



## Direct Healthcare Professional Communication

Nov 2024

### **Azithromycin dihydrate, Zithromax 200 mg in 5 ml suspension and replacement of the syringe inside the box to be graduated in mLs only.**

Dear Healthcare Professional,

Pfizer, in agreement with the Egyptian Drug Authority and the Pharmacovigilance General Administration (PVGA) would like to inform you about the following:

#### **Summary**

- Change in the graduation of the syringe provided inside the box of Zithromax 200mg in 5 ml suspension to remove KGs graduation and to be in mLs only, and this change will directly impact Pediatric population dosage calculation. The new dosing using mL is as follows:
- **Paediatric population:**  
In children under 45 kg body weight: Zithromax Suspension should be used for children under 45 kg. There is no information on children less than 6 months of age. The dose in children is 10 mg/kg as a single daily dose for 3 days:  
Up to 15 kg: Measure the dose as closely as possible using the 10 ml oral dosing syringe provided. The syringe is graduated in 0.25 ml divisions, providing 10 mg of azithromycin in every graduation.  
For children weighing more than 15 kg, Zithromax Suspension should be administered using the syringe provided according to the following guidance:
  - 15-25 kg: 5 ml (200 mg) given as 1 x 5 ml, once daily for 3 days.
  - 26-35 kg: 7.5 ml (300 mg) given as 1 x 7.5 ml, once daily for 3 days.
  - 36-45 kg: 10 ml (400 mg) given as 1 x 10 ml, once daily for 3 days.
- **6.5 Nature and content of the container**  
Zithromax Powder for Oral Suspension is available as:  
600 mg (15 ml) Pack: (Recommended for use in children up to 25 kg).  
Carton box containing one plastic bottle of 600 mg Azithromycin (when reconstituted, each 5 ml contains 200 mg Azithromycin), plastic syringe and an inner leaflet. Reconstitute with 9 ml of water to give 15 ml suspension.  
900 mg (22.5 ml) Pack: (Recommended for use in children from 26-35 kg).  
Carton box containing one plastic bottle of 900 mg Azithromycin (when reconstituted, each 5ml contains 200 mg Azithromycin), plastic syringe and an inner leaflet. Reconstitute with 12 ml of water to give 22.5 ml suspension.



1200 mg (30 ml) Pack: (Recommended for use in children from 36-45 kg).

Carton box containing one plastic bottle of 1200 mg Azithromycin (when reconstituted, each 5 ml contains 200 mg Azithromycin), plastic syringe and an inner leaflet. Reconstitute with 15 ml of water to give 30 ml suspension.

### **Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

