**Targeted Follow-up Form - Hepatotoxicity**

This form has been sent to you in order for Generic Health to collect more detailed information regarding the adverse event associated with liver toxicity that you reported in relation to Tolvaptan Lupin. Your contribution will be of significant help in improving the knowledge of the safety profile of our drug and in minimizing the risk for patients. This data will remain confidential and will only be used for safety analysis.

**Please fill this form online, or print and complete as hard copy. Once completed, please send to Generic Health at** [**ghinfo@generichealth.com.au**](mailto:ghinfo@generichealth.com.au)**.**

**Patient Demographics**:

|  |  |
| --- | --- |
| Patient’s Date of Birth (DD/MM/YYYY) or age: | |
| Gender:  Male  Female | Ethnicity:  Aboriginal  Torres Strait Islander |
| Patient's Weight: | Patient's Height: |
| Report Country of Origin: | |

**Suspect Products:**

Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events].

| **Product Name** | **Daily Dose and Regimen** | **Route of Administration** | **Indication** | **Start Date or Treatment Duration (DD/MM/YY)** | **Stop Date (DD/MM/YY)** | **Lot/Batch Number(s)** | **Expiration Date(s)**  **(MM/YYYY)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Tolvaptan Lupin |  |  |  |  |  |  |  |
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**Details of Adverse Event(s):**

Please mention the respective number as mentioned in the column header for each adverse event.

| **Adverse Event** | **Start Date (DD/MM/YY)** | **Stop Date (DD/MM/YY)** | **Serious**  **Yes / No** | **If serious, mention seriousness criteria (provided at the end of the table)** | **Treatment Received**  **Yes / No** | **Outcome:**  **1. Ongoing**  **2. Recovering**  **3. Recovered**  **4. Recovered with Sequelae**  **5. Death**  **6. Unknown** | **Did the adverse event abate after suspect product stopped or dose reduced?**  **Yes / No /**  **N/A** | **Did the adverse event reappear after re-introduction of the suspect product(s)?**  **Yes / No /**  **N/A** |
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For seriousness criteria, please select as below (more than one option can be mentioned):

1. Death (please mention death date (DD/MM/YY)):

2. Life threatening

3. Hospitalisation or prolongation of existing hospitalisation

4. Persistent or significant disability or incapacity

5. Medically significant

Please add any further comments/information here:

**Diagnostic Tests:**

Please provide test names, dates, results and normal ranges -provide pre-treatment results if available).

| **Test Name** | **Normal Range** | **Results** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Date**  **(DD/MM/YY)** | **Date**  **(DD/MM/YY)** | **Date**  **(DD/MM/YY)** | **Date**  **(DD/MM/YY)** | **Date**  **(DD/MM/YY)** |
| Serum bilirubin (total and direct) |  |  |  |  |  |  |
| Aspartate Aminotransferases (AST) |  |  |  |  |  |  |
| Alanine Aminotransferases (ALT) |  |  |  |  |  |  |
| Alkaline Phosphatase (Alk-P) |  |  |  |  |  |  |
| Albumin |  |  |  |  |  |  |
| Prothrombin Time (PT) |  |  |  |  |  |  |
| Labs for viral hepatitis (antigen/antibody/DNA) |  |  |  |  |  |  |
| Bicarbonate |  |  |  |  |  |  |
| Eosinophils |  |  |  |  |  |  |
| Imaging |  |  |  |  |  |  |
| Histopathology |  |  |  |  |  |  |
| Immune-histochemistry |  |  |  |  |  |  |
| Other, specify |  |  |  |  |  |  |

**Concomitant Medications:**

Please list any concomitant medications and provide medication name, daily dose/ regimen, indication, start/stop date and time or duration.

Please pay special attention to any potential hepatotoxic drugs/substances.

| **Medication Name** | **Daily Dose and Regimen** | **Route of Administration** | **Indication** | **Start Date (DD/MM/YY)** | **Stop Date (DD/MM/YY)** |
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**Relevant Medical History/Risk Factors:**

Please tick (✓) /fill all relevant boxes

| **Medical history/Risk factor** | **Unknown** | **No** | **Yes** | **If Yes, since when** |
| --- | --- | --- | --- | --- |
| Hepato-biliary disease. If yes, please specify: |  |  |  |  |
| Ischemic hepatitis (eg: hypotension or CHF). |  |  |  |  |
| Viral hepatitis A, B, C or E. If yes, please specify: |  |  |  |  |
| Hyperlipidaemia |  |  |  |  |
| Bleeding disorders |  |  |  |  |
| Cardiovascular disease. If yes, please specify: |  |  |  |  |
| Neoplasm. If yes, please specify: |  |  |  |  |
| Liver metastasis. |  |  |  |  |
| Fatty liver. |  |  |  |  |
| Liver cirrhosis/fibrosis. |  |  |  |  |
| Pancreatitis. |  |  |  |  |
| Diabetes mellitus Type I or Type II. |  |  |  |  |
| Autoimmune disease/ immune-compromised status. If yes, please specify: |  |  |  |  |
| Obesity. |  |  |  |  |
| Alcohol and/or tobacco and/or drug abuse. If yes, please specify: |  |  |  |  |
| Recent vaccinations or travels. If yes, please specify: |  |  |  |  |
| Biliary disease. If yes, please specify: |  |  |  |  |
| Occupational toxic agent. If yes, please specify: |  |  |  |  |
| Relevant family history. If yes, please specify: |  |  |  |  |
| Other. If yes, please specify: |  |  |  |  |

**Completed by:**

|  |  |
| --- | --- |
| Name: | Occupation: |
| Address: | |
| Phone: | Email: |
| Signature: | Date: |