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

ADVERSE EVENT REPORTING FORM

Form No.: SOP/QA/101/F1-02

GENO	**GENO PHARMACEUTICALS PRIVATE LIMITED** **Tivim Industrial Estate, Karaswada, Mapusa, Goa 403526** **PHARMACOVIGILANCE CELL** **ADVERSE EVENT REPORTING FORM** (To be filled by patient / patient's relative/ Medical Rep. / lay person / HCPs)	Page 1 of 1

Report Date: ____/____/_____ **ADR reporting ID No. (to be generated by the PV Cell):** _____

A. Patient Information:

Patient Name / Initials: _____
Address: _____
Mobile/Telephone No.: _____
Age at time of Event: _____ or DOB: ___/___/__
Sex: M ( ) F ( ) T ( ) Body Weight: ____kg

B. Reporter Information:

Reporter's Name: _____
Address: _____
Mobile / Telephone & E-mail: _____
Signature: _____ Date : ____/____/_____
Patient / patient's relative / Medical Rep. / lay person / HCPs
[tick (√) whichever is applicable] Occupation: _____

C. Suspected Medication (Prescribed / non-prescribed):

Name of Medicine		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)
Brand	Active Ingredient							

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

1. When Adverse Reaction seen (mention Date and Time)
____/____/____ & ____/____/____
2. When Adverse Reaction stopped (mention Date and Time)
____/____/____ & ____/____/____
3. How stopped ? Medicine withdrawn ? ( )
4. To stop ADR any Medicine needed ? ( )

(Sign & symptoms)

Skin Reaction:
Redness ( ) Swelling ( )
Itching ( ) Rash ( )

Gastrointestinal Reaction:
Vomiting ( ) Diarrhea ( )
Acidity ( ) Gastritis ( )
Indigestion ( ) Hiccups ( )
Loss of appetite ( )
Burning or gnawing feeling in the stomach between meals or at night ( ) stomach pain () Bloating ()

Blood Pressure:
High ( ) Low ( ) Normal ( )

Blood Sugar:
High ( ) Low ( ) Normal ( )

Injection site reactions:
Pain ( ) Abscess ( ) Redness ( )
Swelling ( ) Pus formation ( ) Itching ( )

Musculoskeletal reaction:
Muscle spasm ( )
Musculoskeletal pain ( )
Arthralgia (Joint Pain) ( )
Back and neck pain ( )

Respiratory disorder:
Cough ( ) Sneezing ( ) Sore throat ( )
Chest pain ( ) Running Nose ( )
Broncho-constriction ( )

Others:
Headache ( ) Bodyache ( )
Drowsiness ( ) Fever (≥ 38^{0}C) ( )
Hypersensitivity ( ) Anaphylaxis ( )

Is the adverse event serious? Yes ( ) No ( )

If Yes, please tick why it is serious?

( ) Death
Date of death: (dd/mm/yyyy) _____
( ) Disability
( ) Life threatening
( ) Congenital anomaly / birth defect
( ) Hospitalization
( ) Other important medical events

Adverse Event Description (Other reactions / events not included in list above):

E. Concomitant Medication (if any)

F. Medical History

G. Lab Test/ Diagnosis

Please send this form to: **Pharmacovigilance Cell, GENO PHARMACEUTICALS PRIVATE LIMITED**
Address: **Tivim Industrial Estate, Karaswada, Mapusa, Goa 403 526**
Contact Number: +91 7020979716 Email id: pvcell@genopharma.com

If any additional data (ex. Lab. Reports / diagnosis), then please attach scanned copy with this form.

QAD
ISSUED BY: Sign/ Date

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