GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Date: 25th December 2016

TITLE: Augmentin ® (*amoxicillin/clavulanic acid*) Infant Drops - Incorrect Information in Patient Information Leaflet (PIL)

Dear Healthcare Professional,

GlaxoSmithKline safety advisory would like to inform you of the following:

Therapeutic Indication

Augmentin Infant Drops are indicated in the short-term treatment of susceptible bacterial infections. The current Patient Information Leaflet (PIL) has an error of incorrect information on composition in the last section (Pack Content and Additional Information). The error in the composition states that each *5ml* of the suspension contains 50 mg amoxicillin, whereas the correct information is that each *1ml* of the suspension contains 50 mg amoxicillin.

GlaxoSmithKline (GSK) would like to inform you the dosing information on the **bottle label**, **carton** and **PIL** is correct. It is only the information on Composition in the last section (Pack Content and Additional Information) of the PIL that has this error (as mentioned above). It is important that you follow the correct instructions included in this letter in order to ensure proper dosage of Augmentin drops to infants according to weight.

GSK is alerting prescribers to ensure you have access to the correct product labelling for Augmentin Infant drops 62.5mg/ml sugar-free suspension.

Key Messages

- It is important to follow the usual recommended daily dosage of 25 mg/kg/day* in divided doses every eight hours. In more serious infections the dosage may be increased up to 50 mg/kg/day in divided doses every eight hours.

* Each 25 mg *AUGMENTIN* provides 20 mg amoxicillin and 5 mg clavulanate :

The volumes of *AUGMENTIN* infant drops which correspond to the weight of a child are shown below:

Weight of child (kg)	Volume (ml) of *AUGMENTIN* infant drops **
1	0.13
1.5	0.20
2	0.27
2.5	0.33
3	0.40
3.5	0.47
4	0.53
4.5	0.60
5	0.67

5.5	0.73
6	0.80
6.5	0.87
7	0.93
7.5	1.00
8	1.07
8.5	1.14
9	1.20
9.5	1.27
10	1.34
** These doses may be doubled in cases of severe infection.	

Action Being Taken by GlaxoSmithKline

GSK is ensuring that all health care providers have access to the correct product labelling for Augmentin Infant Drops. In addition, GSK will ensure that in the future Augmentin Infant Drops will contain the correct product leaflet. Packs of Augmentin Infant Drops are not being recalled and it may take a number of weeks or months for all packs of Augmentin Infant Drops containing the incorrect package leaflet to be dispensed and used by patients. Health care providers are requested to clearly explain the correct dosage to parents to insure proper dose is given. This letter is being sent to you after agreement with the Saudi Food and Drug Authority.

Action required by Health Care Providers

- You are advised to refer to the product labeling when calculating the proper dose according to the infant's weight. Please share this information with relevant health care personnel under your supervision.
- You are advised to ensure parents to stick to the calculated dosage by health care providers.

Call for Reporting:

NPC and GlaxoSmithKline Contact details for reporting adverse drug reactions as follow:
The National Pharmacovigilance and Drug Safety Centre at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa
Or contact GlaxoSmithKline safety to report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s by email: sa.aermi-saudi@gsk.com

Contact(s) for Further Information/Questions:

Should you have any questions or require additional information, please contact:

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With regards,
25/12/2016.
Dr. Nauman Rashid
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