

Cyproterone acetate and the risk of meningiomas

Final SPC and PL wording agreed by the PhVWP in October 2009

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Changes apply to cyproterone-containing drugs with dosages higher than 2mg.

SUMMARY OF PRODUCT CHARACTERISTICS

section 4.3

/.../ must not be used in patients with meningioma or a history of meningioma.

section 4.4

The occurrence of (multiple) meningiomas has been reported in association with longer term use (years) of cyproteronacetate at doses of 25mg/day and above. If a patient treated with /.../ is diagnosed with meningioma, treatment with /.../ must be stopped (see section 4.3).

section 4.8

The occurrence of (multiple) meningiomas has been reported in association with longer term use (years) of cyproteronacetate at doses of 25mg/day and above.

PACKAGE LEAFLET

Section 2. Before you use...

Do not use /.../

if you have ever been diagnosed with a meningioma (a generally benign tumor of the tissue layer between the brain and the skull). You should ask your physician if you are in doubt.

Section 4. Possible side effects

The occurrence of meningiomas has been reported in association with longer term use (years) of /.../ at doses of 25mg/day and above.