

**DECISION**  
**No. 6/19.12.2017**  
**on approval of the change of status as regards classification for supply of**  
**Fucidin 20 mg/g, cream and Fucidin 20 mg/g, ointment**  
**(acidum fusidicum)**

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, convened on summons by the NAMMD President in the ordinary session of 19.12.2017, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

**DECISION**

Single Article – The change of status as regards classification for supply of Fucidin 20 mg/g, cream and Fucidin 20 mg/g, ointment (acidum fusidicum) is approved (Marketing Authorisation Holder: LEO Pharma A/S), under the following conditions:

1. Restriction of indications to:
  - infected wounds,
  - boils,
  - folliculitis.

2. Change of trade name.

**PRESIDENT**  
**of the Scientific Council**  
**of the National Agency for Medicines and Medical Devices,**

**Prof. Dr. Anca-Dana Buzoianu**