



Lupin Group Company

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Dear Prescribers

Notification of Important Safety Risks Tolvaptan Lupin Tablets

Distributor: Generic Health Pty Ltd

Generic Name: Tolvaptan

Trade Name: Tolvaptan Lupin

Reference Product: Jinarc

Strength & AUST R Number:

- 417526 – Tolvaptan Lupin 15 mg + 45 mg tablet blister composite pack
- 417521 – Tolvaptan Lupin 30 mg + 60 mg tablet blister composite pack
- 417524 – Tolvaptan Lupin 30 mg + 90 mg tablet blister composite pack

Note: Tolvaptan Lupin 15 mg tablet blister pack & Tolvaptan Lupin 30 mg tablet blister pack are not marketed.

Indications: Tolvaptan Lupin is indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.

Generic Health Pty Ltd wish to provide you with the following important safety risks associated with Tolvaptan therapy:

- Tolvaptan has been associated with idiosyncratic elevations of blood alanine and aspartate aminotransferases (ALT and AST), rarely associated with concomitant elevations in bilirubin-total (BT). To help mitigate the risk of liver injury, blood testing for hepatic transaminases is required prior to initiation of Tolvaptan Lupin, then continually monthly for 18 months, then every 3 months thereafter during treatment with Tolvaptan Lupin (see **Section 4.4 Special Warnings and Precautions for Use** in the full Product Information).
- Prescriber education and certification on the risk of liver injury and the importance of regular liver function monitoring is mandatory. This information is available through the Tolvaptan Lupin portal on the Generic Health website at www.generichealth.com.au/tolvaptan/prescribers. Once you have reviewed the materials provided, please complete the Prescriber Certification form and return it to customer.service@generichealth.com.au.

The following educational materials have been provided:

FOR THE PRESCRIBER

- DHCP Letter
- Prescriber Guide
- Prescriber Certification Form
- Adverse Event Reporting Form
- Tolvaptan Lupin Product Information

The above materials will be provided as a pack via email, in addition to being available to download from the Generic Health website at www.generichealth.com.au/tolvaptan/prescribers. Hard copies can also be requested from Generic Health Customer Service (see contact details below).

Once you have reviewed the materials provided, please complete the Prescriber Certification Form and return it to customer.service@generichealth.com.au.

FOR THE PATIENT

- Patient Guide
- Patient Wallet Card
- Tolvaptan Lupin Consumer Medicine Information

The Patient Guide will be available to download from the Generic Health website. The Patient Wallet Card will be included in each product pack. Hard copies of both the Patient Guide and Patient Wallet Card can also be requested from Generic Health Customer Service (see contact details below).

Please forward this information to all relevant staff members in your organisation.

If you have any questions regarding the above, please do not hesitate to contact Generic Health using the contact details below.

Customer Service Team	Phone: 03 9809 7900, Option 1 Email: customer.service@generichealth.com.au
Medical Information Team	Phone: 03 9809 7900, Option 2 Email: ghinfo@generichealth.com.au

Yours sincerely

Medical Information Team
Generic Health Pty Ltd