ACERUS PHARMA

Natesto®
Testosterone Nasal Gel 4.5% w/w
Gel nasal de testostérone 4.5% p/p

August 07, 2019

Notification to healthcare professionals including endocrinologists, urologists, general or family practitioners and pharmacists.

NATESTO®: Acerus has decided to suspend sale of NATESTO® and has voluntarily recalled all product from pharmacies. The suspension will result in a shortage of NATESTO®, which is expected to continue until the end of October 2019.

There is NO risk to patient safety.

Information for health care providers

Patients may experience difficulties depressing the pump on the dispenser with two recent lots of NATESTO®. This can result in the patient receiving a lower dose of testosterone. Receiving a lower dose is not a safety concerns for patient, but may impact efficacy. The impacted lots are identified on the label by lot numbers **8L8616** and **8K8358**.

Your patients may have been using one of the impacted lots of NATESTO and may have been receiving a lower dose than labelled amount for the past few months. When switching patients to an alternate product for the duration of this supply disruption, patients should be titrated carefully with monitoring of levels of testosterone.

Acerus has received a small number of complaints over the past 6 months relating to this actuation problem. There has been no change in any other type of complaints relating to safety or efficacy.

If an impacted NATESTO product shows dispensing difficulties, you or your patient should contact Acerus Medical Information Department at 1-844-850-1642 (English and or French) to report the issue.

What is the issue?

Two commercial lots of NATESTO released in the Canadian market were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. The impacted lots do not consistently meet the delivered dose uniformity specification (they deliver lower than labelled amount of product). This post-release non-conformity does not pose any safety concerns for patients, but can result in the patient receiving a lower dose of the active ingredient, impacting efficacy. The impacted lots are identified on the label by lot numbers **8L8616** and **8K8358**.

Action taken by Acerus Pharma

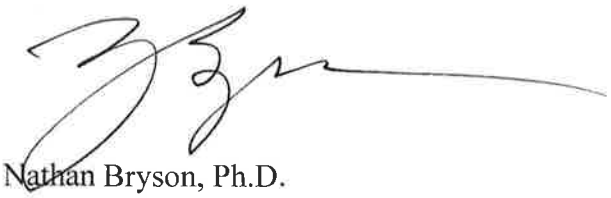
Acerus has stopped sales of NATESTO, made a voluntary recall of product to the pharmacy level and reported this shortage on the "Drug Shortages Database."

Acerus is actively working with partners and Health Canada to remedy the disruption.

Acerus Pharma is implementing corrective measures to ensure that sales of NATESTO will resume by the end of October 2019.

Acerus Pharma apologizes for the inconvenience this may cause to both health care professionals and the patients currently on treatment.

Original Signed by:



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