

**Please use this checklist in conjunction with the Summary of Product Characteristics during combined hormonal contraceptive (CHC) consultations.**

- **Thromboembolism** (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke) is a rare but important risk with use of a CHC.
- 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 Summary of Product Characteristics.
- 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 4 or more weeks.
- CHCs that contain ethinylestradiol in combination with **levonorgestrel, norgestimate or norethisterone** are considered to have the **lowest risk** of venous thromboembolism (VTE).
- The decision to use any 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** of thromboembolism with her CHC
  - that she must be alert for **signs and symptoms** of a thrombosis

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

- Current or personal history of a thromboembolic event e.g. deep vein thrombosis, pulmonary embolism, heart attack, stroke, transient ischaemic attack, angina pectoris?
- Knowledge of predisposition for a blood clotting disorder?
- History of migraine with aura?
- Diabetes mellitus with vascular complications?
- Very high blood pressure eg systolic  $\geq 160$  or diastolic  $\geq 100$ mm Hg?
- Very high blood lipids?
- 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 two weeks after full ambulation.**

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**Discuss the suitability of a CHC with the woman if you tick any of the boxes in this section:**

- Is her BMI over 30 kg/m<sup>2</sup>?
- Is she aged over 35 years?
- 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 method of contraception.**
- Does she have high blood pressure eg systolic 140-159 or diastolic 90-99mm Hg?
- Does she have a close relative (eg parent or sibling) who has had a thromboembolic event (see above list) at a young age (eg before 50)?
- Does she or someone in her immediate family have high blood lipids?

*Discuss the suitability of a CHC with the woman if you tick any of the boxes in this section: (continued)*

- Does she get migraines?
- Does she have a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease?
- Does she have diabetes mellitus?
- Has she given birth in the last few weeks?
- Is she about to go on a long distance flight (>4 hours) or does she travel for more than 4 hours per day?
- Does she have any other medical conditions that might increase the risk of thrombosis (eg. cancer, systemic lupus erythematosus, sickle cell disease, Crohn's disease, ulcerative colitis, haemolytic uraemic syndrome)?
- Is she taking any other medicines that can increase the risk of thrombosis (eg. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapy etc)?

**More than one of the above risk factors may mean a CHC should not be used.**

**Don't forget, a woman's risk factors may change over time and the checklist should be revisited at regular intervals with each patient.**

**Please make sure your patient understands that she should tell a healthcare professional she is taking a combined hormonal contraceptive if she:**

- Needs an operation
- Needs to have a period of prolonged immobilisation (eg because of an injury or illness, or if her leg is in a cast)

**In these situations it would be best to discuss whether a non-hormonal contraceptive should be used until the risk of VTE returns to normal.**

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

- Travels for extended periods (eg longer than 4 hours or during long-haul flights)
- Develops one or more of the above risk factors for VTE
- 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. This includes the symptoms of blood clots that she must watch out for.

Call for reporting: Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance website: [www.hpra.ie](http://www.hpra.ie)

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), the free Yellow Card app available in <https://apps.apple.com/gb/app/yellow-card-mhra/id990237487> Apple App Store or [https://play.google.com/store/apps/details?id=uk.org.mhra.yellowcard&hl=en\\_GB&gl=US](https://play.google.com/store/apps/details?id=uk.org.mhra.yellowcard&hl=en_GB&gl=US) Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm. By reporting side effects, you can help provide more information on the safety of this medicine.