Information on SteriMax-Vancomycin Hydrochloride Injection USP, 1g/vial and French Labelling Error for Reconstituted Solution

Date: 07/07/2015

Audience
Health care professionals working in hospitals, clinics and pharmacies.

Key messages
- A typographical error has been identified on one lot (Lot# BK112A14) of SteriMax Vancomycin Hydrochloride for Injection USP, 1g/vial, DIN # 02396386.
- This error is only displayed on the French text of the secondary (outer) carton's reconstitution instructions of the product where it presents the recommended volume for reconstitution to be 20.6mg/mL instead of 20.6mL to yield a final concentration of 50mg/mL
- Although unlikely, there is a potential for a dosing error if only the reconstitution information on the secondary (outer) carton of the French text is used.
- Health care professionals are requested to follow the information found on the vial label and package insert which correctly indicates the dosing information: "20.6 mL (50 mg/mL)".

What is the issue?
A typographical error was identified on one lot (Lot# BK112A14) of SteriMax Vancomycin Hydrochloride for Injection USP, 1g/vial, (DIN# 02396386). Although unlikely, there is a potential for a dosing error (i.e. final dose greater than 2X the intended dose) to occur if the reconstitution information on the secondary (outer) carton of the French text is used.

Products affected
The product impacted is:

Product	DIN No.	Lot No.	Distribution Date	Exp. Date
SteriMax - Vancomycin Hydrochloride Injection USP, 1g/vial	02396386	BK112A14	January 23, 2015 to June 26, 2015	June 2016

Background information
Vancomycin Hydrochloride Injection USP is indicated for the treatment of severe or life-threatening staphylococcal infections in patients who cannot receive or have failed to respond to penicillins or cephalosporins or who have infections with

staphylococci resistant to other antibiotics, including methicillin.

A typographical error is found on one lot (Lot# BK112A14) of SteriMax Vancomycin Hydrochloride for Injection USP, 1g/vial, (DIN# 02396386). This error is displayed on the French text of the secondary (outer) carton of the product, under the section *Réconstitution* as shown in italics below:

Error: *Donne **20.6 mg/mL** (50mg/mL)*
Label should read as follows: *Donne **20.6 mL** (50mg/mL)*

The text on the English label of the secondary (outer) carton for SteriMax Vancomycin Hydrochloride for Injection USP, 1g/vial, has the correct information.

The English and French information is correct in the Reconstitution table, on the vial label and in the packaging insert of this lot.

There are no concerns with the quality of the product.

Information for consumers

This product is generally administered by health care professionals, in a hospital setting. Vancomycin Hydrochloride Injection is used to treat serious bacterial infections.

The risk of a dosing error is considered unlikely. Consumers with any questions about their Vancomycin treatment should contact their health care professional for more information.

Information for health care professionals

Health care professionals are requested to follow the information found on the vial label and package insert which correctly indicates the dosing information, "20.6 ml (50 mg/mL)".

Action taken by Health Canada

Health Canada is communicating this information to health care professionals and to the public through its MedEffect Canada website. Health Canada is also monitoring the implementation of necessary corrective and preventive actions.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any health product-related concerns due to this labelling error for SteriMax Vancomycin Hydrochloride Injection USP, 1g/vial should be reported to SteriMax Inc. or Health Canada.

SteriMax Inc.
2770 Portland Drive, Oakville, ON, L6H 6R4
Phone number: 1-800-881-3550, Fax number: 1-877-546-7667

To correct your mailing address or fax number, contact SteriMax 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

For other health product inquiries related to this communication, contact Health Canada at:

Health Products and Food Branch Inspectorate (HPFBI)
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Telephone: 1-800-237-9675
Fax: 1-613-946-5636

