Notification on FLOLAN (epoprostenol sodium) 0.5 mg/vial (DIN 02230845) and 1.5 mg/vial (DIN 02230848) with regards to changes on the use conditions of the reconstituted solution

2024/03/27

GlaxoSmithKline Inc.
100 Milverton Drive
Suite 800
Mississauga, Ontario
L5R 4H1

Audience

Critical care medical doctors, pulmonary hypertension doctors, chief pharmacists (hospitals) and healthcare professionals within the Patient Support Program, i.e., specialty pharmacists and prescribing physicians.

Key messages

- The purpose of this letter is to inform Healthcare Professionals about changes regarding the period of maximum use of reconstituted solutions of FLOLAN (epoprostenol sodium) with concentration ≤ 150,000 ng/mL at 25°C and 30°C temperature.
- This is applicable to FLOLAN 0.5 mg/vial (DIN 02230845) and 1.5 mg/vial (DIN 02230848), used to treat Pulmonary Arterial Hypertension.
- The reconstituted solutions can be used as freshly prepared or upon storage for up to 8 days at 2°C to 8°C. In either case, the **maximum use period for the reconstituted solution** has been shortened:

From	To
72 hours at a temperature of up to **25°C**	**48 hours** at a temperature of up to **25°C**
48 hours at a temperature of up to **30°C**	**36 hours** at a temperature of up to **30°C**

  Any unused solution is to be discarded after this timeframe.
- The changes in maximum use period for the reconstituted solution are being made to ensure potency is maintained through the in-use period.
- Product used as per previous conditions of reconstitution is not anticipated to adversely impact the benefit-risk for patients receiving FLOLAN.
- GlaxoSmithKline has updated the product monograph and associated leaflet for FLOLAN to include the updated maximum use periods for the reconstituted solution as detailed above.
- There are no changes to the reconstitution and administration methods of FLOLAN.

Information for healthcare professionals

Healthcare professionals are advised to follow the revised maximum use periods for the reconstituted solution of FLOLAN as indicated above.

Healthcare professionals are advised to share this information with other healthcare personnel under their supervision and with patients or patient's caregivers for their awareness.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving FLOLAN should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc.
100 Milverton Drive
Suite 800
Mississauga, Ontario
L5R 4H1
Tel: 1-800-387-7374

To correct your mailing address or fax number, contact GlaxoSmithKline Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (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; or
- Calling toll-free at 1-866-234-2345

For more information, please contact GlaxoSmithKline Inc. Medical Information at 1-800-387-7374.

Sincerely,

Original signed by

Marni Freeman
Country Medical Director, Canada
GlaxoSmithKline Inc.