

31-Jan-2017

Direct Healthcare professional communication (DHPC) regarding a typing error in the "Duration of treatment" mentioned in the Arabic leaflet of Zithromax (Azithromycin) 200mg/5ml suspension.

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 Zithromax 200 mg powder for oral suspension where the Arabic translation incorrectly states the dose for children weighing between 15 - 25 kg (3 - 7 years) as 5 mL (200mg) once daily for five days .
- 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 Zithromax 200 mg powder for oral suspension **correctly states** the dose for children weighing between 15 - 25 kg (3 - 7 years) is 5 mL (200mg) **once daily for three days**, while the **Arabic translation incorrectly states that this same dose is to be given for 5 days**.

Kindly be informed that the correct dosage for children weighing between 15 - 25 kg (3 - 7 years) is 5 mL (200mg) once daily for three days.

To correct this issue, the Arabic translation of this section of the package insert for Zithromax 200mg in 5 ml suspension has been revised and amended. **Find attached the correct revised Arabic package insert in annex 1.**

Further information

Azithromycin is indicated for the treatment of the following infections when known or likely to be due to One or more susceptible microorganisms:

- Bronchitis
- Community-acquired pneumonia
- Sinusitis
- Pharyngitis/tonsillitis
- Otitis media
- Skin and soft tissue infections
- Uncomplicated genital infections due to Chlamydia trachomatis.

Considerations should be given to official guidance regarding the appropriate use of antibacterial agents.