PHARMACOVIGILANCE POLICY

INTRODUCTION

Ontop Pharmaceuticals Private Limited has a strong commitment towards manufacturing quality products. Patient safety is a fundamental principle for Ontop Pharmaceuticals Private Limited. As a pharmaceutical company, Ontop has a mandatory responsibility to monitor the safety of Ontop products marketed in India. We comply with all regulations governing the reporting, and communication of side effects. We are committed to transparency in our evaluation and communication of these benefits and risks with patients, healthcare professionals and regulators.

PURPOSE OF ADR DATA COLLECTION

ADR data collection is very important for public health and safety. Ontop Pharmaceuticals Private Limited is required to report Pharmacovigilance relevant information to health authorities in India, where our products are authorised for marketing.

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DATA PRIVACY

We are required to process certain personal data of a patient/consumer and/ or the reporter of an adverse event that we receive, in order to comply with strict obligations to perform benefit/risk assessments of Ontop Products and to report suspected Adverse Drug Reactions (ADR) to relevant regulatory authorities. All personal data received by Ontop Pharmacovigilance Operations is processed exclusively for Pharmacovigilance purposes.

WHAT IS PHARMACOVIGILANCE AND WHY PHARMACOVIGILANCE.

Pharmacovigilance, also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. An adverse event is any untoward medical occurrence in a patient following administration of a pharmaceutical product and which does not necessarily have a causal relationship with the administered product.

The ultimate goals of Pharmacovigilance are to ensure rational and safe use of medical drugs, to assess the risk and benefits of drugs and to educate and inform patients on the same.

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WHAT SHOULD YOU REPORT?

- Report any serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - ✓ Death
  - ✓ Life-threatening
  - ✓ Hospitalization (initial or prolonged)
  - ✓ Disability (significant, persistent or permanent)
  - ✓ Congenital anomaly
  - ✓ Required intervention to prevent permanent impairment or damage

- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines.

WHO CAN REPORT?

All healthcare professionals (Clinicians, Pharmacists and all allied healthcare Professionals) can report adverse drug reactions.

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HOW CAN YOU REPORT?

If you wish to report a suspected adverse reaction/side effect with our drug, you can do so by choosing any of the following options:

- Call our ADR Reporting Number- 080 4165 8728/ 080 2960 3775 (Monday to Friday between 8.30 am to 5.30 pm, except on public holidays.)
- If you wish to send us information by post or email, please download the form here and mail to the following address:

Mailing Address for ADR Reporting:

Regulatory Department,
Ontop Pharmaceuticals Private Limited
9-D, Bommasandra Jigani Link Road,
Bommasandra Industrial Area, Bengaluru,
Bommasandra, Karnataka - 560099, India.

Email ID for ADR Reporting

ontoppharma@ontoppharma.com

We thank you for reporting adverse events or other pharmacovigilance relevant information to Ontop Pharmaceuticals Private Limited.