JYNARQUE® (tolvaptan) REMS INPATIENT PHARMACY ENROLLMENT FORM

Instructions

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.

Only inpatient pharmacies that are certified in the REMS may dispense JYNARQUE for a specific enrolled patient(s) being treated in the inpatient setting. Certified inpatient pharmacies are only authorized to order JYNARQUE from contracted distributors. If you have any questions about the REMS or need more information, please call **1-866-244-9446**.

You must designate an authorized representative to complete and submit this form on behalf of this inpatient pharmacy.

Instructions for Authorized Representative:

1) **Review** the ***Prescribing Information*** and the ***REMS Program Overview***.
2) **Complete** and **submit** this ***Inpatient Pharmacy Enrollment Form*** online at **www.JYNARQUErems.com**, or fax it 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 the pharmacy upon successful certification.

**Indicates required field*

Inpatient Pharmacy Information

Inpatient Pharmacy Name*: _____

Type*: ☐ Hospital ☐ Nursing home ☐ Hospice ☐ Mental facility ☐ Assisted Living ☐ Prison ☐ Rehabilitation Facility ☐ Other

Pharmacy Address Line 1*: _____

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

Pharmacy Address Line 2: _____

Pharmacy National Provider Information No. (NPI)*: _____

Inpatient Pharmacy Ship to Address, if different than above

Pharmacy Address*: _____

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

Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to carry out the certification process and oversee implementation of and compliance with the REMS. By signing this form, I agree to comply with the requirements of REMS and as the Authorized Representative, understand that my Pharmacy must also comply with the REMS requirements:

1. Review the ***Prescribing Information*** and ***REMS Program Overview***.
2. Enroll in the REMS by completing the ***Inpatient Pharmacy Enrollment Form*** and submitting it to the REMS.
3. Train all relevant staff involved in dispensing JYNARQUE using the ***REMS Program Overview***.
4. Establish processes and procedures to verify the prescriber is certified and the patient is enrolled in the REMS.
5. Establish processes and procedures to dispense no more than a 15 days' supply upon discharge of the patient.
6. Inform the REMS if the Authorized Representative changes and complete a new ***Inpatient Pharmacy Enrollment Form*** with the new Authorized Representative.

Before dispensing I will ensure that all pharmacy staff must:

1. Verify that the prescriber is certified and the patient is enrolled in the REMS.

Reference ID: 4707327

JYNARQUE® (tolvaptan) REMS INPATIENT PHARMACY ENROLLMENT FORM

Authorized Representative Responsibilities (cont'd)

At/upon discharge, I will ensure that all pharmacy staff must not dispense more than a 15 days' supply.

At all times, I will ensure that all pharmacy staff must:

1. Report adverse events suggestive of serious and potentially fatal liver injury by contacting the REMS by phone or using the ***Liver Adverse Events Reporting Form***.
2. Not distribute, transfer, loan, or sell JYNARQUE.
3. Maintain records documenting staff's completion of REMS training.
4. Maintain and make available appropriate documentation reflecting that all processes and procedures are in place and are being followed for the REMS.
5. Comply with audits carried out by Otsuka Pharmaceutical Company, Ltd or third party acting on behalf of Otsuka Pharmaceutical Company, Ltd to ensure that all processes and procedures are in place and are being followed.

I understand and acknowledge that I must maintain compliance with the requirements of the REMS; otherwise, my pharmacy will no longer have the ability to dispense JYNARQUE.

Inpatient Pharmacy Authorized Representative Information

First Name*: _____ Last Name*: _____ Middle Initial: _____
Telephone Number*: _____ Alternate Telephone Number: _____
Office Fax*: _____
Email*: _____ Preferred Method of Contact: _____

Authorized Representative 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.

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.

©2019 Otsuka America Pharmaceutical, Inc. [Month Year of Approval] XXXXXXXXXXXXX

JYNARQUE®
(tolvaptan) tablets

Reference ID: 4707327