Important Safety Information on Vincristine Sulfate Injection USP, 1mg/mL and incorrect labelling

2015/10/23

Audience

Healthcare professionals working in hospitals and in out-patient cancer clinics.

Key messages

- Certain lots of Vincristine Sulfate Injection USP, 1 mg/mL have incorrect or outdated safety information on the inner/outer labels and package insert. Without this information, there may be an increase in the risk to the patient and it may result in significant patient harm requiring medical intervention.

- Missing information includes:
  - Vincristine sulfate should only be administered by the intravenous (IV) route. Administration of Vincristine sulfate by any other route can be fatal.
  - Syringes containing this product should be labelled “WARNING- FOR IV USE ONLY”.
  - Extemporaneously prepared syringes containing this product must be packaged in an overwrap which is labelled “DO NOT REMOVE COVERING UNTIL MOMENT OF INJECTION. FOR INTRAVENOUS USE ONLY-FATAL IF GIVEN BY OTHER ROUTES.”
  - Contraindication in patients with Charcot-Marie –Tooth Syndrome.
  - Potential risk of acute shortness of breath when coadministered with Mitomycin-C and gastrointestinal toxicities including necrosis.

- Healthcare professionals are requested to consult with the approved Canadian Product Monograph for Vincristine Sulfate Injection USP 1 mg/mL which has the most updated information.
What is the issue?
The labels on the product and the package insert currently being distributed by Hospira do not reflect the most up-to-date information and warnings. The missing information and warnings may increase the risk to patients and may result in significant patient harm requiring medical intervention. Specifically, these warnings are detailed below:

- Vincristine sulfate should only be administered by the intravenous (IV) route. Administration of Vincristine sulfate by any other route can be fatal.

- Syringes containing this product should be labelled “WARNING- FOR IV USE ONLY”.

- Extemporaneously prepared syringes containing this product must be packaged in an overwrap which is labelled “DO NOT REMOVE COVERING UNTIL MOMENT OF INJECTION. FOR INTRAVENOUS USE ONLY-FATAL IF GIVEN BY OTHER ROUTES.”


- Potential risk of acute shortness of breath when Vincristine is coadministered with Mitomycin-C and gastrointestinal toxicities including necrosis with administration of Vincristine.

Products affected

The product impacted is:

<table>
<thead>
<tr>
<th>Description</th>
<th>DIN</th>
<th>List Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vincristine Sulfate Injection USP, 1 mg/mL (2 mL vial)</td>
<td>02183013</td>
<td>7077A001</td>
</tr>
<tr>
<td>Vincristine Sulfate Injection USP, 1 mg/mL (5 mL vial)</td>
<td>02183013</td>
<td>7082A001</td>
</tr>
</tbody>
</table>

Background information

Vincristine Sulfate Injection USP, 1 mg/mL is an antineoplastic agent indicated in the treatment of acute leukemia. It has also been shown to be useful in combination with other oncolytic agents in Hodgkin’s disease, soft-tissue sarcoma, bony-tissue sarcoma, sarcomas of specialized structures, breast cancer, small cell cancer of the lung, cancer of the uterine cervix, malignant melanoma, colorectal cancer, non-Hodgkin’s lymphoma and Wilms’ tumor. It is also used in pediatric patients to treat a variety of malignant disorders.
To date, there have been no adverse events reported to be associated with this issue. There are no concerns with the quality of the product.

The labels on the product, and the package insert will be corrected to include the most updated information approved by Health Canada.

**Information for consumers**
This product is administered by a healthcare professional, in a hospital setting or in out-patient specialized cancer clinics. Vincristine Sulfate Injection USP 1 mg/mL is used in cancer treatment.

Consumers with any questions about their Vincristine treatment should contact their healthcare professional for more information.

**Information for health care professionals**
Healthcare professionals should refer to the approved [Canadian Product Monograph](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php) for the most up-to-date information on Vincristine Sulfate Injection USP 1 mg/mL.

**Action taken by Health Canada**
Health Canada is communicating this important safety information to healthcare professionals and the public through its MedEffect Canada Website. Health Canada is also monitoring the company’s implementation of necessary corrective and preventative actions.

**Report health or safety concerns**
Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving Vincristine Sulfate Injection USP, 1 mg/mL should be reported to Hospira HealthCare Corporation or Health Canada.
Hospira Healthcare Corporation, a Pfizer Company  
2600 Alfred-Nobel Blvd, Suite 500  
Saint-Laurent (Quebec), H4S 0A9  
Telephone: 1-866-488-6088, Option 6  
Fax: 1-877-906-0208

To correct your mailing address or fax number, contact Hospira Healthcare Corporation

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:

Lead Directorate: Health Product and Food Branch Inspectorate (HPFBI)  
E-mail: DCVI_UVCME@hc-sc.gc.ca  
Telephone: 1-800-267-9675  
Fax: 1-613-946-5636

Sincerely,

[Signature]

Rania Al-Ammar  
Regional Director, Commercial Quality  
Hospira Healthcare Corporation, a Pfizer company