



Government of Pakistan  
Ministry of National Health Services, Regulation and Coordination  
(Drug Regulatory Authority of Pakistan)

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"SAY NO TO CORRUPTION"

No. F.290-DRB/2019 (PE&R)

Islamabad, the 11<sup>th</sup> October, 2019


ADVISORY

Subject: - REVIEW OF FORMULATIONS OF CIPROFLOXACIN ORAL SUSPENSION.

I am directed to refer the subject captioned above. Registration Board in its various meetings deliberated the matter regarding the formulation and use of different diluents/solvents for ciprofloxacin oral suspension and after detailed deliberations and consideration of approval status in reference regulatory authorities and innovator drug product, Registration Board in its 290<sup>th</sup> meeting held on 3<sup>rd</sup> - 4<sup>th</sup> July, 2019 decided as follows:


- a) All formulations of ciprofloxacin dry suspension shall contain micro-granules of ciprofloxacin base instead of hydrochloride salt. Accordingly, registration holders need to submit cases for necessary correction of formulation in post registration variation section of Pharmaceutical Evaluation and Registration (P.E&R) Division.
- b) All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product.
  - Soya lecithin
  - Medium chain triglycerides
  - Flavor
  - Sucrose
  - Purified water.

2. In order to ensure provision of safe, effective and quality products, all pharmaceutical manufacturers/importers having registration of Ciprofloxacin oral suspension are, therefore, advised to comply with the above directions of Registration Board.

  
(ABDULLAH) 11/10/19  
Additional Director (PE&R)/  
Secretary, Registration Board

Distribution:-

- i. PS to CEO, DRAP.
- ii. PA to Director (PE&R)/Chairman, Registration Board.
- iii. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- iv. Executive Director, Pharma Bureau, Karachi.
- v. Executive Director, PC&DA, Karachi.
- vi. Additional Director (MIS), DRAP for uploading on DRAP's website.
- vii. Additional Director/Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective areas of jurisdiction.

 Please upload all the advisories on website under the (PE&R) and newspapers  
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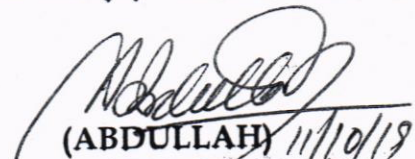
ADVISORY

Subject: - REVIEW OF DOMPERIDONE CONTAINING MEDICINAL PRODUCTS.

I am directed to refer to the subject captioned above. Registration Board in its 290<sup>th</sup> meeting held on 3<sup>rd</sup> - 4<sup>th</sup> July, 2019 while discussing a case of review of domperidone containing medicinal products, decided to update the clinical indications, adverse events, contraindications and Patient Information Leaflet (PIL) as per the recommendations of EMA.

2. The Board further advised all firms having registration of domperidone containing medicinal products to use the clinical indications, adverse events and contraindications in their leaflets which are approved by EMA (Ref: [https://ansm.sante.fr/content/download/162841/2129989/version/1/file/DHPC-190628\\_motilium.pdf](https://ansm.sante.fr/content/download/162841/2129989/version/1/file/DHPC-190628_motilium.pdf)).

3. In order to ensure provision of safe, effective and quality products, all pharmaceutical manufacturers/importers having registration of domperidone containing medicinal products are, therefore, advised to comply with the above directions of Registration Board.

  
(ABDULLAH) 11/10/19  
Additional Director (PE&R)/  
Secretary, Registration Board

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