Meningioma risk associated with cyproterone medicines: PRAC starts a review

02.08.2019 | Circular Number P15/2019

Information on cyproterone acetate

- Cyproterone is an antiandrogen medicine used to treat a range of conditions such as hirsutism, alopecia, early puberty, amenorrhoea, acne, prostate cancer and in hormone replacement therapy
- Cyproterone acts by blocking the action of androgens, which are a type of sex hormone found in both women and men. Cyproterone medicines can contain cyproterone alone or a lower dose of cyproterone in combination with a third type of sex hormone (oestrogen).

In Malta the following products are authorised through national procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Cyproterone acetate 50 milligram(s)	Cyproterone Acetate	Tablet	POM	MA154/01001	Wockhardt UK Limited
Cyproterone acetate 50 milligram(s)	Androcur 50mg Tablets	Tablet	POM	MA513/03601	Bayer PLC
Cyproterone acetate 50 milligram(s)	Cyproterone Acetate 50mg Tablets	Tablet	POM	AA267/00201	Stragen UK Limited
Cyproterone acetate 50 milligram(s)	Cyproterone Acetate Tablets 50mg	Tablet	POM	AA729/17901	Cherubino Limited
Cyproterone acetate 50 milligram(s)	Cyproterone Acetate 50mg Tablets	Tablet	POM	AA565/26901	Central Procurement & Supplies Unit
Cyproterone acetate 2 milligram(s) | Ethinylestradiol 35 microgram(s)	Clairette 2000/35 Tablets	Coated Tablet	POM	AA267/00501	Stragen UK Limited

Information from the EMA about meningioma risk associated with cyproterone medicines

The Pharmacovigilance Risk Assessment Committee (PRAC) started a review on meningioma risk associated with cyproterone under Article 31 of Directive 2001/83/EC, following the request of France.

Meningioma is a rare, usually non-malignant tumour which can cause serious problems due to its location in and around the brain and spinal cord. Meningioma risk associated with daily doses of cyproterone 10 mg or higher has been known since 2008 and included in the prescribing information along with a warning that cyproterone should not be used in people who have or have had a meningioma tumour. However, information on the magnitude of meningioma risk associated with cyproterone and how risk could change with different doses was not known when prescribing information was updated.

Following a study carried out in France, high doses of cyproterone taken for long periods might be associated to greater risk of developing meningioma, although the risk remains low. Furthermore, the study showed that meningioma risk associated with cyproterone was diminished in patients who had stopped cyproterone treatment for at least one year, although slightly higher than normal. The PRAC will now evaluate available information and make recommendation accordingly.

PRAC's recommendation will be forwarded to the CMDh which will adopt a position

For more information please see the European Medicines Agency's Cyproterone-containing medicines referral page

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Cyproterone-containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000