

CHECKLIST FOR PRESCRIBERS – COMBINED HORMONAL CONTRACEPTIVES

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.
- 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).
- 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 decision to use any CHC other than one with the lowest VTE risk should be taken only after a discussion with the woman to ensure she understands
 - the risk of thromboembolism with her CHC
 - the effect of any intrinsic risk factors on her risk of thrombosis
 - that she must be alert for signs and symptoms of a thrombosis

Do not use 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"/>	Known blood clotting disorder personally?
<input type="checkbox"/>	History of migraine with aura?
<input type="checkbox"/>	Diabetes mellitus with vascular complications?
<input type="checkbox"/>	Very high blood pressure eg 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>discontinue use and advise a non-hormonal method of contraception for at least 4 weeks beforehand and two weeks after full ambulation.</u>

Discuss the suitability of a CHC 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 <u>strongly advised to stop smoking or use a non-hormonal method of contraception.</u>
<input type="checkbox"/>	Does she have high blood pressure eg systolic 140-159 or diastolic 90-99mm Hg?
<input type="checkbox"/>	Does she have a close relative who has had a thromboembolic event (see above list) at a

	young age (eg below about 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"/>	Is she about to go on a long distance flight (>4 hours) or does she travel for more than 4 hours per day?
<input type="checkbox"/>	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)?
<input type="checkbox"/>	Is she taking any other medicines that can increase the risk of thrombosis (eg. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapy etc)?
<p>More than one risk factor may mean a CHC should not be used.</p> <p>Don't forget, a woman's risk factors may change over time. It is important to use this checklist at regular intervals with each patient.</p>	

<p>Please make sure your patient understands that she should tell a healthcare professional she is taking a combined contraceptive if she:</p> <ul style="list-style-type: none"> • 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) <p>➤ <u>In these situations it would be best to discuss whether a non-hormonal contraceptive should be used 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 (>4 hours) • Develops any of the contraindications or risk factors for combined contraceptives • Has given birth within the last few weeks <p>➤ <u>In these situations your patients should be particularly alert for any signs and symptoms of a thromboembolism.</u></p>
<p>Please advise your patient to tell you if any of the above situations change or get much worse.</p> <p>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.</p>

Please report any adverse events suspected to be caused by a combined contraceptive to Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland; 1800 633 363 or to the HPRA via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland; Tel: +353 1 6764971; Fax: +353 1 6762517. www.hpra.ie E-mail: medsafety@hpra.ie