

IMPORTANT INFORMATION ABOUT THE COMBINED HORMONAL CONTRACEPTIVE AND RISK OF BLOOD CLOTS

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

All combined hormonal contraceptives increase the risk of having a blood clot. The overall risk of a blood clot related to the use of the combined hormonal contraceptive is small but clots can be serious and may in very rare cases even be fatal.

It is very important that you recognise when you might be at greater risk of a blood clot, what signs and symptoms you need to look out for and what action you need to take.

The risk of a blood clot is the highest:

- in the first year of use, when you start to using any combined hormonal contraceptive for the first time in your life (or if you are re-starting use after a break of 4 weeks or more)
- if you are very overweight
- if you are older than 35 years
- if you have a family member who has had a blood clot at a relatively young age (e.g. below 50)
- if you have given birth in the previous few weeks

If you smoke and are over 35 years old you should stop smoking or use another contraception method of instead of a combined hormonal contraceptive.

Seek medical attention immediately if you experience any of the following symptoms:

- Severe pain or swelling in either of your legs that may be accompanied by tenderness, warmth or changes in the skin colour such as turning pale, red or blue. You may be experiencing a **deep vein thrombosis**.
- Sudden unexplained breathlessness or rapid breathing; severe pain in the chest which may increase with deep breathing; sudden cough without an obvious cause (which may bring up blood). You may be experiencing a serious complication of deep vein thrombosis called a **pulmonary embolism**. This occurs if the blood clot travels from the leg to the lung.
- Chest pain, often acute, but sometimes just discomfort, pressure, heaviness, upper body discomfort radiating to the back, jaw, throat, arm together with a feeling of fullness associated with indigestion or choking, sweating, nausea, vomiting or dizziness. You may be experiencing a **heart attack**.
- Face, arm or leg weakness or numbness, especially on one side of the body; trouble speaking or understanding; sudden confusion; sudden loss of vision or blurred vision; severe headache/migraine that is worse than normal. You may be experiencing a **stroke**.

Watch out for symptoms of a blood clot, especially if you have:

- just had an operation
- been off your feet for a long time (e.g. because of an injury or illness, or if your leg is in a cast)
- a long journey (more than about 4 hours)

Remember to tell your doctor, nurse or surgeon that you are taking a combined hormonal contraceptive when you:

- are due to or have had surgery
- when a healthcare professional asks you if you are taking any medications

Further information can be found in the product's Patient Information Leaflet or on the Malta Medicines Authority website
<http://www.medicinesauthority.gov.mt>.

If you suspect you have an adverse reaction associated with the use of your combined hormonal contraceptive, take contact with a Healthcare Professional. You can also report the adverse reaction as instructed in the Patient Information leaflet.

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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>