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Important Safety Information from GSK on PrFLOLAN® (epoprostenol sodium): Administration with a REFORMULATED DILUENT

July 27th 2016

Dear Healthcare Practitioner,

GlaxoSmithKline (GSK) would like to inform you that two different sterile diluents for FLOLAN® (epoprostenol sodium) will be available until approximately early fall 2016, each with different instructions for storage and administration.

What is the potential issue?

- Both the STERILE DILUENT for FLOLAN® and the reformulated **pH 12 STERILE DILUENT for FLOLAN®** will be on the market simultaneously, while existing STERILE DILUENT for FLOLAN® supplies are transitioned to the reformulated **pH 12 STERILE DILUENT for FLOLAN®**.
- Use of STERILE DILUENT for FLOLAN® without concurrent use of a cold pouch could result in possible rebound of PAH symptoms. You are advised to ensure patients have appropriate instructions regarding reconstitution, storage and administration of each diluent.
- GSK will cease sale of STERILE DILUENT FOR FLOLAN®, approximately early fall 2016. Please ensure transition to **pH 12 STERILE DILUENT for FLOLAN®** before this date. Please contact the Shoppers Drug Mart-Specialty Health Network (SDM-SHN) Distribution line at 1-888-360-6929 if you have questions regarding the availability of each diluent.

For More Information

- Please see the FLOLAN® Product Monograph, available via:
  - http://ca.gsk.com/en-ca/products/flolan/
- Please contact GlaxoSmithKline Medical Information at 1-800-387-7374.
- Please read page 3, Overview of Storage and Administration Differences.

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

About FLOLAN®

FLOLAN® (epoprostenol sodium) 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. Prior to initiation of therapy, the potential benefit of FLOLAN® should be weighed against the risks associated with use of the drug and the presence of an indwelling central venous catheter. FLOLAN® should be used only by clinicians experienced in the diagnosis and treatment of PAH. The diagnosis of idiopathic or heritable PAH or PAH/CTD should be carefully established by standard clinical tests.

Consult the product monograph for contraindications, warnings, precautions, adverse reactions, dosing and administration, and other information.

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® should be reported to GSK or Health Canada.

GlaxoSmithKline Inc.
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Tel: 1-800-387-7374

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

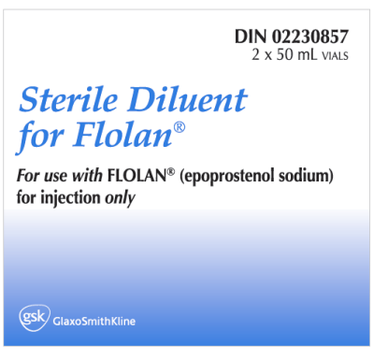
- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

Sincerely,

Original signed by

Dr. Sally Taylor
Country Medical Director, Canada
GlaxoSmithKline Inc

Overview of Storage and Administration Information for FLOLAN® and its Diluents

STERILE DILUENT for FLOLAN® (Existing)	**pH 12 STERILE DILUENT for FLOLAN®** (Reformulated)
If used to make FLOLAN® solution: The temperature of the FLOLAN® solution inside the pump can be maintained for up to 24 hours at 2° to 8 °C with the use of a 'cold pouch' containing two frozen 6-oz gel packs. **Remember to change the gel packs every 12 hours or every 8 hours if room temperature approaches 30 °C. When stored or in use the solution must not be exposed to light.**	If used to make FLOLAN® solution: The use of a 'cold pouch' is not required. **When stored or in use the solution must not be exposed to light.**
Details: Reconstituted solutions must be refrigerated at 2° to 8°C (36° to 46°F) for up to 24 hours if not used immediately. Refrigerated solutions that have been stored for up to 24 hours at 2° to 8°C (36° to 46°F) or freshly prepared reconstituted solutions may be used for no longer than 24 hours with the use of a cold pouch during infusion. Change cold pouch every **12 hours** or every 8 hours if the ambient temperature approaches 30°C. Discard any reconstituted solution if it has been refrigerated for more than **24 hours** (before being transferred to the infusion pump).	**Details:** Freshly prepared solutions for infusion can be administered immediately or stored for up to 8 days at 2°C to 8°C prior to administration. Following this preparation or storage, the solution for infusion should be used within: • 72 hours at up to 25°C or • 48 hours at up to 30ºC or • 24 hours at up to 35 ºC or • 12 hours at up to 40 °C
	
STERILE DILUENT for FLOLAN® is supplied in glass vials with aluminum overseal and yellow plastic flip-off cap containing 50 mL of diluent.	**pH 12 STERILE DILUENT for FLOLAN®** is supplied in plastic vials with aluminum overseal and lavender plastic flip-off cap containing 50 mL of diluent.
DIN: 02230857	DIN: 02443651

Reference: FLOLAN® (epoprostenol sodium) Product Monograph
http://ca.gsk.com/en-ca/products/flolan/