

JYNARQUE® (tolvaptan) REMS OUTPATIENT 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.

Dispensing of JYNARQUE is limited to a small number of contracted outpatient pharmacies. These outpatient pharmacies must enroll in the REMS in order to dispense JYNARQUE. If you have any questions about the REMS, please call **1-866-244-9446**.

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

Instructions for Authorized Representative:

- 1) **Review** the **Prescribing Information** and the **REMS Program Overview**.
- 2) **Complete** and **submit** this **Outpatient Pharmacy Enrollment Form** and fax it to the JYNARQUE REMS at **1-866-750-6820**.

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*

Outpatient Pharmacy Information:

Pharmacy Name*: _____

Pharmacy Address 1*: _____

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

Pharmacy Address 2: _____

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

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 **Outpatient Pharmacy Enrollment Form** and submitting it to the REMS.
3. Train all relevant staff involved in dispensing JYNARQUE using the **REMS Program Overview** and maintain a record of training.
4. Establish processes and procedures to dispense no more than a 30 days' supply.
5. Inform the JYNARQUE REMS if the Authorized Representative changes and complete a new **Outpatient Pharmacy Enrollment Form** with the new Authorized Representative.

Before dispensing, I will ensure that all pharmacy staff must:

1. Obtain authorization to dispense each prescription by contacting the REMS by phone or checking the REMS website to verify the prescriber is certified, and the patient is enrolled and authorized to receive the drug.
2. Dispense no more than 30 days' supply.

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

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Authorized Representative Responsibilities (cont'd)

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.

Outpatient 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*: _____

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Otsuka America Pharmaceutical, Inc.

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Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA.
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