



Date: 25-Aug-2021

Direct Healthcare Professional Communication

Phentolep® (Phenytoin): Typographical error in the Patient Information Leaflet (PIL) in batch #7185.

Dear healthcare professional,

Hikma in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of important information regarding a typographical error in Phentolep® Arabic PIL.

Summary:

- The Arabic PIL of Phentolep® (batch #7185) incorrectly stated that “in adults and adolescents 13 years (or older), Phentolep® is administered with maximum injection rate of 0.5 mg/min. (corresponding to 23 mg phenytoin/min.)”, which does not reflect the correct translation for the English PIL and should be amended.
- The correct statement, as mentioned in the English PIL, is that Phentolep® is administered with maximum injection rate of 0.5 ml/min.
- This typographical error shouldn't affect the patient's safety or product's quality, as the product is given by a healthcare professional in a hospital setting who is aware of the correct posology of the product.

Background on the typographical error:

In the Arabic PIL for Phentolep®, it is mistakenly stated that in adults and adolescents 13 years (or older), Phentolep® is administered with maximum injection rate of 0.5 mg/min, instead of the correct unit 0.5 ml/min. The English version does not have this typographical error.

This typographical error is not likely to affect the patient's safety and product's quality, as the product is given by a healthcare professional in a hospital setting who is aware of the correct posology of the product.

Hikma would like to disseminate this letter to inform healthcare professionals about this error.

This error is only present in batch #7185, and other batches are not affected.

Please rest assured that patient safety is our top priority, thus, healthcare professionals, are encouraged to contact Hikma through the contact details mentioned below, should they require any further clarification.



Call for reporting for adverse reactions

The National Pharmacovigilance and Drug Safety Centre (NPC):

Website <https://ade.sfda.gov.sa>

Email: npc.drug@sfda.gov.sa

Call center number: 19999

Company contact point

Abdulkareem bin Mubarak

Local QPPV

Hikma Pharmaceuticals

email: SAPV@hikma.com

Tel.: 00966114173731 Ext. 1086

Website: www.hikma.com