

CHECKLIST FOR PRESCRIBERS

cyproterone acetate/ethinylestradiol [CLAIRETTE 2000/35 Tablets]

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

Indication for which CLAIRETTE 2000/35 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, CLAIRETTE 2000/35 Tablets should only be used after topical therapy or systemic antibiotic treatments have failed.

Since CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 Tablets].
- A woman's risk will also depend on her baseline risk of thromboembolism. The decision to use cyproterone acetate/ethinylestradiol [CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 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 CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 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 CLAIRETTE 2000/35 Tablets, use a non-hormonal treatment for their skin condition and if necessary a nonhormonal 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 [CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 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 [CLAIRETTE 2000/35 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 cyproterone acetate/ethinylestradiol [CLAIRETTE 2000/35 Tablets] 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 [CLAIRETTE 2000/35 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>
<p>Please advise your patient to tell you if any of the above situations get much worse or change.</p> <p>Please strongly encourage women to read the Patient Information Leaflet that accompanies each pack of CLAIRETTE 2000/35 Tablets. This leaflet includes the symptoms of blood clots that she must watch out for.</p>

Adverse events

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

