

Sun Pharmaceutical Industries Ltd.
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FOR IMMEDIATE RELEASE

Sun Pharmaceutical Industries Inc. Issues Voluntary Nationwide Recall of Riomet® (Metformin Hydrochloride Oral Solution) Manufactured by a Contract Manufacturer due to Microbial Contamination

Mumbai, India & Cranbury, New Jersey, November 24, 2017 – Sun Pharmaceutical Industries, Inc. (SPII), a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) is voluntarily recalling two lots of Riomet® (Metformin Hydrochloride Oral Solution), 500 mg/5mL, to the retail level (Class II Recall). This product is manufactured for SPII by a contract manufacturer. The Riomet® (Metformin Hydrochloride Oral Solution) has been found to be contaminated (*Scopulariopsis brevicaulis*). The contamination was discovered during sample preparation for the Antimicrobial Preservative Effectiveness Testing (AMPET) being performed as part of the 12 month stability study interval.

Use of Riomet® (Metformin Hydrochloride Oral Solution) potentially could result in a risk of infection, especially in the immunocompromised patient. The most plausible portal of entry of *Scopulariopsis brevicaulis* is the respiratory tract, where it may cause pneumonia, sinusitis and disseminated infections. To date, SPII has not received any reports of adverse events related to this recall.

Riomet® (Metformin Hydrochloride Oral Solution) is indicated to treat type 2 diabetes mellitus in adult and children age 10 and above. Riomet is packaged in 118 mL (4 fl. oz.) and 473 mL (16 fl. oz.) bottles. The affected Riomet® (Metformin Hydrochloride Oral Solution) includes product with NDC Code 10631-206-01 Lot A160031A, Exp.: 01/2018, and NDC 10631-206-02 Lot: A160031B, Exp.: 01/2018. The product can be identified by its bottle labeled as Riomet® (Metformin Hydrochloride Oral Solution) containing the specific Lot and Exp. dates mentioned above. This product was distributed nationwide to wholesale customers.

Photos for 16 oz. bottle for reference:



On April 18, 2017, SPII notified its wholesale customers through its 3rd party Recall Coordinator (Inmar Inc.) via FedEx standard overnight shipping and has arranged for the return via prepaid FedEx Ground shipping of all recalled products. Consumers that have Riomet® (Metformin Hydrochloride Oral Solution) which has been recalled should stop using and return it to place of purchase, discard and/or contact their doctor.

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Consumers with questions regarding this recall can contact SPII by calling 1-800-406-7984, Monday through Friday between 8:00 am to 5:00 pm EST or emailing drug.safetyUSA@sunpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 41 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 11 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 3 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of approximately 8% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live

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