

Flexipharm Austrading announces product update on Arsenic Trioxide Phebra

Extension to in-use stability time

FARNBOROUGH, England, [23] March, 2020: Flexipharm Austrading, the UK specialty pharmaceutical company focused on supplying the NHS with *Better, Critical Care Medicines*, today announced an important improvement to the 'Summary of Product Characteristics' for its differentiated arsenic trioxide injection product, Arsenic Trioxide Phebra (1mg/ml concentrate for solution for infusion).

The MHRA has granted approval for Section 6.3 of the Summary of Product Characteristics to be changed, such that:

"After dilution in intravenous solutions, Arsenic Trioxide Phebra is chemically and physically stable for 48 hours at 15°C-30°C and 72 hours at refrigerated (2°C-8°C) temperatures. From a microbiological point of view, the product must be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C-8°C, unless dilution has taken place in controlled and validated aseptic conditions."

Previously, after dilution in intravenous solutions, the chemical and physical stability of the product was 24 hours at 15°C-30°C and 48 hours at refrigerated (2°C-8°C) temperatures.

Arsenic Trioxide Phebra is the first arsenic trioxide product available in a vial presentation and the only vial presentation with these timelines for storage prior to use. The vial presentation removes the very real and common risk of sharps injuries when opening glass ampoules and saves NHS pharmacists time to make up infusions as no filter needles or filter straws are needed.

Commenting on today's development, Michael Clark, Founder and Director of Flexipharm Austrading, said: "We are very pleased to be making this important product update. Feedback from NHS specialist pharmacists indicates that in-use stability time is of great importance for products like Arsenic Trioxide. Given as an infusion, the product is routinely prepared prior to the patient attending the hospital. If, for any reason, the planned timing for the infusion is delayed, the amount of time the product can be stored prior to use is critical and may help avoid the need to discard product and start manufacturing again."

Notes to editors

About Flexipharm Austrading

Flexipharm Austrading's vision is to become a UK-based specialty pharmaceutical company that is genuinely respected and trusted by NHS hospitals. It was founded in 2018 by Michael Clark, an experienced specialty pharmaceutical company founder and board director.

Flexipharm Austrading has a singular focus on commercialising established molecules embedded in hospital use where there are concerns around security of ongoing supply; where the current presentation is not optimal for the needs of the NHS staff; and where the current presentations can contribute to medication errors. The Company has a deep understanding of the conditions where its medicines are used and builds enduring meaningful dialogue with the NHS staff involved in using these medicines. It has an exclusive distribution agreement with Phebra Pty Ltd, an Australian pharmaceutical company developing and manufacturing injectable pharmaceutical products.

Flexipharm Austrading will be launching several products from the Phebra portfolio in the UK in 2021 and 2022. For further information visit our website, www.flexipharmaustrading.com.

About Arsenic Trioxide Phebra

Arsenic Trioxide Phebra is a glass vial presentation of arsenic trioxide 1mg/ml concentrate solution for infusion, a NICE-recommended treatment (in combination with all-trans retinoic acid) for newly diagnosed low-intermediate risk and relapsed acute promyelocytic leukaemia or APML1,2.

Arsenic Trioxide Phebra is the first generic arsenic trioxide injection product to be launched in the UK and the first in a preferred vial presentation. The product is supplied by Flexipharm Austrading's partner, Phebra Pty Ltd, an Australian-based development and manufacturing company which has a successful track record in the supply of arsenic trioxide injection (www.phebra.com).

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