# Patient Information Card

**Indication for which Vreya 2 mg/0.035 mg coated tablets (cyproterone acetate / ethinylestradiol) is prescribed:**

Vreya 2 mg/0.035 mg coated tablets is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties, it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Vreya 2 mg/0.035 mg coated tablets if your skin condition has not improved after use of other anti- acne treatments, including topical treatments and antibiotics

**IMPORTANT INFORMATION ABOUT VREYA 2 MG/0.035 MG COATED TABLETS AND RISK OF BLOOD CLOTS**

All estrogen-progestagen combination products like Vreya 2 mg/0.035 mg coated tablets 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 using Vreya 2 mg/0.035 mg coated tablets (including if you are re-starting use after a break of 1 month or more)
- if you are very overweight (body mass index over 30 kg/m2);
- if one of your close relatives (parent or sibling) has had a blood clot at a relatively young age (e.g. below 50)
- if you are older than 35 years
- 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 treatment for your acne and/or hirsutism.

**Seek urgent medical attention if you experience any of the following:**

- 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.**
- Weakness or numbness of the face, arm or leg, especially on one side of the body; sudden confusion; trouble speaking or 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. a long-haul flight)

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**Remember to tell your doctor, nurse or surgeon that you are taking Vreya 2 mg/0.035 mg coated tablets if you:**

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

For further information please read the accompanying Patient Information Leaflet or go to https://medicinesauthority.gov.mt/.

**Adverse events**

If you suspect you have an undesirable effect associated with the use of your medication, you can report it to a Healthcare professional.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

This information can also be reported to MAH HEATON k.s. by email:

farmakovigilance@heaton.cz
Tel.: +420 602 440 229
HEATON k.s.
Na Pankráci 332/14
Prague 4, 140 00
Czech Republic
www.heaton.cz

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

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