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## Worldwide Biopharmaceutical Businesses

23 November 2021

### Direct Healthcare Professional Communication

Dear Healthcare Professional,

**ZAVEDOS® (idarubicin) 5mg and 10mg Powder for Solution for Injection:  
Temporary supply of unlicensed 5mg/5ml and 10mg/10ml presentations to UK market;  
important differences in storage, preparation and administration**

#### Summary

To ensure continuity in supply, Pfizer Ltd has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Australian Zavedos (idarubicin) 5mg/5ml and 10mg/10ml products as unlicensed medicines, which are expected to be on the UK market from November 2021 to January 2022.

Please note the following:

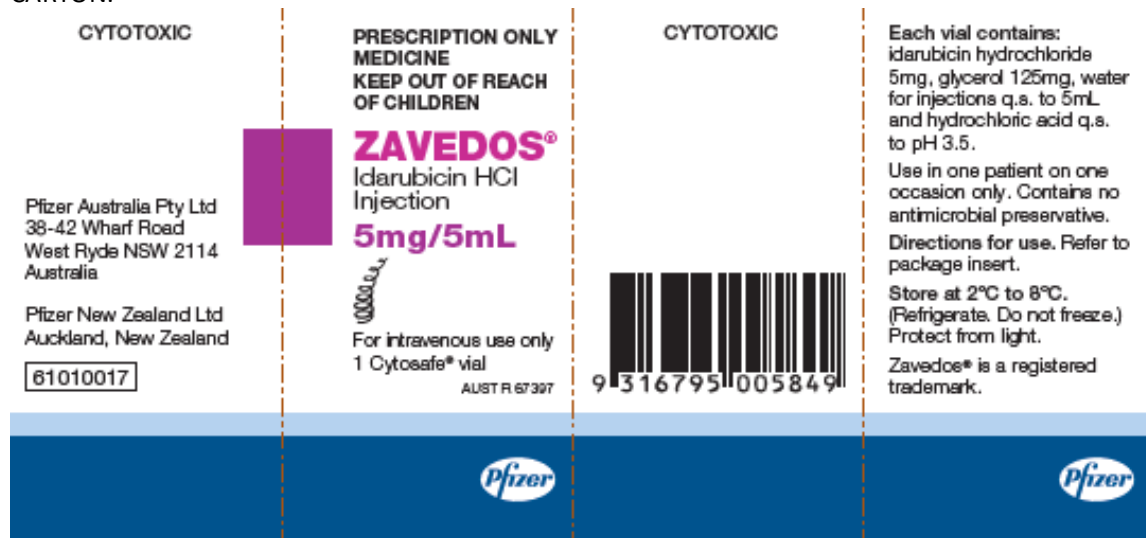
- The Australian Zavedos (idarubicin) solution for injection has a different formulation than the UK Zavedos powder for solution product; key differences are shown in the tables on pages 4 and 5
- The Australian Zavedos (idarubicin) are provided as solutions that do not require reconstitution, whereas the licensed UK product is a powder.
- Store the Australian Zavedos (idarubicin) vials at 2 to 8°C, refrigerated (do not freeze) and protected from light
- Please ensure the Australian Product Information (equivalent to Summary of Product Characteristics (SPC)) and Consumer Medicine Information (equivalent to Patient Information Leaflet (PIL)) are followed and the Australian PIL provided to patients
- The Australian Zavedos product is unlicensed in the UK; this means that the imported product has not been given a Marketing Authorisation by the MHRA.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

**Australian Zavedos (idarubicin) solution for injection batch and packaging information**

Zavedos 5 mg/5 mL solution for injection batch number is **CA7895**

CARTON:



VIAL LABEL:



Zavedos 10 mg/10 mL solution for injection batch number is **CG6123**

CARTON:



VIAL LABEL:



Registered in England: No 526209  
Registered Office: Ramsgate Road  
Sandwich, Kent CT13 9NJ, UK

### **Background to safety issue**

Zavedos (idarubicin hydrochloride) Powder for Solution Injection is authorised in the UK in adults for the treatment of acute myeloid leukaemia (AML), for remission induction in untreated patients or for remission induction in relapsed or refractory patients; and for second line treatment of relapsed acute lymphoblastic leukaemia (ALL). It is also authorised in children for first line treatment of AML, in combination with cytarabine, for remission induction and for second line treatment of relapsed ALL. Zavedos may be used in combination chemotherapy regimens involving other cytotoxic agents.

