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23 August 2023

Direct Healthcare Professional Communication
Notification of temporary supply interruption

Cisplatin 1 mg/ml Sterile Concentrate - Temporary supply of unlicensed imported product

Dear Healthcare Professional,

Summary: Pfizer UK is currently out of stock of Cisplatin 50mg/50ml and 100mg/100ml due to a delay in manufacturing.

To ensure continuity of supply, Pfizer Limited has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Cisplatin from Ireland. Batch number GM6308, Expiry date 31 May 2024. The product is unlicensed in the UK which means it has not been given a Marketing Authorisation by the MHRA.

Please note the following:

- The imported product has the same formulation as the UK licensed product. A comparison of the two products is shown in the table below however please note the differences in the storage information.
- The benefit-risk profile is consistent with the UK formulation.
- There are minor differences between the Irish and UK product information. Please ensure UK Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.

Cisplatin will be out of stock in the UK from 31 August 2023. Resupply is expected by November 2023. 900 packs will be imported which is 1 week's supply in the UK.

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

Product comparison

To help mitigate the shortage we have obtained for supply to the UK a batch of unlicenced Cisplatin 100 mg/100 ml from Ireland.

Key aspects of the UK licensed product and Irish unlicensed product are detailed below:

	UK Product	Unlicensed product
Pack Size	100 mg/100 ml	100 mg/100 ml
Appearance	Clear, colourless to pale yellow solution	Clear, colourless to pale yellow solution.
Excipients (per vial)	Mannitol Sodium chloride Dilute hydrochloric acid Water for injections	Mannitol (E421) Sodium chloride Dilute hydrochloric acid (for pH adjustment) Water for injections
Packaging information	100 mg/100 ml presentations in Type I amber glass vials and Onco-Tain® vials with rubber closures, packed as single vials.	100 mg/100 ml presentation in Type I amber glass vials and Onco-Tain vials. Packs contain a single vial.
Storage	Prior to first use: Do not store above 25°C. Do not refrigerate or freeze. Keep container in the outer carton in order to protect from light. In use: Following dilution in 0.9% sodium chloride injection, chemical and physical in-use stability has been demonstrated for up to 14 days at 20°C. The diluted product should not be refrigerated. From a microbiological point of view, however, the product should be used immediately. If not used immediately, in-use storage times and conditions	Prior to first use: Do not store above 25°C. Do not refrigerate or freeze. Keep vial in the outer carton in order to protect from light. In use: Following dilution in 0.9% Sodium Chloride Injection to a final concentration of 0.15 mg/ml, chemical and physical in-use stability has been demonstrated for up to 14 days at 4°C when protected from light. From a microbiological point of view, however, the product should be used immediately. If not used immediately, in-

	prior to use are the responsibility of the user and dilution should take place in controlled and validated aseptic conditions.	use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C unless dilution has taken place in controlled and validated aseptic conditions.

Call for reporting:

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Contact Pfizer Customer Service on 0345 608 8866.
If you have any questions about this letter, please contact Pfizer Medical Information at:

Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS. United Kingdom.
Telephone: 01304 616161 or visit https://www.pfizermedicalinformation.co.uk/

Yours faithfully,

Seema Patel
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