

▼ This medicine is new and is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

NEXTSTELLIS® (14.2 mg estetrol/3 mg drospirenone) INFORMATION CARD FOR WOMEN

IMPORTANT INFORMATION ABOUT NEXTSTELLIS® AND RISK OF BLOOD CLOTS

All combined hormonal contraceptives like NEXTSTELLIS increase the risk of having a blood clot. The overall risk of a blood clot due to NEXTSTELLIS 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 using NEXTSTELLIS (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 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 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 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) or on a long journey (more than about 4 hours)

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

- are due to or have had surgery
- have been asked by a healthcare professional if you are taking any medications

For further information please read the accompanying Consumer Medicines Information or go to nextstellis.com.au.

If you suspect you have an undesirable effect associated with the use of NEXTSTELLIS, you can report it to a Healthcare professional or call Mayne Pharma Medical Information line on 1300 739 436 (Australia) or go to www.tga.gov.au/reporting-problems.