

CHECKLIST FOR PRESCRIBERS OF COMBINED HORMONAL CONTRACEPTIVES

The contents of the letter have been agreed with the European Medicines Agency (EMA), the marketing authorisation holders and the Malta Medicines Authority.

Please use this checklist in conjunction with the Summary of Product Characteristics when discussing the use of combined hormonal contraceptives with the patient.

- It is important to take into account that the use of combined hormonal contraceptives is associated with a risk of thromboembolism (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke).
- The risk of a thromboembolism with a combined hormonal contraceptive is higher:
 - during the first year of use
 - when re-starting use after an intake break of 4 or more weeks.
- Combined hormonal contraceptives that contain ethinylestradiol in combination with levonorgestrel, norgestimate or norethisterone are considered to have the lowest risk of venous thromboembolism.
- The risk will also depend on the woman's individual risks. The decision to use a combined hormonal contraceptive should therefore take into consideration the contraindications and individual risk factors, particularly those for thromboembolism – see boxes below and the Summary of Product Characteristics.
- The decision to use any combined hormonal contraceptive other than one associated with the lowest venous thromboembolism risk should be taken only after a discussion with the woman.
- During the discussion it has to be ensured that the woman understands
 - the effect of individual risk factors on the risk of thrombosis
 - what the risk of thromboembolism associated with the chosen combined hormonal contraceptive is
 - how important it is that she pays attention to possible signs and symptoms of a thrombosis.

Do not prescribe a combined hormonal contraceptive if you tick any of the boxes in this section. The woman has:	
<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
<input type="checkbox"/>	History of migraine with aura
<input type="checkbox"/>	Diabetes with vascular complications
<input type="checkbox"/>	Very high blood pressure (e.g. systolic ≥ 160 or diastolic ≥ 100 mmHg)
<input type="checkbox"/>	Very high blood lipid concentration
<input type="checkbox"/>	Upcoming major surgery or a period of prolonged immobilisation

Discuss the suitability of the combined hormonal contraceptive with the woman if you tick any of the boxes in this section:	
<input type="checkbox"/>	The woman's BMI is over 30kg/m ²
<input type="checkbox"/>	The woman is aged over 35 years
<input type="checkbox"/>	The woman is a smoker. If the woman is a smoker and also over the age of 35 she should be <u>strongly advised to stop smoking or use some other method than combined hormonal contraception.</u>
<input type="checkbox"/>	The woman has high blood pressure (e.g. systolic ≥ 140 -159 or diastolic ≥ 90 -99mmHg)
<input type="checkbox"/>	The woman has a close relative who has had a thromboembolic event (see above list) at a young age (e.g. below the age of 50)
<input type="checkbox"/>	The woman or someone in her immediate family has high blood lipid concentration
<input type="checkbox"/>	The woman gets migraines
<input type="checkbox"/>	The woman has a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease
<input type="checkbox"/>	The woman has diabetes
<input type="checkbox"/>	The woman has given birth in the last few weeks
<input type="checkbox"/>	The woman is about to go on a long distance flight (>4 hours) or she travels for more than 4 hours per day
<input type="checkbox"/>	The woman has 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"/>	The woman is taking other medicines that can increase the risk of thrombosis (e.g. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapy etc.)
The suitability of the combined hormonal contraceptive has to be assessed more precisely if the woman has more than one of the risk factors. Take into account that the individual risk factors may change over time. It is important to use this checklist at every consultation.	

Make sure your patient understands that she should tell a healthcare professional she is taking a combined hormonal contraceptive if she: <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) ➤ <u>In these situations discuss with the woman whether the usage of the combined hormonal contraceptive should be paused and another method of contraception used until the risk returns to normal.</u>
Also tell your patient that the risk of a blood clot is increased if she: <ul style="list-style-type: none"> • Travels for extended periods (>4 hours) • Develops any of the contraindications for combined hormonal contraceptives or any of the risk factors for a blood clot • Has given birth within the last few weeks ➤ <u>In these situations one should be particularly alert for any signs and symptoms of a thromboembolism.</u>
Advise your patient to tell a physician if any of the above situations change or get worse. Encourage the patient to read the accompanying Patient Card during your consultation so that she has a possibility to discuss its contents with you. Advise her also to read the product's Patient Information Leaflet before use. Both include information on the symptoms of blood clots that she must watch out for.

You can report any adverse events that you suspect to be caused by the use of a combined hormonal contraceptive to Malta Medicines Authority or the marketing authorisation holder.

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

More information is available on the [Guidance Notes for Pharmaceutical Companies on Pharmacovigilance Obligations for Medicinal Products for Human Use](#) which can be found on the Medicines Authority's website following this link: <http://www.medicinesauthority.gov.mt/adrindustry?l=1>