Important Safety Information from GSK on
FLOLAN (epoprostenol sodium) used with polyethylene terephlalate (PET) or polyethylene terephthalate glycol (PETG) Administration Sets

2018/03/05

Audience
Health care professionals who prescribe, dispense, or administer the pulmonary arterial hypertension medication called FLOLAN, prepared with pH 12 STERILE DILUENT for FLOLAN.

Key messages

- **FLOLAN solution prepared with pH 12 STERILE DILUENT FOR FLOLAN must not be used with any preparation or administration materials containing polyethylene terephthalate (PET) or polyethylene terephthalate glycol (PETG).**
- **Check if your patients use any preparation or administration materials that contain PET or PETG, to deliver FLOLAN solution prepared with pH 12 STERILE DILUENT for FLOLAN.**
- **Administration sets provided to patients enrolled in the Horizons Patient Support Program do not contain PET or PETG.**
- **Please share this information with relevant healthcare professionals.**

This material was developed by GlaxoSmithKline as part of the risk minimization plan for FLOLAN. This material is not intended for promotional use.

What is the issue?
GSK has recently received reports of leakage of administration materials used with FLOLAN solution prepared with pH 12 STERILE DILUENT for FLOLAN due to cracking or damage. The leakage occurred in components containing polyethylene terephthalate glycol (PETG) that were being used in renal dialysis in markets outside of Canada with an approved use in renal dialysis. In Canada, FLOLAN is not approved for use in renal dialysis. Polyethylene terephthalate (PET) is not considered to be compatible with highly alkaline solutions, based on reports of administration set damage when used with highly alkaline medications. PETG is thought to be similarly susceptible to alkaline solutions.

There have been no reports of leakage from administration materials used in the treatment of pulmonary arterial hypertension. Administration sets (infusion pump,

cassette and external tubing) provided to patients enrolled in the Horizons Patient Support Program do not contain PET or PETG.

However, it is possible that PET or PETG may be present in some administration materials used in the administration of FLOLAN outside of the Horizons Patient Support Program.

As a precautionary measure, GSK would like to advise that such administration materials may develop damage resulting in cracking or leakage of fluids when used for administration of FLOLAN solution prepared with pH 12 STERILE DILUENT for FLOLAN.

Products affected
pH 12 Sterile Diluent for FLOLAN, DIN: 02230857
FLOLAN 0.5 mg vial, DIN: 02230845
FLOLAN 1.5 mg vial, DIN: 02230848

Background information
FLOLAN is indicated for the long-term intravenous treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) or PAH associated with connective tissue diseases (CTD) in patients with WHO Functional Class III-IV symptoms who did not respond adequately to conventional therapy.

Information for health care professionals
You should confirm if your patients who are receiving FLOLAN solution prepared with pH 12 STERILE DILUENT for FLOLAN use any preparation or administration materials that contain PET or PETG.

If you are unsure of the materials that are used by your patients for preparation or administration of FLOLAN solution, you should consult the manufacturer of the sets to confirm if they are considered compatible with highly alkaline solutions, such as FLOLAN solution prepared with pH 12 STERILE DILUENT for FLOLAN.

Please share the information in this letter with relevant health care personnel under your supervision.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving FLOLAN, including leakage from administration materials used to administer FLOLAN solution, should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
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:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

If you have any questions about this new information, including information regarding compatibility testing conducted by GSK, please contact the GlaxoSmithKline Medical Information Department at 1-800-387-7374.

Original signed by

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