



CHECKLIST FOR PRESCRIBERS

Combined hormonal contraceptives (CHCs) and risk of thromboembolism^a

PATIENT NAME: _____ DATE (MM/DD/YYYY): _____

Please use this checklist in conjunction with the prescribing information and at regular intervals.

- Thromboembolism (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke) is a rare but important risk with use of combined hormonal contraceptives.
- A woman's risk will also depend on her baseline risk of thromboembolism. The decision to use a CHC should therefore take into consideration the contraindications and a woman's risk factors, particularly those for thromboembolism – see boxes below and the prescribing information.
- The risk of a thromboembolism with a CHC is higher:
 - during the first year of use
 - when re-starting use after an intake break of 1 month or more.
- The decision to use a CHC 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 increase associated with CHC use
 - that she must be alert for signs and symptoms of a thrombosis

Do not prescribe a CHC if you tick any of the boxes in this section. Does the woman have:

- | | |
|--|--|
| <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"/> Very high blood pressure e.g. systolic ≥ 160 or diastolic ≥ 100 mm Hg? |
| <input type="checkbox"/> Knowledge of predisposition for blood clotting disorder? | <input type="checkbox"/> Very high blood lipids? |
| <input type="checkbox"/> History of migraine with aura? | <input type="checkbox"/> Major surgery or a period of prolonged immobilisation coming up? If so, advise to use a non-hormonal method of contraception for at least 4 weeks beforehand and 2 weeks after full ambulation. ^b |
| <input type="checkbox"/> Diabetes mellitus with vascular complications? | |

Discuss the suitability of a CHC as method of contraception 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"/> Does she get migraines? |
| <input type="checkbox"/> Is she aged over 35 years? | <input type="checkbox"/> Does she have a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease? |
| <input type="checkbox"/> Is she a smoker? If yes and also over the age of 35 years she should be strongly advised to stop smoking or use a contraceptive method other than CHCs. | <input type="checkbox"/> Does she have diabetes mellitus? |
| <input type="checkbox"/> Does she have high blood pressure e.g. systolic 140–159 or diastolic 90–99 mm Hg? | <input type="checkbox"/> Has she given birth in the last few weeks? |
| <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 years)? | <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"/> Does she or someone in her immediate family have high blood lipids? | <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 that a CHC 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.

^aChecklist based on guidance from the review of CHCs, particularly of the risk of venous thromboembolism (VTE or blood clots in veins) associated with their use, completed by the European Medicines Agency in November 2013 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Combined_hormonal_contraceptives/human_referral_prac_000016.jsp&mid=WC0b01ac05805c516f)

^bThis should be weighed against the risk of venous thromboembolism after stopping a CHC for 4 weeks or more



Please make sure your patient understands that she should tell a healthcare professional she is taking a CHC if she:

- 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)
- > **In these situations it would be best to discuss to discontinue the CHC until the risk returns to normal.**

Please also tell your patient that the risk of a blood clot is increased if she:

- Travels for extended periods (e.g. on long-haul flights)
- Develops one or more of the above risk factors for venous thromboembolism/arterial thromboembolism
- Has given birth within the last few weeks
- > **In these situations your patients should be particularly alert for any signs and symptoms of a thromboembolism.**

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

Please strongly encourage women to read the Patient Information Leaflet that accompanies each pack of CHC product. This includes the symptoms of blood clots that she must watch out for.

**For further information please refer to product SmPC or go to www.medicinesauthority.gov.mt
If you suspect you have an undesirable effect associated with the use of a CHC, you can report it to the Medicines
Authority on
[www.medicinesauthority.gov.mt/adr
portal](http://www.medicinesauthority.gov.mt/adr_portal)**

Additional comments