JYNARQUE® (tolvaptan) REMS PRESCRIBER ENROLLMENT FORM

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. Fields marked * are required.

Instructions:

1) **Review** the ***JYNARQUE Prescribing Information***, the ***REMS Program Overview***, and the ***Prescriber Training***.
2) **Complete** and **submit** the ***Prescriber Knowledge Assessment*** and this ***Prescriber Enrollment Form*** online at **www.JYNARQUErems.com**, or fax them to the REMS at **1-866-750-6820**.
3) **Complete** all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you upon successful certification.

**Indicates required field*

Prescriber Information

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

National Provider Identifier No. (NPI)*: _____ State License No.: _____

Preferred Method of Contact: ☐ Phone ☐ Email ☐ Fax Preferred Time of Contact: ☐ AM ☐ PM

Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other Specialty*: ☐ Nephrology ☐ Other: _____

Practice/Facility Name: _____

Address Line 1*: _____

Address Line 2: _____

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

Phone*: _____ Fax*: _____ Email*: _____

Office Liaison First Name: _____ Office Liaison Last Name: _____

Office Liaison Email: _____

Prescriber Agreement

By signing this form, I agree JYNARQUE is only available through the REMS and I must comply with the following REMS requirements:

I have:

1. Reviewed the ***Prescribing Information***.
2. Reviewed the ***REMS Program Overview***.
3. Completed the ***Prescriber Training***.
4. Successfully completed the ***Prescriber Knowledge Assessment*** and submitted it to the REMS.

Before treatment initiation with the first dose I must:

1. Counsel the patient on the risk of serious and potentially fatal liver injury and the requirement for liver function monitoring at baseline, 2 weeks and 4 weeks after treatment initiation, then monthly for the first 18 months and then every 3 months thereafter using the ***Patient Guide***.
2. Provide a copy of the ***Patient Guide*** to the patient.
3. Assess the patient's liver function and appropriateness of initiating treatment.
4. Document appropriateness of initiating treatment using the ***Patient Enrollment Form***.
5. Enroll the patient by completing and submitting the ***Patient Enrollment Form*** to the REMS. Provide a copy of the form to the patient.

During treatment; at 2 weeks and 4 weeks after treatment initiation, then monthly for the first 18 months and every 3 months thereafter I must assess the patient's liver function and appropriateness of continuing treatment.

During treatment; every 3 months for the first 18 months and every 6 months thereafter I must:

1. Assess the patient's liver function and appropriateness of continuing treatment.
2. Document appropriateness of continuing treatment and submit to the REMS using the ***Patient Status Form***.

At all times, I must:

1. Report adverse events suggestive of serious and potentially fatal liver injury by contacting the REMS by phone, using the ***Liver Adverse Events Reporting Form***, or using the ***Patient Status Form***.
2. Report treatment discontinuation or transfer of care to the REMS.

I understand and acknowledge that:

1. I will only be able to prescribe JYNARQUE if certified in the REMS.
2. I will not share my credentials for the REMS website or allow others to sign into the website using my credentials.
3. I will allow Otsuka Pharmaceutical Company, Ltd and its agents to contact me via phone, mail, fax, or email to support administration of the REMS.
4. I will be contacted for further information regarding any reports of serious and potentially fatal liver injury and will be requested to provide pertinent laboratory test results.

Prescriber Signature*: _____ Date*: _____

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.

JYNARQUE®
(tolvaptan) tablets

Reference ID: 4528293

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.
JYNARQUE is a registered trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

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