

Package leaflet: Information for the user

Cyklonova 500 mg film-coated tablet

tranexamic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cyklonova is and what it is used for
2. What you need to know before you take Cyklonova
3. How to take Cyklonova
4. Possible side effects
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1. What Cyklonova is and what it is used for

Cyklonova is a medicine that reduces bleeding. Cyklonova contains tranexamic acid which inhibits the enzyme that dissolves clotted blood (clots). This leads to less blood loss.

Cyklonova is used for heavy menstrual bleeding.

2. What you need to know before you take Cyklonova

Do not take Cyklonova:

- if you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6).
- if you are treated for a blood clot e.g. in your legs, lungs or brain.
- if you are treated for a kidney disease.
- if you have a history of convulsions.
- if you have a bleeding in the brain.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cyklonova:

- if you have irregular menstrual bleeding the cause should be established before using Cyklonova.
- if you have had a blood clot and if any of your parents and/or siblings have had blood clots.
- if you have had blood in your urine (between menstrual periods).
- if you have impaired renal function.

There is little information on the use of Cyklonova in heavy menstrual bleeding in children and adolescents under 15 years of age. Ask your doctor for advice whether it may be appropriate for you.

If Cyklonova does not have adequate effect there are other ways to treat heavy menstrual bleeding, contact your doctor for more information.

Other medicines and Cyklonova

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking medicines that reduce the blood's ability to clot (anticoagulants such as Warfarin for example), concurrent treatment with Cyklonova should only be made under the supervision of a doctor who specialises in coagulation.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Cyklonova should be used for regular heavy menstrual bleeding and is not intended to be used during pregnancy or breast feeding.

Driving and using machines

Undesirable effects such as dizziness have been reported, which might influence the ability to drive and use machines.

3. How to take Cyklonova

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 2-3 tablets 3-4 times daily for 3-4 days. If used for very heavy menstrual bleeding, the dosage may be increased up to 2 tablets 6 times daily. Treatment with Cyklonova should not be initiated until menstrual bleeding has started.

The tablet can be divided into equal doses.

Renal insufficiency

It may be necessary to reduce the dose. Follow your doctor's instructions.

If you take more Cyklonova than you should

If you have taken more Cyklonova than you should, always contact a doctor, a hospital or the poison information centre for an assessment of the risk and consultation.

Symptoms of overdose include the following: Nausea, diarrhoea, dizziness, headache. Light-headedness, faintness, low blood pressure, muscle weakness and convulsions may occur. There is a risk of thrombosis (blood clots) in predisposed individuals.

If you forget to take Cyklonova

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most common side effects are mild and transient.

Serious side effects

The following side effects are very serious and may require immediate treatment. If any of the following side effects occur, stop taking the medicine straight away and seek urgent medical advice.

Rare side effects (may affect up to 1 in 1,000 people):

- Shortness of breath, chest pain radiating to the arms or neck, severe pain in the stomach, paralysis, sensory disturbances, difficulty in speaking, aching and possibly swelling of the arms or legs due to blood clots.

Not known (*cannot be estimated from available data*):

- Convulsions

Other side effects

Common side effects (*may affect up to 1 in 10 people*):

- Nausea, vomiting, diarrhoea, abdominal pain, headache and dizziness.

Uncommon side effects (*may affect up to 1 in 100 people*):

- Allergic skin reactions may occur.

Rare side effects (*may affect up to 1 in 1,000 people*):

- Disturbances of the colour vision and other visual disturbances have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cyklonova

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information

What Cyklonova contains

- The active substance is tranexamic acid 500 mg.
- The other ingredients are microcrystalline cellulose, povidone, croscarmellose sodium, colloidal anhydrous silica, talc and magnesium stearate.
- The film-coating contains methacrylate polymer (Eudragit E100), titanium dioxide (E 171), talc, magnesium stearate, macrogol and vanillin.

What Cyklonova looks like and contents of the pack

Appearance

White, capsule shaped tablet with a scoreline, length 18 mm.

Contents of the pack

Blister: 18, 20, 30, 50, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Alternova A/S, Energivej 15, 5260 Odense S, Denmark

Manufacturer

Orifarm Generics A/S, Energivej 15, 5260 Odense S, Denmark

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden, Denmark: Cyklonova

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