

Sikkerhetsoppdatering

April 2010

Cyproteronacetat og risiko for meningeomer

Tekst til preparatomtale

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.

Tekst til pakningsvedlegg

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.