Patient Information Leaflet

Boots Cyklo-f[®] Heavy Period Relief 500 mg Tablets Tranexamic Acid

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to take it carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side-effects get serious, or if you notice any side effect not listed in this leaflet, please tell your pharmacist.

In this leaflet:

- 1. What this medicine is and what it is used for
- 2. Before you take this medicine
- 3. How to take this medicine
- 4. Possible side effects
- 5. How to store this medicine
- 6. Further information

1. What this medicine is and what it is used for

This medicine contains Tranexamic acid which belongs to a group of medicines called antifibrinolytics. These are used to control bleeding. When you bleed your body forms clots to stop the bleeding. In some people these clots break down causing too much bleeding. This medicine stops these clots from dissolving and so reduces bleeding.

This medicine is used only when your periods are regular to control heavy menstrual bleeding (see section 2 if you are unsure whether or not your periods are regular). This medicine reduces the amount of blood lost during your period but may not help other symptoms such as period pain.

Heavy menstrual bleeding can cause anaemia (reduction in red blood cells). People with anaemia may be pale and feel tired, weak, dizzy or faint. If you think you may have anaemia, you should see your doctor.

2. Before you take this medicine

How do I know if my periods are heavy?

Your periods are heavy if:

- you bleed through to your clothes or onto bedding at night called "flooding"
- you need to change your sanitary protection every 2 hours or more often
- you need to use double sanitary protection (tampon plus towels)
- you pass large blood clots
- your periods prevent you from doing normal activities, such as going out, working or shopping.

Do not take this medicine if your periods are not heavy.

How do I know if my periods are regular?

Your periods are regular if both of the following apply to you:

- your menstrual cycle (i.e. the number of days between the 1st day of one period and the 1st day of the next) is between 21 and 35 days long
- your menstrual cycle is about the same number of days long each time (i.e does not change by more than 3 days each time).

Do not take this medicine if your periods are not regular.

Do not take this medicine if:

- you are allergic to tranexamic acid or any of the other ingredients in this medicine (listed in section 6)
- you are under 18 years of age
- your periods are irregular
- you are pregnant
- you are taking the combined oral contraceptive ("the pill")
- you have kidney disease
- you have blood in your urine between your periods
- you have or have ever had a blood clot in your blood vessels (called a "thrombosis").
 See immediately below for the warning signs of a blood clot.
- anyone in your family has suffered from blood clots in their blood vessels
- you are taking medicines to prevent or treat blood clots (e.g. warfarin).

If any of the above applies to you, do not take this medicine.

Warning signs of a blood clot to look out for:

- pains or feelings of heaviness in your chest
- unusual pains or swellings of your arms or one of your legs
- · sudden shortness of breath
- fainting
- coughing up blood.

If you experience any of these symptoms you should see your doctor immediately.

Check with your doctor before starting this medicine if:

- you have recently noticed a change in your normal bleeding pattern
- you are over 45 years old
- your mother, grandmother, aunt or sister has suffered from endometrial cancer
- you are diabetic
- you are very overweight (obese)
- you have polycystic ovary syndrome (PCOS)
- you have abnormal bleeding between your periods
- you bleed after sexual intercourse
- you thought you had gone through the menopause, but now you have started bleeding again
- you have pain during sexual intercourse
- you have pain before the start of your period (also known as premenstrual pain)
- you have pelvic pain (pain in the lower abdomen).

Your doctor may prescribe a different medicine which is better for treating your symptoms.

Warning signs of endometrial cancer

Occasionally heavy periods may be due to an abnormality of the lining of the womb. One of the most serious conditions is endometrial cancer. There are almost always other warning signs of endometrial cancer such as:

- irregular periods
- prolonged periods
- abnormal bleeding between periods.

If any of the above applies to you, see your doctor.

Important: Regular AND heavy periods alone are unlikely to be caused by endometrial cancer.

Tell your doctor before starting to take this medicine if you are taking any of the following medicines:

- the "pill" (a combined oral contraceptive). You must not take this medicine if you are already taking this medicine
- fibrinolytic drugs such as streptokinase (used to dissolve blood clots)
- tamoxifen (a drug used to treat breast cancer)
- an oestrogen
- any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant as it may cause problems for your unborn baby. If you are breast-feeding, you should ask your doctor for advice before taking this medicine.

3. How to take this medicine

Remember: This medicine should only be taken on the days when your period is heavy

Do not take this medicine before your period has started as it will not work

properly

Swallow the tablets whole, with water if needed

Do not take this medicine for more than 4 days during each of your periods.

Adults:

- The usual dose is two tablets taken 3 times a day (e.g. in the morning, afternoon, and evening) for up to 4 days
- If your bleeding is not reduced, you can take an extra 2 tablets at night
- Heavy bleeding usually only lasts for the first two days of your period. When the bleeding becomes less, you should reduce the number of tablets you take, for example, to 2 tablets twice a day
- Do not take more than 8 tablets per day.

Children under 18 years of age:

• Do not give to children under 18 years of age.

Elderly:

• This medicine is not for use in the elderly.

Using this medicine every month

This medicine may be used every month as long as it continues to reduce your bleeding AND there are no changes in your bleeding pattern.

If this medicine is not working

See your doctor if:

- Your bleeding has not been reduced by this medicine after using it for 3 periods in a row
- · This medicine seems to have stopped working.

If you take more of this medicine than you should

If you accidentally take too many tablets you should contact your doctor immediately, or go to the nearest hospital casualty department.

If you forget to take this medicine

Do not take a double dose to make up for a missed dose. Take your next dose at the usual time.

If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

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

Stop taking this medicine and go immediately to hospital if you experience any of the following rare symptoms:

- pain or feelings of heaviness in your chest
- unusual pain or swelling in your arms or legs
- · sudden shortness of breath
- fainting
- coughing up blood.

You may have developed a blood clot in your leg or lungs.

Stop taking this medicine and tell your doctor immediately if you experience any of the following rare symptoms:

- problems with your eyesight, especially your colour vision
- a blood clot in the eye. This may cause bleeding in the eye, or a loss of vision
- itchy, red or swollen skin.

Other side effects:

- feeling sick
- being sick
- diarrhoea.

These are usually mild and pass very quickly, but if they continue, stop taking this medicine and tell your doctor or pharmacist.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.yellowcard.gov.uk; alternatively you can call Freephone 0808 100 3352 (available between 10 am to 2 pm Monday to Friday) or fill in a paper form available from your local pharmacy.

5. How to store this medicine

Keep out of reach and sight of children.

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

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further Information

What this medicine contains:

- The active substance is tranexamic acid. Each tablet contains 500 mg tranexamic acid.
- The other ingredients are microcrystalline cellulose (E460), hyprolose (E463), talc (E553b), magnesium stearate (E572), colloidal anhydrous silica, povidone (E1201), methacrylate copolymer, titanium dioxide (E171), macrogol 8000 and vanillin.

What this medicine looks like

The tablets are white, oblong film-coated tablets. They are marked with CY with an arc above and below the lettering. They come in packs of 18 tablets.

Marketing Authorisation Holder

Meda Pharmaceuticals, Skyway House, Parsonage Road, Takeley, Bishop's Stortford,

CM22 6PU, UK.

Manufacturers

MEDA Manufacturing GMBH, Neurather Ring 1, 51063 Cologne, Germany.

Distributor

The Boots Company PLC, Nottingham, NG2 3AA.

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This leaflet was last updated August 2010

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Cyklo-f Heavy Period Relief 500 mg Tablets

Reference number: 15142/0131

This is a service provided by the Royal National Institute of Blind People.

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