



FDA MedWatch

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Sandoz Inc. Issues Voluntary Nationwide Recall of One Lot of Losartan Potassium and Hydrochlorothiazide Due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)

Announcement

Sandoz Inc. is voluntarily recalling one lot of Losartan Potassium Hydrochlorothiazide Tablets, USP 100mg/25mg to the consumer level. This product is being recalled due to the trace amount of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Losartan, USP manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. Sandoz Inc. Losartan Potassium Hydrochlorothiazide product is manufactured by Lek Pharmaceuticals dd, Ljubljana, Slovenia. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC).

To date, Sandoz Inc. has not received any reports of adverse events related to this lot.

Losartan Potassium Hydrochlorothiazide Tablets, USP are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. The product can be identified as Losartan Potassium Hydrochlorothiazide, 100 mg/25 mg tablets in 1000-count plastic bottles, NDC 0781-5207-10, Lot number JB8912; Exp. Date 06/2020. This product was distributed nationwide to distributors. The affected product was not distributed prior to October 8, 2018.

Sandoz Inc. is notifying its distributors by letter via overnight mail and patients by this public notification. Distributors and retailers that have product which is being recalled should immediately stop distribution of the identified lot above and quarantine any quantities remaining in your control and return the recalled product to the identified Reverse Distributor.

Patients with questions regarding this recall can contact Sandoz Inc. at 1-800-525-8747 Monday-Friday 8:30 AM – 5:00 PM (EST) or email usdrugsafety.operations@novartis.com. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Losartan Potassium Hydrochlorothiazide should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Losartan Potassium Hydrochlorothiazide.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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 made with the knowledge of the Food and Drug Administration.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached more than 500 million patients. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.