PHARMACOVIGILANCE PRIVACY NOTICE AND DATA PROTECTION STATEMENT

1. DATA CONTROLLER AND CONTACT DETAILS

This Pharmacovigilance Privacy Notice and Data Protection Statement ("Notice") has been prepared by WORLD MEDICINE OPHTALMICS LIMITED ("Company", "we", "us") in accordance with applicable data protection laws, including but not limited to Law No. 6698 on the Protection of Personal Data (Türkiye) and, where applicable, the EU/UK General Data Protection Regulation ("GDPR").

For the purposes of pharmacovigilance (drug safety monitoring), WORLD MEDICINE OPHTALMICS LIMITED is the data controller responsible for the processing of your personal data.

Data Controller: WORLD MEDICINE OPHTALMICS LIMITED
Address: WORLD MEDICINE OPHTALMICS HEAD OFFICE, Registered Office, Ground Floor, Gadd House, Arcadia Avenue, Finchley, London, N3 2JU, United Kingdom
Phone: +44 (0) 204 602 73 62
E-mail: info@wm-ophthalmics.com
Pharmacovigilance contact: pv@dayrimgroup.by
Website: http://wm-ophthalmics.com/

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2. CATEGORIES OF PERSONAL DATA PROCESSED

In the context of adverse reaction (side effect) reporting and pharmacovigilance activities, we may process the following categories of personal data:

– Identification data: name, surname, title, profession (e.g. physician, pharmacist, other healthcare professional).
– Contact data: telephone number, e-mail address, country and city of residence or work.
– Relationship to the patient: whether you are the patient, a relative/caregiver, a healthcare professional, or another reporter.
– Patient information: age or age range, gender, weight, height, pregnancy or breastfeeding status if relevant, and other limited demographic information.
– Health and medical data (special category / sensitive data):
• Medical history, current conditions, concomitant diseases;
• Details of the suspected medicinal product (name, strength, dosage, pharmaceutical form, batch/lot number, indications, start and stop dates);
• Description of the adverse reaction(s), onset and duration, outcome, relevant laboratory test results and other clinical information.
– Product and usage data: list of medicinal products used, indication, duration of use, concomitant medications.
– Technical and log data: IP address, date and time of submission, basic logs generated by our information systems to ensure security and traceability.

Health-related data are considered special category / sensitive personal data under applicable data protection laws.

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3. PURPOSES OF PROCESSING YOUR PERSONAL DATA

Your personal data are processed strictly for pharmacovigilance and legal compliance purposes, including:

1. Receiving, recording and evaluating adverse reaction (side effect) reports related to our medicinal products;
2. Following up with the reporter or healthcare professional to obtain additional information where necessary;
3. Monitoring and assessing the safety profile of our products, including the detection of new safety issues and risk management;
4. Fulfilling our national and international pharmacovigilance obligations, including mandatory reporting to regulatory authorities and pharmacovigilance systems;
5. Preparing aggregated and anonymised safety reports and analyses;
6. Ensuring the accuracy, integrity and security of pharmacovigilance databases and records;
7. Compliance with record-keeping, audit and inspection requirements;
8. Protecting public health and ensuring the safe use of medicinal products.

Your personal data will not be used for marketing or promotional purposes.

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4. LEGAL BASIS FOR PROCESSING

Depending on the nature of the data and the jurisdiction, we process your personal data on the basis of the following legal grounds:

– Compliance with legal obligations related to pharmacovigilance and drug safety (e.g. laws and regulations on medicinal products and pharmacovigilance);
– Public interest in the area of public health, such as ensuring high standards of quality and safety of healthcare and medicinal products;
– Establishment, exercise or defence of legal claims;
– Legitimate interests of the Company, provided that such interests are not overridden by your fundamental rights and freedoms;
– Explicit consent, where required by applicable law, particularly regarding special category (sensitive) personal data such as health information.

Where applicable (for example in Türkiye, the EU/EEA or the UK), the legal bases correspond to Articles 5, 6 and 9 of the GDPR and/or the relevant provisions of Law No. 6698 and secondary legislation.

