

Checklist for prescribers - Core elements

CHECKLIST FOR PRESCRIBERS – COMBINED HORMONAL CONTRACEPTIVES

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

- Thromboembolism (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke) is an 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)?

More than one risk factor may mean a CHC should not be used.

Don't forget, a woman's risk factors may change over time. It is important to use this checklist at every consultation.

Please make sure your patient understands that she should tell a healthcare professional she is taking a combined 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 returns to normal.

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

- 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
- 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.

**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**

Alternatively, Suspected Adverse Drug Reactions (side effects) or medication errors may be reported directly to Marketing Authorisation Holder via contact details provided below:

**Gedeon Richter Plc.
H-1103 Budapest, Gyömrői út 19-21., Hungary
<https://www.gedeonrichter.com>
Drugsafety.mt@gedeonrichter.com**