Zavedos (idarubicin) 5mg and 10mg Powder for Solution for Injection has been out of stock in the UK since 1<sup>st</sup> November 2021. Resupply is expected in January 2022 and this will take the form of a new presentation of Zavedos, which will be the UK licensed Zavedos 1mg/mL Solution for Injection, which will replace the powder for solution presentation.

To help mitigate the shortage we have obtained for supply to the UK alternative Australian Pfizer Zavedos (Idarubicin) 5mg/5ml and 10mg/10ml solution for injection products. Australian vials of Zavedos are considered unlicensed products in the UK.

### **Instructions for storage, preparation and administration:**

#### *Storage*

Store the Australian Zavedos (idarubicin) vials at 2 to 8°C, refrigerated (do not freeze) and protected from light

#### *Preparation*

Unlike Zavedos powder for solution for injection, the Zavedos presentation does not need to be reconstituted.

#### *Administration*

Zavedos for injection must only be administered by the intravenous (IV) route and should be added to the tube of a freely running infusion of 0.9% sodium chloride injection, given over 10-15 minutes. The tubing should be attached to a butterfly needle or other suitable device and inserted preferably into a large vein. The technique minimises the risk of thrombosis or perivenous extravasation, which can lead to severe cellulitis and necrosis.

Full Product Information for the Australian Zavedos product can be found at:

[TGA Search -- zavedos](#)

Electronic pdf copies are also provided with this letter.

### **Differences in presentation:**

There are some differences between UK licensed Zavedos and Australian unlicensed Zavedos. A summary of these for each vial size can be found in the following tables:

	<b>Zavedos 5mg Powder for Solution Injection (UK licensed idarubicin)</b>	<b>Zavedos 5mg/5ml solution for injection (Australian idarubicin, unlicensed in UK)</b>
Pack Size	1 vial (to be reconstituted)	1 vial (ready to use)
Appearance	Powder for Solution for Injection  Sterile, pyrogen-free, orange-red, freeze-dried powder in vial containing 5 mg or 10mg of idarubicin hydrochloride, with 50 mg of lactose monohydrate.	Solution for Injection  Sterile, pyrogen-free, preservative free, orange-red, clear solution in vial containing 5mg of idarubicin hydrochloride.
Excipients (per vial)	50mg of lactose monohydrate	Glycerol, Hydrochloric acid for adjustment to pH 3.5, Water for injections.
Packaging information	Colourless glass vial, type I, with chlorobutyl rubber bung and aluminium seal with insert yellow polypropylene disk.	Polypropylene vial, which is closed with a siliconised, halobutyl rubber stopper and sealed with an aluminum cap with a plastic flip off
Storage	Unreconstituted solution: No special storage conditions	Store at 2 to 8°C, refrigerated (do not freeze) and protected from light
Warning		ZAVEDOS solution for injection do not contain antimicrobial preservative. Use in one patient on one occasion only. Discard any residue.

	<b>Zavedos 10 mg Powder for Solution Injection (UK licensed idarubicin)</b>	<b>Zavedos 10 mg/10ml solution for injection (Australian idarubicin, unlicensed in UK)</b>
Pack Size	1 vial (to be reconstituted)	1 vial (ready to use)
Appearance	Powder for Solution for Injection  Sterile, pyrogen-free, orange-red, freeze-dried powder in vial containing 10 mg of idarubicin hydrochloride, with 100 mg of lactose monohydrate.	Solution for Injection  Sterile, pyrogen-free, preservative free, orange-red, clear solution in vial containing 10mg of idarubicin hydrochloride

Excipients (per vial)	100 mg of lactose monohydrate	250mg of glycerol, Water for Injections q.s. to 10mL and HCL to pH 3.5
Packaging information	Colourless glass vial, type I, with chlorobutyl rubber bung and aluminium seal with insert yellow polypropylene disk.	Polypropylene vial, which is closed with a siliconised, halobutyl rubber stopper and sealed with an aluminum cap with a plastic flip off
Storage	Unreconstituted solution: No special storage conditions	Store at 2 to 8°C, refrigerated (do not freeze) and protected from light
Warning		ZAVEDOS solution for injection do not contain antimicrobial preservative. Use in one patient on one occasion only. Discard any residue.

### Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

### Further Information

Unlicensed Australian Zavedos can be ordered through the standard Zavedos 5mg PIP code 036-8936 or the standard Zavedos 10mg PIP code 036-9249 with Alliance Healthcare. You will receive a message to call the Pfizer Customer Contact Centre at **0345 608 8866** who will manage your order.

If you have any questions about this letter, please contact Pfizer Medical Information on **01304 616161** or visit <https://www.pfizermedicalinformation.co.uk/>

Yours faithfully,



Seema Patel

Hospital Medical Director

Pfizer UK