

## 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.

## **Combined hormonal contraceptives: important information for women**

### **Why have I been given this leaflet?**

The person who prescribes your contraception has given you this sheet to give you a bit more information about the recommendations coming from a recent Europe-wide review of the safety of combined hormonal contraceptives, in particular the risk of blood clots.

The review recommended that all women should understand: the small risk of blood clots with combined hormonal contraceptives; what other conditions increase the risk of a blood clot; the signs and symptoms of a blood clot; and when you need to tell a healthcare professional that you are using a combined hormonal contraceptive. Although the risk is small, blood clots can be serious. This information will help you minimise your risk.

For all other information on the safe use of combined hormonal contraceptives please refer to the Information Leaflet that accompanies each pack of contraceptives (see below).

### **Key points to bear in mind**

1. Combined hormonal contraceptives are highly effective in preventing unwanted pregnancy. They offer substantial benefits and these far outweigh the small risk of serious side effects.
2. No important new information on the safety of combined hormonal contraceptives has become available as a result of the recent review. The risk of blood clots with combined hormonal contraceptives has been known about for many years and much information has already been provided to prescribers and women.
3. There is no need for anyone who has been using a combined hormonal contraceptive without any problems to stop taking it on the basis of this review. If any woman has concerns, they should discuss them with their contraceptive provider at the next routine appointment, but should keep taking their combined hormonal contraceptive until they have done so. Suddenly stopping a combined hormonal contraceptive may result in accidental pregnancy.

### **Risk of a blood clot with combined hormonal contraception**

4. It is important to remember that the overall risk of having a blood clot is small in most women for whom use of a combined hormonal contraceptive is appropriate.
  5. The risk of a blood clot is greater during the first year of use and may also be higher after a break of 4 weeks or more.
  6. The risk of a blood clot returns to normal within a few months of stopping taking combined hormonal contraception.
  7. Blood clots usually occur initially in the legs (called a deep vein thrombosis), but may in some cases break off and travel to the blood vessels in the lungs (called a pulmonary embolism). This can be very serious and even fatal in rare cases. Blood clots can also form in the vessels of the heart (causing a heart attack) or the brain (causing a stroke) or in very rare cases in other parts of the body.
  8. There is good evidence that the risk of a blood clot may vary between combined hormonal contraceptives, depending on the type of progestogen hormone it contains. Those that are considered to have the lowest risk of blood clots contain the progestogens levonorgestrel, norgestimate or norethisterone. The risk with other progestogens may be slightly higher.
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### What to expect when getting a contraceptive prescription

9. The person who prescribes your contraceptive should discuss the benefits and risks of combined hormonal contraceptives with you. In particular, they should highlight: the small risk of blood clots; the conditions that increase the risk of clots; and some of the key signs and symptoms to be aware of. They may also go through a short checklist with you to make sure that a combined hormonal contraceptive is right for you. This is because some women may have a condition that means they should not take a combined hormonal contraceptive.
10. If your prescriber thinks you are suitable for a combined hormonal contraceptive but your circumstances mean you have a naturally higher risk of a blood clot—eg, if you are older than about 35 years, or you are very overweight, or have a family history of a blood clot, then they may advise you to start on one of the lower-risk products (see 8). If you have more than one of the above risk factors, your contraceptive provider may consider that you should use a different method of contraception.
11. If you smoke you are at increased risk of the type of blood clots that may cause a heart attack or stroke and your doctor may recommend that you stop smoking if you wish to use a combined hormonal contraceptive. If you smoke and are also over 35 years old you may be strongly advised to consider using a different form of contraception.

### What signs and symptoms of a clot should I look out for?

- It is important to 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 injury or illness or if your leg is in a cast)
  - been on a long journey (eg a long haul flight)

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

Are you experiencing any of these signs?	What are you possibly suffering from?
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.	Deep vein thrombosis
Sudden unexplained breathlessness or rapid breathing; sudden cough without an obvious cause (which may bring up blood); severe chest pain which may increase with deep breathing.	Pulmonary embolism
Chest pain, discomfort, pressure, heaviness, upper-body discomfort extending to the back, jaw, throat or arm; feeling of fullness, indigestion or choking; sweating, nausea, vomiting or dizziness.	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.	Stroke

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

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

For further information, read the Patient Information Leaflet that is in every packet of combined contraceptives. Information is also available at

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-GL/Hormonalcontraceptives/index.htm>