

**ADVERSE EVENT REPORTING FORM**

Form No.: SOP/QA/101/F1-03

<b>GENO</b>	<b>GENO PHARMACEUTICALS PRIVATE LIMITED</b> <b>Tivim Industrial Estate, Karaswada, Mapusa, Goa 403526</b> <b>PHARMACOVIGILANCE CELL</b> <b>ADVERSE EVENT REPORTING FORM</b> (To be filled by patient / patient's relative / Medical Rep. / lay person / HCPs )	Page 1 of 1
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Report Date: ___/___/___	ADR reporting ID No. (to be generated by the PV Cell): _____
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<b>A. Patient Information:</b> Patient Name / Initials: _____ Address: _____ Mobile/Telephone No.: _____ Age at time of Event: _____ or DOB: ___/___/___ Sex: M ( ) F ( ) T ( ) Body Weight: ___kg	<b>B. Reporter Information:</b> Reporter's Name: _____ Address: _____ Mobile / Telephone & E-mail: _____ Signature: _____ Date : ___/___/___ Patient / patient's relative / Medical Rep. / lay person / HCPs [tick (√) whichever is applicable] Occupation: _____
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C. Suspected Medication (Prescribed / non-prescribed):								
Brand	Active Ingredient	Start Date & Time of Medicine	Stop date & Time of medicine	Each Dose content / Frequency	Route of taking medicine (oral/ sublingual/skin cream/suppository/ injection etc.)	Mfd. by / imported by (write Company name in short)	Batch No. & Expiry Date	If injectable, diluent used (Mfr. name / Batch No. & Expiry Date)

**D. Adverse Event (choose the nearest possible adverse finding and tick √ whichever is applicable, can be more than one):**

<b>1. When Adverse Reaction seen (mention Date and Time)</b> ___/___/___ & ___/___/___ <b>2. When Adverse Reaction stopped (mention Date and Time)</b> ___/___/___ & ___/___/___ <b>3. How stopped ? Medicine withdrawn ? ( )</b> <b>4. To stop ADR any Medicine needed ? ( )</b> <b>(Sign &amp; symptoms)</b> <u>Skin Reaction:</u> Redness ( ) Swelling ( ) Itching ( ) Rash ( ) <u>Gastrointestinal Reaction:</u> Vomiting ( ) Diarrhea ( ) Acidity ( ) Gastritis ( ) Indigestion ( ) Hiccups ( ) Loss of appetite ( ) Burning or gnawing feeling in the stomach between meals or at night ( ) stomach pain ( ) Bloating ( ) <u>Blood Pressure:</u> High ( ) Low ( ) Normal ( ) <u>Blood Sugar:</u> High ( ) Low ( ) Normal ( )	Is the adverse event serious? Yes ( ) No ( )  If Yes, please tick why it is serious? <input type="checkbox"/> Death Date of death: (dd/mm/yyyy) _____ <input type="checkbox"/> Disability <input type="checkbox"/> Life threatening <input type="checkbox"/> Congenital anomaly / birth defect <input type="checkbox"/> Hospitalization <input type="checkbox"/> Other important medical events
<u>Injection site reactions:</u> Pain ( ) Abscess ( ) Redness ( ) Swelling ( ) Pus formation ( ) Itching ( ) <u>Musculoskeletal reaction:</u> Muscle spasm ( ) Musculoskeletal pain ( ) Arthralgia (Joint Pain) ( ) Back and neck pain ( ) <u>Respiratory disorder:</u> Cough ( ) Sneezing ( ) Sore throat ( ) Chest pain ( ) Running Nose ( ) Broncho-constriction ( ) <u>Others:</u> Headache ( ) Bodyache ( ) Drowsiness ( ) Fever (≥ 38°C) ( ) Hypersensitivity ( ) Anaphylaxis ( )	Adverse Event Description (Other reactions / events not included in list above):

<b>E. Concomitant Medication (if any)</b>	<b>F. Medical History</b>	<b>G. Lab Test/ Diagnosis</b>
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Please send this form to: **Pharmacovigilance Cell, GENO PHARMACEUTICALS PRIVATE LIMITED**  
 Address: **Tivim Industrial Estate, Karaswada, Mapusa, Goa 403 526**  
 Contact Number: +91 8888733200 Email id: [pvcell@genopharma.com](mailto:pvcell@genopharma.com)  
**## If any additional data (ex. Lab. Reports / diagnosis), then please attach scanned copy with this form.**

QAD
ISSUED BY: _____
Sign/ Date

**GENO PHARMACEUTICALS PRIVATE LIMITED**  
Tivim Industrial Estate, Karaswada Mapusa Goa. 403526

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