLMENT FORM

Fax#: 1-866-750-6820

JYNARQUE is available only through the JYNARQUE REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive JYNARQUE. Your certified healthcare provider will help you complete this form and provide you with a copy. Fields marked * are required.

Prescribers and Patients: Please complete this form online at www.JYNARQUErems.com or once completed, fax it to the REMS at 1-866-750-6820.

**Indicates required field*

Patient Information

First Name*: _____ Middle Initial: _____ Last Name*: _____

Birthdate*: _____ Sex*: ☐ Male ☐ Female

Race*: ☐ White ☐ Black or African American ☐ American Indian or Alaska Native
☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Other, Specify _____

Ethnicity*: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Address Line 1*: _____

Address Line 2: _____

City*: _____ State*: _____ Zip code*: _____

Phone*: _____ Mobile Phone*: _____ Email*: _____

Medical History

The information in this section is only collected to help determine if there are reasons why some people have elevations in their liver function tests and others do not.

Alcohol Classification*: ☐ Never Drank ☐ Ex-Drinker (stopped drinking at least 1 month ago) ☐ Current Drinker

Typical Alcohol Consumption (required for Current Drinker):

- ☐ Occasional (drink alcohol less than once each week)
- ☐ Light (1-2 beers, 1-2 glasses of wine, or 1-2 liquor drinks each week)
- ☐ Moderate (3-7 beers, 3-7 glasses of wine, or 3-7 liquor drinks each week)
- ☐ Heavy (more than 7 beers, more than 7 glasses of wine, or more than 7 liquor drinks each week)

Previously Treated with Tolvaptan Prior to REMS Enrollment*: ☐ Yes ☐ No

If yes, how long did you take tolvaptan? _____ years _____ months _____ days

Was this part of a clinical trial? ☐ Yes ☐ No

If yes, please provide clinical trial number/patient ID: _____

Prescriber Information

First Name*: _____ Last Name*: _____

NPI No.*: _____

Practice/Facility Name (where you see this patient): _____

Address Line 1: _____

City: _____ State: _____ Zip code: _____

Phone*: _____ Fax: _____ Email: _____

Prescriber Agreement

*Has the patient's liver function been assessed by evaluating ALT, AST, and bilirubin prior to enrolling this patient in the REMS?
☐ Yes ☐ No

If the answer is No, you must assess the patient's liver function by evaluating ALT, AST, and bilirubin prior to submitting this form to the REMS.

I have reviewed and discussed the risks of JYNARQUE and the requirements of the JYNARQUE REMS with this patient.

Prescriber Signature*: _____ Date*: _____

Healthcare Provider: Provide a copy of this form to the patient.

Phone: 1-866-244-9446 | www.JYNARQUErems.com | Fax: 1-866-750-6820

Healthcare providers must report cases of liver injury to the REMS Program Coordinating Center.

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Patient Agreement

Before my treatment begins, I will:

- Review the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my healthcare provider. Enrollment information will be provided to the REMS.
- Get a blood test to check my liver.
- Receive counseling from my healthcare provider on the risk of serious liver problems and possibly death and requirements to get blood tests by using the ***Patient Guide***.

During treatment, I will get a blood test to check my liver:

- 2 weeks after my treatment begins,
- 4 weeks after treatment begins, and then
- every month after that for the first 18 months, and then
- every 3 months

I will contact my healthcare provider if I have any side effects, reactions, or symptoms after receiving JYNARQUE.

I understand and acknowledge that:

1. I have received, read, and understand the ***Patient Guide*** that my healthcare provider has given me.
2. JYNARQUE can cause serious side effects. It can cause serious liver problems and possibly death. This complication can be identified through monthly testing and awareness of side effects, reactions, or symptoms. My healthcare provider has reviewed with me the risks of treatment with JYNARQUE.
3. In order to receive JYNARQUE, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive JYNARQUE in the United States.
4. I should tell the REMS right away if I change my JYNARQUE healthcare provider, if my contact information changes, or if I discontinue JYNARQUE.
5. Otsuka Pharmaceutical Company, Ltd and its agents may contact me via phone, mail, fax, or email to support administration of the REMS.
6. Otsuka Pharmaceutical Company, Ltd and its agents may use and share my personal health information, including lab results and prescription data collected as part of the REMS for the purpose of the operations, analysis, and reporting of the REMS including enrolling me into, administering, and evaluating the REMS, coordinating the dispensing of JYNARQUE, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.

Patient or Legal Guardian Signature*: _____

Date*: _____

Printed Patient/Legal Guardian Name: _____

Healthcare Provider: Provide a copy of this form to the patient.

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Otsuka

Otsuka America Pharmaceutical, Inc.

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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