

IMPORTANT INFORMATION FOR WOMAN ABOUT THE COMBINED HORMONAL CONTRACEPTIVES AND RISK OF BLOOD CLOTS

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 use, when you start using any CHC for the first time in your life (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 (e.g. parent or sibling) who has had a blood clot at a relatively young age (i.e. 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 non-hormonal method of contraception.

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 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 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, sudden confusion or lack of understanding; 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 (e.g. more than about 4 hours)

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 www.indlaegsseddel.dk.

If you suspect you have an undesirable effect associated with the use of your CHC, you can report it to your doctor or nurse. You can also report side effects directly to Lægemiddelstyrelsen at: www.meldenbivirkning.dk or by ordinary mail to Lægemiddelstyrelsen, Axel Heides Gade 1, 2300 København S.

By reporting side effects, you can help provide more information on the safety of this medicine.