Original signed by

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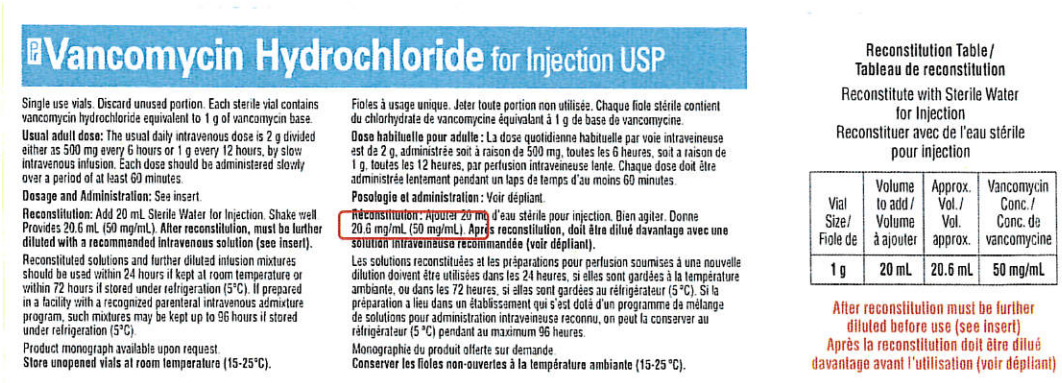
Images



Vancomycin Hydrochloride for Injection USP

Single use vials. Discard unused portion. Each sterile vial contains vancomycin hydrochloride equivalent to 1 g of vancomycin base.

Usual adult dose: The usual daily intravenous dose is 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours, by slow intravenous infusion. Each dose should be administered slowly over a period of at least 60 minutes.

Dosage and Administration: See insert.

Reconstitution: Add 20 mL Sterile Water for Injection. Shake well Provides 20.6 mL (50 mg/mL). **After reconstitution, must be further diluted with a recommanded intravenous solution (see insert).**

Reconstituted solutions and further diluted infusion mixtures should be used within 24 hours if kept at room temperature or within 72 hours if stored under refrigeration (5°C). If prepared in a facility with a recognized parenteral intravenous admixture program, such mixtures may be kept up to 96 hours if stored under refrigeration (5°C).

Product monograph available upon request.
Store unopened vials at room temperature (15-25°C).

Fioles à usage unique. Jeter toute portion non utilisée. Chaque fiole stérile contient du chlorhydrate de vancomycine équivalant à 1 g de base de vancomycine.

Dose habituelle pour adulte : La dose quotidienne habituelle par voie intraveineuse est de 2 g, administrée soit à raison de 500 mg, toutes les 6 heures, soit à raison de 1 g, toutes les 12 heures, par perfusion intraveineuse lente. Chaque dose doit être administrée lentement pendant un laps de temps d'au moins 60 minutes.

Posologie et administration : Voir dépliant.

Reconstitution : Ajouter 20 mL d'eau stérile pour injection. Bien agiter. Donne 20.6 mg/mL (50 mg/mL). **Après reconstitution, doit être dilué davantage avec une solution intraveineuse recommandée (voir dépliant).**

Les solutions reconstituées et les préparations pour perfusion soumises à une nouvelle dilution doivent être utilisées dans les 24 heures, si elles sont gardées à la température ambiante, ou dans les 72 heures, si elles sont gardées au réfrigérateur (5 °C). Si la préparation a lieu dans un établissement qui s'est doté d'un programme de mélange de solutions pour administration intraveineuse reconnu, on peut la conserver au réfrigérateur (5 °C) pendant au maximum 96 heures.

Monographie du produit offerte sur demande.
Conserver les fioles non-ouvertes à la température ambiante (15-25 °C).

Reconstitution Table/
Tableau de reconstitution

Reconstitute with Sterile Water for Injection
Reconstituer avec de l'eau stérile pour injection

Vial Size/ Fiole de	Volume to add / Volume à ajouter	Approx. Vol./ Vol. approx.	Vancomycin Conc./ Conc. de vancomycine
1 g	20 mL	20.6 mL	50 mg/mL

After reconstitution must be further diluted before use (see insert)
Après la reconstitution doit être dilué davantage avant l'utilisation (voir dépliant)