

CHECKLIST FOR PRESCRIBERS

cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets

Please use this checklist in conjunction with the Summary of Product Characteristics and at regular intervals.

Indication for which Vreya 2 mg/0.035 mg coated tablets is prescribed:

Treatment of moderate to severe acne related to androgen sensitivity (with or without seborrhoea) and/or hirsutism, in women of reproductive age.

For the treatment of acne, Vreya 2 mg/0.035 mg coated tablets should only be used after topical therapy or systemic antibiotic treatments have failed.

Since Vreya 2 mg/0.035 mg coated tablets is also a hormonal contraceptive, it should not be used in combination with other hormonal contraceptives.

- Thromboembolism (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke) is a rare but important risk with use of cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets.
- A woman's risk will also depend on her baseline risk of thromboembolism. The decision to use cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets should therefore take into consideration the contraindications and a woman's risk factors, particularly those for thromboembolism – see boxes below and the Summary of Product Characteristics.
- The risk of a thromboembolism with cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets is highest:
 - during the first year of use
 - when re-starting use after an intake break of 1 month or more.
- The decision to use cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets should be taken only after a discussion with the woman to ensure she understands:
 - the effect of any intrinsic risk factors on her risk of thrombosis
 - the risk of thromboembolism with Vreya 2 mg/0.035 mg coated tablets
 - that she must be alert to the signs and symptoms of a thrombosis.

Remember to consider the possibility of a thromboembolic event in healthy women of reproductive age also in case of non-distinct, unexplained complaints like pain in the leg, cough/dyspnoea, or headache.

Do not prescribe cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets **if you tick any of the boxes in this section. Does the woman have:**

<input type="checkbox"/>	Concomitant use of another hormonal contraceptive?
<input type="checkbox"/>	Current or personal history of a thromboembolic event e.g. deep vein thrombosis, pulmonary embolism, heart attack, stroke, transient ischaemic attack, angina pectoris?
<input type="checkbox"/>	Knowledge of a predisposition to a blood clotting disorder?
<input type="checkbox"/>	History of migraine with aura?
<input type="checkbox"/>	Diabetes mellitus with vascular complications?
<input type="checkbox"/>	Very high blood pressure e.g. systolic ≥ 160 or diastolic ≥ 100 mm Hg?
<input type="checkbox"/>	Very high blood lipids?
<input type="checkbox"/>	Major surgery or a period of prolonged immobilisation coming up? If so, <u>advise the patient to stop using Vreya 2 mg/0.035 mg coated tablets, use a non-hormonal treatment for their skin condition and if necessary a non-hormonal method of contraception for at least 6 weeks beforehand and two weeks after full ambulation. This should be weighed against the risk of VTE after stopping cyproterone acetate/ethinylestradiol for 6 weeks or more.</u>

Discuss the suitability of cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets with the woman if you tick any of the boxes in this section:	
<input type="checkbox"/>	Is her BMI over 30 kg/m ² ?
<input type="checkbox"/>	Is she aged over 35 years?
<input type="checkbox"/>	Is she a smoker? If yes and also over the age of 35 she should be strongly advised to stop smoking or use a non-hormonal treatment for her acne and/or hirsutism.
<input type="checkbox"/>	Does she have high blood pressure e.g. systolic 140-159 or diastolic 90-99mm Hg?
<input type="checkbox"/>	Does she have a close relative (e.g. parent or sibling) who has had a thromboembolic event (see above list) at a young age (e.g. before 50)?
<input type="checkbox"/>	Does she or someone in her immediate family have high blood lipids?
<input type="checkbox"/>	Does she get migraines?
<input type="checkbox"/>	Does she have a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease?
<input type="checkbox"/>	Does she have diabetes mellitus?
<input type="checkbox"/>	Has she given birth in the last few weeks?
<input type="checkbox"/>	Does she have any other medical conditions that might increase the risk of thrombosis (e.g. cancer, systemic lupus erythematosus, sickle cell disease, Crohn's disease, ulcerative colitis, haemolytic uraemic syndrome)?
<input type="checkbox"/>	Is she taking any other medicines that can increase the risk of thrombosis (e.g. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapy etc)?
More than one risk factor may mean cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets should not be used. Don't forget, a woman's risk factors may change over time and might need to be revisited at regular intervals.	

<p>Please make sure your patient understands that she should tell a healthcare professional she is taking cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets if she:</p> <ul style="list-style-type: none"> • needs an operation • needs to have a period of prolonged immobilisation (e.g. because of an injury or illness, or if her leg is in a cast) <p>➤ <u>In these situations it would be best to discuss discontinuation of</u> cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets <u>until the risk returns to normal.</u></p>
<p>Please also tell your patient that the risk of a blood clot is increased if she:</p> <ul style="list-style-type: none"> • travels for extended periods (e.g. on long-haul flights) • develops one or more of the above risk factors for cyproterone acetate/ethinylestradiol Vreya 2 mg/0.035 mg coated tablets. • has given birth within the last few weeks <p>➤ <u>In these situations your patients should be particularly alert to any signs and symptoms of a thromboembolism.</u></p>

Please advise **your patient to tell you** if any of the above situations get much worse or change.

Please strongly encourage women to read the Patient Information Leaflet that accompanies each pack of Vreya 2 mg/0.035 mg coated tablets. This leaflet includes the symptoms of blood clots that she must watch out for.

Adverse events

If you suspect you have an undesirable effect associated with the use of your medication, you can report it to a Healthcare professional.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt

This information can also be reported to MAH HEATON k.s. by email:

farmakovigilance@heaton.cz

Tel.: +420 602 440 229

HEATON k.s.

Na Pankráci 332/14

Prague 4, 140 00

Czech Republic

www.heaton.cz

By reporting side effects, you can help provide more information on the safety of this medicine.