5. RECIPIENTS AND TRANSFER OF PERSONAL DATA

For the purposes described in this Notice, your personal data may be disclosed or transferred to the following categories of recipients on a need-to-know basis:

– Group companies and affiliates of WORLD MEDICINE OPHTALMICS LIMITED, including those located outside your country of residence;
– Pharmacovigilance service providers, consultants and contractors who process data on our behalf (as data processors);
– National and international regulatory and health authorities, pharmacovigilance databases and competent bodies as required by law;
– Healthcare professionals and healthcare institutions, where additional medical information is required to assess a case;
– Legal and professional advisors, auditors and other third parties where necessary for compliance and defence of legal claims;
– Courts, law enforcement and other public authorities, where we are under a legal obligation to disclose information.

Where personal data are transferred to countries outside the EU/EEA or other jurisdictions with specific transfer rules, such transfers will be carried out in accordance with applicable data protection laws (for example, using appropriate safeguards such as standard contractual clauses, adequacy decisions or other applicable grounds).

6. METHODS OF COLLECTION

Your personal data may be collected by:

– Online adverse reaction / side effect reporting forms provided on our Website;
– E-mail, telephone, fax or postal mail communications;
– Reports submitted by healthcare professionals, patients, caregivers or other reporters;
– Information provided during follow-up calls, letters or additional documentation requested by our pharmacovigilance personnel;
– Data shared by regulatory authorities, distributors, partners or other entities in the pharmacovigilance network, as permitted by law.

Data may be collected automatically and/or manually, through electronic systems and paper-based records.

7. RETENTION PERIODS

We are required by pharmacovigilance legislation and relevant regulations to retain pharmacovigilance data for minimum periods that may be very long (often for the lifetime of the product plus a defined number of years after its withdrawal from the market).

Your personal data will be retained only for as long as necessary to fulfil the purposes described in this Notice and to comply with applicable legal, regulatory and pharmacovigilance record-keeping requirements. After the relevant retention periods expire, personal data will be deleted, anonymised or otherwise rendered unusable in accordance with applicable laws and our internal policies.

8. YOUR RIGHTS AS A DATA SUBJECT

Subject to the conditions and limitations set out in applicable data protection laws, you may have the following rights regarding your personal data:

1. To obtain confirmation as to whether or not your personal data are being processed and, where that is the case, to access such data;
2. To request rectification of inaccurate or incomplete personal data;
3. To request erasure of your personal data where applicable (for example, where they are no longer necessary for the purposes for which they were collected);
4. To request restriction of processing in certain circumstances;
5. To object to the processing of your personal data, where applicable (for example, if processing is based on legitimate interests);
6. To request information about the recipients or categories of recipients to whom your personal data have been disclosed;
7. To obtain a copy of your personal data in a commonly used electronic format and, where technically feasible and legally applicable, to have such data transmitted to another controller (data portability);
8. To withdraw your consent at any time where processing is based on consent (without affecting the lawfulness of processing before such withdrawal);
9. To lodge a complaint with the competent data protection authority in your country of residence, place of work or place of the alleged infringement.

Please note that, due to strict pharmacovigilance and public health obligations, we may not be able to delete or fully restrict processing of certain data if such processing is required by law.

You may exercise your rights by contacting us in writing using the contact details provided in Section 1 of this Notice. We will respond to your request as soon as reasonably possible and within the time limits set by applicable law.

9. DATA SECURITY

We implement appropriate technical and organisational security measures to protect your personal data against unauthorised access, alteration, disclosure or destruction. These measures include, among others:

– Access controls and role-based permissions;
– Secure transmission protocols and encryption where appropriate;
– Logging and monitoring of access to pharmacovigilance systems;
– Regular training and awareness programmes for staff on data protection and confidentiality;
– Policies and procedures for incident response and data breach management.

However, no system can be guaranteed to be completely secure. You are responsible for ensuring that any information you provide is accurate and that you use secure means when communicating with us.

10. UPDATES TO THIS NOTICE

We may update this Pharmacovigilance Privacy Notice and Data Protection Statement from time to time to reflect changes in our practices, legal requirements or regulatory guidance.

The most recent version of this Notice will always be available on http://wm-ophthalmics.com/ and will indicate the date of the latest update.