

5th March 2017

Direct Healthcare professional communication (DHPC) regarding a typing error in the "The maximum dose for serious or refractory infections in pediatrics" mentioned in the English leaflet of Sulperazone (cefoperazone sodium, sulbactam sodium) 1 gm + 0.5 gm powder for solution for injection and a discrepancy between English and Arabic leaflets regarding reconstitution.

Dear Healthcare professional,

Pfizer Egypt would like to inform you of the following:

Summary

- There has been an error in the dosing information in the package insert for Sulperazone 1 gm + 0.5 gm powder for solution for injection where the English leaflet **incorrectly states the maximum dose for serious or refractory infections in pediatrics**. It is stated that dosages may be increased up to **160 mg/kg/day**.
- There has also been a discrepancy between English and Arabic leaflets regarding reconstitution where **the Arabic leaflet incorrectly states the volume of diluent as 6.7ml**.
- The Egyptian Ministry of Health has been informed of this issue and this letter is being distributed with their endorsement.

Further information on the safety concern and the recommendations

The dosing section in the **English package insert** of Sulperazone 1 gm + 0.5 gm powder for solution for injection **incorrectly states the maximum dose for serious or refractory infections in pediatrics**. It is stated that dosages **may be increased up to 160 mg/kg/day**, while the **Arabic translation correctly states that dosages may be increased up to 240 mg/kg/day**.

Kindly be informed that **the correct maximum dose for serious or refractory infections in pediatrics is 240 mg/kg/day**.

The reconstitution section in the Arabic package insert of Sulperazone 1 gm + 0.5 gm powder for solution for injection **incorrectly states that the volume of diluent to be used is 6.7 ml** while the **English text correctly states that the volume of diluent to be used is 3.2 ml**.

Kindly be informed that **the correct volume of diluent to be used is 3.2 ml**

To correct this issue, the English label of Sulperazone 1 gm + 0.5 gm powder for solution for injection has been amended. Kindly find attached the correct revised English label in **Annex I**.

Further information

- SULPERAZONE is indicated for the treatment of the following infections when caused by susceptible organisms:
- Respiratory tract infections (upper and lower)
- Urinary tract infections (upper and lower)



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- Peritonitis, cholecystitis, cholangitis and other intra-abdominal infections
 - Septicemia
 - Meningitis
 - Skin and soft tissue infections
 - Bone and joint infections
 - Pelvic inflammatory disease, endometritis, gonorrhoea, and other infections of the genital tract.