

Package leaflet: Information for the user

Cyklo-f 500 mg film-coated tablets

tranexamic acid

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Cyklo-f is and what it is used for
2. What you need to know before you take Cyklo-f
3. How to take Cyklo-f
4. Possible side effects
5. How to store Cyklo-f
6. Contents of the pack and other information

1. What Cyklo-f is and what it is used for

Cyklo-f is used for heavy menstrual bleedings.

Cyklo-f is a drug that prevents bleeding. It contains tranexamic acid, which prevents the enzyme which dissolves blood clots to act. This causes less blood loss and quicker cure rate.

2. What you need to know before you take Cyklo-f

Please note that Cyklo-f should only be used if your periods are regular and heavy. To be sure you should answer yes to both the following questions:

1. Are your periods regular, i.e. your menstrual cycle is between 21 to 35 days long?
2. Do you need to use double sanitary protection, towels plus tampons or double towels to prevent bleeding through, alternatively change sanitary protection very often?

Do not take Cyklo-f if

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

Warnings and precautions

Talk to your doctor before taking Cyklo-f if you have any of the following:

- Your periods are irregular
- You have ever had a blood clot and your parents and/or brothers or sisters have had a blood clot
- You have had blood in your urine in between your periods
- Impaired kidney function

Heavy menstrual bleedings can occur due to diseases in the womb such as myoma or polyps. If they are taken care of, the heavy menstrual bleeding decreases. If anything is unclear, you should ask your gynaecologist.

Continued gynaecological health controls are recommended.

Children and adolescents

Ask your doctor before starting treatment if you are under 15 years old.

Pregnancy and breast-feeding

Cyklo-f is indicated for regular heavy menstrual bleedings and is not intended for use during pregnancy and breast-feeding.

Driving and using machines

Side effects that can affect the ability to drive and use machines have been reported. If you feel dizzy or have problems with your eyesight you should not drive or use machines until the symptoms have passed.

3. How to take Cyklo-f

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

Treatment should start when your period has started. Take 2 tablets 3 times daily as long as needed, for a maximum of 4 days. The dosage can be increased if the bleedings are very heavy. Do not use more than 8 tablets per day. Your doctor may prescribe a different dose. If effect (decreased bleeding) has not occurred after the first day, stop treatment and discuss with your doctor.

If you take more Cyklo-f than you should

If you have taken more Cyklo-f than you should, or if children have been taking medicine by accident, contact your doctor or hospital to get an opinion of the risk and advice on action to be taken. Signs of an overdose may include dizziness, headache, low blood pressure and convulsions.

If you forget to take Cyklo-f

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

Use in patients with kidney problems

If you have kidney problems, the dose of tranexamic acid will be reduced based on a blood test (serum creatinine level).

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 patients): Nausea, vomiting, diarrhoea, stomach pain, headache, dizziness. These side effects are often mild and transient.

Uncommon (may affect up to 1 in 100 patients): Allergic skin reactions.

Not known (frequency cannot be estimated from the available data): Rare cases of blood clots, changes in colour vision and other problems with the eyesight, convulsions. Sudden onset kidney problems due to death of the tissue in the outer part of the kidney (acute renal cortical necrosis). An allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

If Cyklo-f does not have sufficient effect or if you do not tolerate Cyklo-f, there are other methods to treat heavy menstrual bleedings. Contact gynaecologist who can give information about those methods.

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 Cyklo-f

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

Do not use this medicine after the expiry date which is stated on the carton after EXP.

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 to protect the environment.

6. Contents of the pack and other information

What Cyklo-f contains

- The active substance is tranexamic acid. Each tablet contains 500 mg tranexamic acid.
- The other ingredients are:
 - Tablet core:* Microcrystalline cellulose, hypromellose, talc, magnesium stearate, colloidal anhydrous silica, povidone
 - Coating:* Methacrylate copolymer, titanium dioxide (E 171), talc, magnesium stearate, macrogol 8000, vanillin.

What Cyklo-f looks like and contents of the pack

Carton containing 18 tablets or 20 tablets in a blister. The tablets are white, capsule shaped, engraved with a score and with arcs above and below the letters CY.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

Viatis AB

Box 23033

104 35 Stockholm

Manufacturer:

Madaus GmbH

Lütticher Str. 5

53842 Troisdorf,

Germany

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