

## FSRH CEU Statement : New advice from the MHRA regarding cyproterone acetate: how does this affect prescribing of Co-cyprindiol/Dianette® for acne/hirsutism?

13 July 2020

### Background

New data from a French cohort study [1] indicate that use of high dose cyproterone acetate (high dose products contain 50-100mg per tablet) is associated with significantly increased risk of meningioma. In the study, meningioma risk increased with increasing cumulative cyproterone acetate exposure over time; a cumulative dose of 12-36g was associated with an estimated 6-fold greater risk (annual incidence 26 per 100,000 users) than a cumulative dose of less than 3g (annual incidence 4.5 per 100,000). For reference, the MHRA estimates annual incidence of meningioma in the general population to be about 6 per 100,000.[2]

### Preparations containing low dose cyproterone acetate with ethinylestradiol

Co-cyprindiol/Dianette® tablets containing cyproterone acetate with ethinylestradiol are used for treatment of acne and hirsutism in women of reproductive age. In contrast to the high dose products described above, they contain only 2mg of cyproterone acetate; annual cumulative exposure to cyproterone acetate is only about 0.8g. The Yellow Card scheme has received no reports of meningioma associated with use of these low-dose products. The MHRA advises that although exposure to this low dose of cyproterone acetate has not been shown to increase risk of meningioma, an association is plausible and cannot be excluded.

### Advice from the MHRA

MHRA advice [2] is that individuals who have had a meningioma should not use **any** product containing cyproterone acetate. Women without a history of meningioma may use Co-cyprindiol/Dianette for management of acne/hirsutism; clinicians should be vigilant for symptoms and signs of meningioma.

### Recommendation from the FSRH CEU

Cyproterone acetate should not be used by individuals with a history of meningioma. Individuals that have not had meningioma may consider use of cyproterone acetate 2mg with ethinylestradiol for acne/hirsutism. They should be made aware that increased risk of meningioma associated with cumulative exposure to low dose cyproterone acetate cannot be excluded, but risk is likely to remain very low.

### References

1. Weill A, Nguyen P, Yoldjian I, Fontanel S, Froelich S, Coste J. Exposition prolongée à de fortes doses d'acétate de cyprotérone et risque de méningiome chez la femme: une recherche-action de santé publique en France. *Revue d'Épidémiologie et de Santé Publique* 2020;**68**:S3-4.
2. MHRA. Gov.uk. Cyproterone acetate: new advice to minimise risk of meningioma. 29 June 2020. Available online [here](#) (accessed 9 July 2020)

*The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual and Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a member's enquiry service, evidence based guidance, new SRH product reviews and clinical audit/research. [Find out more here.](#)*