



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy and Ward Level

Date: 18 September 2018

EL (18)A/15

Our Ref: MDR 11-09/18

Dear Healthcare Professional,

Cadiusun Pharma GmbH

**Caspofungin 70mg powder for concentrate for
solution for infusion**

PL 42069/0003

Batch Number	Expiry Date	Pack Size	First Distributed
180524AD	04/2020	1 x vial	19/07/2018
180530AD	04/2020	1 x vial	n/a

Cadiusun Pharma GmbH has informed us that there is an error on the patient information leaflet for the above product.

The error is on the portion of the leaflet which is intended for Healthcare Professionals, in the sections providing instructions for preparation of both 70mg/m² and 50mg/m² infusion for paediatric patients > 3 months of age. In the incorrect version of the leaflet, the final concentration of the solution is given as 5.2mg/ml for both dilutions. **The correct final concentration is 7.2mg/ml, however**

In addition to the error on the Patient Information Leaflet, there is also an error on the Summary of Product Characteristics for the product. The heading for preparation of the 70mg/m² infusion for paediatric patients > 3 months and the heading for preparation of the 50mg/m² infusion for paediatric patients > 3 months incorrectly state in brackets 'using a 50-mg vial'. **The headings should read as follows:**

Preparation of the 70 mg/m² infusion for paediatric patients > 3months of age (using a 70-mg vial)

Preparation of the 50 mg/m² infusion for paediatric patients > 3months of age (using a 70-mg vial)

Steps have already been taken to correct the errors on both the patient information leaflet and the Summary of Product Characteristics.

Please note, the patient information leaflet and Summary of Product Characteristics for the 50mg presentation of the product are correct.



Medicines & Healthcare products
Regulatory Agency



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For medical information enquiries on this matter, please contact Tillomed Medical Information, email pvuk@tillomed.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Please ensure that it is passed on to paediatric wards if the product is prepared on site.

Yours faithfully

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