PHARMACOVIGILANCE POLICY

INTRODUCTION

Mapra Laboratories Private Limited has a strong commitment towards manufacturing quality products.

Patient safety is a fundamental principle for Mapra Laboratories Private Limited. As a pharmaceutical company, Mapra has a mandatory responsibility to monitor the safety of Mapra's products marketed worldwide.

We comply with international regulations governing the reporting, analysis 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.

Mapra Laboratories Private Limited is obliged to report Pharmacovigilance relevant information to health authorities in India as well as in other countries where our products are authorised for marketing.

MAPRA | MAPRA
LABORATORIES PRIVATE LIMITED

PHARMACOVIGILANCE POLICY

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 Mapra's Products and to report suspected Adverse Drug Reactions (ADR) to relevant regulatory authorities.

All personal data received by Mapra's Pharmacovigilance Operations is processed exclusively for Pharmacovigilance purposes.

WHAT IS 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.

PHARMACOVIGILANCE POLICY

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, Dentists, Pharmacists and Nurses) can report adverse drug reactions.

MAPRA | MAPRA
LABORATORIES PRIVATE LIMITED

PHARMACOVIGILANCE POLICY

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 Toll-Free Number 1800-22-59-60 (Monday to Friday between 9.30 am to 5.30 pm, except on public holidays.)
- WhatsApp ADR information on +918879607724 (messages only)
- Complete and submit the ADR Reporting form online available on this website.
- 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
Pharmacovigilance Operations,
Scientific Department,
Mapra Laboratories Private Limited
201, Adhyaru Industrial Estate, Sun Mill Compound, Lower Parel.
Mumbai – 400013, India.

Email ID for ADR Reporting
aepvc.scientific@mapra.com

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

MAPRA | MAPRA LABORATORIES PRIVATE LIMITED