

ANNEX 3

IMPORTANT INFORMATION FOR WOMEN ABOUT RISK OF BLOOD CLOTS WITH COMBINED HORMONAL CONTRACEPTIVES

All combined hormonal contraceptives (CHC) increase the rare but important risk of having a blood clot. The overall risk of a blood clot 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.

In which situations is the risk of a blood clot highest?

- in the first year of CHC use (including 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 close family member (eg parent or sibling) who has had a blood clot at a relatively young age (ie below 50)
- if you have given birth in the previous few weeks

If you smoke and are over 35 years old you are strongly advised to stop smoking or use a different method of contraception.

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

- Severe pain or swelling in either leg that may be accompanied by tenderness, warmth or changes in skin colour such as turning pale, red or blue. You may be experiencing a **deep vein thrombosis**.
- Sudden unexplained breathlessness or rapid breathing; severe chest pain 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 or arm; feeling of fullness, indigestion or choking; sweating, nausea, vomiting or dizziness. You may be experiencing a **heart attack**.
- Weakness or numbness of the face, arm or leg, especially on one side of the body; trouble speaking, sudden confusion or lack of understanding; sudden loss of vision or blurred vision; severe headache or 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 (eg. because of an injury or illness, or if your leg is in a cast)
- a long journey (e.g. long-haul flight)

Remember to tell your doctor, nurse or surgeon that you are taking a CHC if you:

- Are due to or have recently had surgery
- Are asked by a healthcare professional if you are taking any medication

➤ For further information please read the accompanying Patient Information Leaflet for your CHC or go to <http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/>.

➤ If you think you have a side effect from using your CHC you can report it to a healthcare professional.

➤ 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, the free Yellow Card app available in Apple App Store or 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.