

PATIENT SHEET Q&A

QUESTIONS AND ANSWERS ON COMBINED HORMONAL CONTRACEPTIVES INCLUDING YASMIN®: LATEST INFORMATION FOR WOMEN

- This document is intended to give you more information about the risk of blood clots with combined hormonal contraceptives; including which conditions increase your risk of a 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 a lot of information on blood clots is provided here, this is because the review focussed specifically on this risk. It is important to remember that combined hormonal contraceptives are highly effective medicines for preventing unwanted pregnancy and the overall risk of a blood clot is small. For most women, these medicines offer benefits which far outweigh the small risk of serious side effects.
- This information does not apply to any products that contain only a progestogen (no ethinylestradiol or estradiol).
- For all other information on the safe use of combined hormonal contraceptives please refer to the Patient Leaflet that accompanies each pack of contraceptives.

What are combined hormonal contraceptives?

- Combined hormonal contraceptives are highly effective at preventing unintentional pregnancy. They contain two hormones: an estrogen and a progestogen. The estrogen in most products is called ethinylestradiol, but some products contain a different estrogen called estradiol. A wide range of progestogens are available.

What are the risks of combined hormonal contraceptives?

- As with all medicines, combined hormonal contraceptives are associated with some risks. The most common risks include breast discomfort, mood changes, and weight changes. Large studies have also found a very small increase in risk of breast cancer and cervical cancer.
- Perhaps the most important risk with combined hormonal contraceptives use is having a blood clot.

What can happen if I have a blood clot?

- 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). Blood clots can also form in the blood vessels of the heart, causing heart attacks, or the brain, causing strokes. Blood clots can therefore be very serious and, in very rare cases, can be fatal.

How high is the risk of a blood clot with combined hormonal contraceptives?

- All combined hormonal contraceptives slightly increase your risk of a blood clot; however, it is important to remember that this risk is small.
- Your risk of having a blood clot in association with the use of a combined hormonal contraceptive is highest in the first year of use – this applies ,if you have never used a combined hormonal contraceptive before or if you have had a break from taking your contraceptive (of 4 weeks or longer). The risk of a blood clot is also greater if you are naturally at higher risk (please see “**What other factors may increase my risk of a blood clot?**”).

The risk of having a blood clot with a combined hormonal contraceptive falls after the first year of use but remains higher than if you were not using one. The risk goes back to normal a few months after you stop taking it.

What other factors may increase my risk of a blood clot?

- Even without using a combined hormonal contraceptive the likelihood of a blood clot occurring differs between individuals. A number of conditions mean you will have a naturally higher risk of a blood clot—e.g.:
 - you are older than about 35 years;
 - you are very overweight;
 - you have a brother, sister or parent who had a blood clot at a relatively early age (e.g. younger than about 50)
 - you have a medical condition that increases the risk of a blood clot, such as cancer

Women who smoke are at increased risk of blood clots causing heart attacks and strokes, particularly if they are over 35 years old.

- You may have none of the above factors in which case your risk of developing a blood clot with use of a combined hormonal contraceptive is extremely low.
- If you have several of these factors your risk of a blood clot with use of a combined hormonal contraceptive is higher. In some cases having several risk factors may mean that you should not use a combined hormonal contraceptive and you should discuss another form of contraception with your prescriber.
- Remember that your natural risk of a blood clot will change over time—for example if you gain a lot of weight, change your smoking status, have major surgery, it is important that you tell the person who prescribes your contraception.

What should I look out for?

- It is important to watch out for symptoms of a blood clot, especially if you:
 - Just had an operation
 - have been off your feet for a long time (e.g. because of an injury or illness) or have been on a long journey

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? |
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| 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. | 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). | Pulmonary embolism |
| Chest pain, discomfort, pressure, heaviness, upper body discomfort radiating to the back, jaw, throat, arm together with a 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 | Stroke |

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| speaking sudden confusion, or understanding; sudden loss of vision or blurred vision; severe headache/migraine that is worse than normal. | |
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What should I expect when I see my doctor?

- When you see the person who prescribes your contraceptive, they should discuss the benefits and risks of the combined hormonal contraceptives with you. In particular they should highlight the small risk of blood clots, the conditions that increase your risk of blood clots and go through some of the key signs and symptoms to be aware of.

What do I need to do if I take a combined hormonal contraceptive?

- There is no need for anyone who has been using their combined hormonal contraceptive without any problems to stop taking it on the basis of this review. If you have concerns about your contraception you should discuss them with your contraceptive provider at the next routine appointment. You should keep taking your contraceptive until you have done so.
- Remember that suddenly stopping your combined hormonal contraceptive may result in unintended pregnancy. The risk of a blood clot during pregnancy and immediately after birth is higher than the risk associated with combined hormonal contraceptive use.
- It is important that you remember to tell any doctor or nurse who is treating you (for example if you are going to have planned or unplanned surgery) that you are taking a combined hormonal contraceptive.

Where can I find further information?

- If you use a combined hormonal contraceptive you should carefully read the patient information leaflet to make sure you: are aware of the risk of blood clots; know the signs and symptoms of a blood clot (e.g. deep vein thrombosis, pulmonary embolism, heart attack or stroke); and that you know what to do if you think you have any of these

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

Please report any adverse events suspected to be caused by a combined contraceptive to the National Pharmacovigilance and Drug Safety Centre

SFDA call center: 19999

E-Mail: npc.drug@sfda.gov.sa

Online: <https://ade.sfda.gov.sa/Home/Report>

Or

Pharmacovigilance department in Bayer Saudi LLC:

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