



November 5th, 2019

Update to Temporary NATESTO[®] Shortage

- Health Canada has classified minor modifications to the manufacturing process of a new batch of Natesto[®] as a Level 1 change, requiring the submission of a Supplemental New Drug Submission (“SNDS”) prior to its release.
- Acerus expects the revised batch to be released in the Canadian Market in Q1-2021
- Acerus is working diligently with Health Canada to facilitate an expeditious review of the SNDS and minimize market disruptions.
- Reports that NATESTO[®] has been discontinued in Canada are not correct.

Dear Health Care Professional:

On August 7th, 2019, you received a communication that Acerus had initiated a voluntary recall of two commercial lots of NATESTO[®] released in the Canadian market, resulting in a temporary shortage. These lots (lot **8L8616** and **8K8358**) were found to be non-conforming during long-term stability studies. This post-release non-conformity **does not pose any safety concerns for patients**, but may result in patients receiving a lower dose of the active ingredient, testosterone, which may impact efficacy.

Acerus has made minor modifications to the manufacturing process that appear to have resolved the previously identified issues and has produced a batch of NATESTO[®] (the “Revised Batch”). While Acerus believed the changes would have been classified by Health Canada as level III, thereby requiring only an annual notification update to Health Canada and allowing for product to be released in Q4-2019, Health Canada, after much deliberation, classified the modifications as level I, requiring the submission of a Supplemental New Drug Submission (“SNDS”) prior to the release of the Revised Batch in the Canadian market. In the event that Health Canada utilizes the full regulatory allotted time for reviewing a SNDS, **Acerus would expect the Revised Batch to be released in the Canadian Market in Q1-2021.** Acerus continues to work with Health Canada to facilitate an expeditious review of the SNDS and minimize market disruptions.

Acerus apologizes for any inconveniences this may cause you and your patients across Canada, and should you have any questions, please contact Acerus Medical Information Department at 1-844-850-1642 (English and or French).

Original Signed by:

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