

STERIMAX

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Important Information Regarding the Impact of Temperature on the SteriMax Triamcinolone Acetonide Injectable Suspension

The labelled storage conditions for Triamcinolone Acetonide Injectable Suspension 200 mg/5ml Vials are “Store at 15 °C – 30 °C. Do not freeze. Protect from light.”.

It is important to store Triamcinolone Acetonide Injectable Suspension 200 mg/5ml Vial products at the labelled storage condition because it is known that temperature, specifically low temperatures (including freezing) can affect product quality.

Data is available to demonstrate that the particle size distribution of this product is negatively affected if the product is stored at below 15 °C or at freezing temperature. The product may stick to the walls/shoulder of the vial, or agglomerates may form.

This can impact the ability to maintain the suspension in the appropriate form to administer to patients.

Also, the Triamcinolone Acetonide Injectable Suspension 200 mg/5ml Vial products must be stored in the vertical position to avoid product agglomeration on the shoulder of the vial.

Therefore, it is important to store the Triamcinolone Acetonide Injectable Suspension 200 mg/5ml Vial products at 15 °C – 30 °C, vertically all the time.

Any complaints of this nature can be reported to the SteriMax product complaint department, via email, phone call, or fax.

Contact information is provided below:

Tel: 905-890-0661

Toll Free: 1-800-881-3550

Fax: 905-890-0508

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Sincerely,

DocuSigned by Courtney Wood
 | I approve this document
Nov 27, 2023 | 12:05:01 PM EST

Courtney Wood ^{54E2614BE553473C9125E99FC43CD3BC}

Manager, Investigations and CAPA

SteriMax Inc.