

STERIMAX

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Important Safety Information regarding SteriMax Orfenace Tablets 100mg

Date: April 13, 2021

Audience

Wholesalers, Health Care Professionals and Customers

Subject: Voluntary Type 1 Recall of SteriMax Orfenace Tablets 100mg

SteriMax has initiated a voluntary Type I recall at the Wholesale and Retail Level for "SteriMax Orfenace Tablets 100mg" for the presence of Nitrosamines.

SteriMax recently discovered that all batches of Orfenace Tablets 100mg contain an N-Nitrosamine impurity above the acceptable limit. N-Nitrosamines are common chemicals in water, beverages, cosmetics, tobacco products, and foods such as cured and grilled meats. They can also form endogenously. The N-Nitrosamine impurity observed in Orfenace Tablets 100mg is called NMOA.

NMOA is believed to be a potential human carcinogen (a substance that could potentially cause cancer) based on its similarity to other probable carcinogens. For this reason, SteriMax has voluntarily recalled the following affected products listed below.

Product Name & Strength	DIN	UPC Code
Orfenace Tablets 100mg (Blisters)	02047535	834324000848
Orfenace Tablets 100mg (Bottles)	02047535	834324000206

Orfenace Tablets 100mg is indicated for the the relief of acute skeletal muscle spasm.

To request further information regarding this communication or to report a suspected adverse reaction associated with any SteriMax product, please contact SteriMax Inc. By email: medinfo@sterimaxinc.com, By phone: Call +1 905-890-0661 or +1 800-881-3550, extension: 5 for product information or technical support). Patients may also report any suspected adverse reactions associated with the use of health products to Health Canada by calling toll free at 1-866-234-2345 or by visiting MedEffect Canada's Web page on Adverse Reaction Reporting to <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> for information on how to report online, by mail or by fax.