

The National Agency for Medicines and Medical Devices (NAMMD) hereby reminds the importance of proper use of ibuprofen-containing medicines in the context of recent media articles.

Ibuprofen is a non-steroidal anti-inflammatory medicinal product (NSAID), mainly used to treat pain and fever.

The NAMMD has become aware of results of a study conducted in Denmark¹, jointly with a team of the National Institute for Health and Medical Research (INSERM) in France, on ibuprofen effects on testicular physiology.

The results of the study, which included 31 healthy male volunteers, athletes, 14 of whom have received daily 1200 mg ibuprofen doses for 6 weeks, suggest that, taken as such, ibuprofen may affect testicular physiology.

At this stage, results do not alter the benefit / risk ratio for ibuprofen, if used in accordance with its Marketing Authorisation terms. In this context, the NAMMD would like to remind the public of the importance of compliance with treatment indications (dose and duration) as specified in the Product information of ibuprofen-containing medicines, namely use of the lowest effective dose for the shortest period necessary for symptom improvement.

Please refer to the Summary of Product Characteristics (SPCs) and Patient Leaflet of ibuprofen-containing medicines (INN ibuprofen), provided on the NAMMD website, at <https://www.anm.ro/nomenclator/medicamente>.

The European Medicines Agency (EMA), in collaboration with other competent authorities in the European Union, will evaluate the results of the study and communicate accordingly.

The NAMMD has undertaken to provide constant information for healthcare professionals, patients and the general public on any developments regarding results of a review of medicinal product safety profile as received from European bodies in the field.

¹ Kristensen D.M. et al., Ibuprofen alters human testicular physiology to produce a state of compensated hypogonadism, PNAS, 2018: www.pnas.org/cgi/doi/10.1073/pnas.1715035115.