

PACKAGE LEAFLET

Package Leaflet: Information for the User
Evana® Heavy Period Relief 500mg 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 pharmacist or doctor 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 pharmacist or doctor. 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 after 4 days.

What is in this leaflet:

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

1. What Evana Heavy Period Relief is and what it is used for

Evana Heavy Period Relief contains the active substance tranexamic acid which belongs to a group of medicines called anti-fibrinolytics. These are used to control bleeding. When you bleed your body forms clots or plugs as part of healing. In some people these plugs do not stay in place long enough. This can cause too much bleeding. Evana Heavy Period Relief helps these plugs to stay in place and so reduces the amount of blood lost during your period.

Evana Heavy Period Relief **is used only when your periods are regular to control heavy menstrual bleeding** (see section 2 if you are unsure whether or not you have regular periods).

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

2. What you need to know before you take Evana Heavy Period Relief

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 Evana Heavy Period Relief 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 Evana Heavy Period Relief if your periods are not regular.

Do not take Evana Heavy Period Relief if:

- you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- you are under 18 years of age
- you are pregnant
- you have kidney problems
- you have or have ever had a blood clot, for example in your leg or lungs. 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 have blood in your urine between your periods
- your periods are irregular
- you are taking medicines to prevent or treat blood clots (e.g. warfarin)
- you are taking oral contraceptives (“the pill”)
- you have disseminated intravascular coagulation (DIC), a disease where your blood starts to clot throughout your body
- you have fits or seizures.

If any of the above applies to you, do not take Evana Heavy Period Relief.

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 stop taking the medicine and seek urgent medical advice.

Talk to your pharmacist or doctor before taking Evana Heavy Period Relief if:

- you are over 45 years old
- you are diabetic
- you are very overweight (obese)
- you have polycystic ovary syndrome (PCOS)
- your mother, grandmother, aunt or sister has or has had endometrial cancer
- you have recently noticed a change in your normal bleeding pattern
- you have abnormal bleeding between your periods
- you bleed after sexual intercourse
- 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)
- you thought you had gone through the menopause, but now you have started bleeding again.

Your pharmacist or doctor may recommend 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, talk to your pharmacist or doctor.

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

Other medicines and Evana Heavy Period Relief

Tell your pharmacist or doctor if you are taking, or have recently taken or might take any other medicines, in particular if you are taking any of the following medicines:

- the “pill” (an oral contraceptive). You must not take Evana Heavy Period Relief if you are already taking these medicines
- fibrinolytic drugs such as streptokinase (used to dissolve blood clots)
- tamoxifen (a drug used to treat breast cancer)
- oestrogen (present in some oral contraceptives or hormone replacement therapies (HRT)).

Pregnancy and breastfeeding

Do not take Evana Heavy Period Relief if you are pregnant as it may cause problems for your unborn baby. If you think you may be pregnant or are planning to have a baby or are breastfeeding, you should ask your pharmacist or doctor for advice before taking this medicine.

Driving and using machines

Evana Heavy Period Relief should not have an effect on your ability to drive or use machinery. Visual disturbances may occur after taking tranexamic acid.

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Evana Heavy Period Relief

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

Remember

- Evana Heavy Period Relief should only be taken on the days when your period is heavy.
- Do not take Evana Heavy Period Relief before your period has started as it will not work properly.
- Do not take Evana Heavy Period Relief for more than 4 days during each of your periods.
- Swallow the tablets whole, with water if needed - do not crush or chew them.

Adults

- The recommended 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.

Use in children and adolescents

- Do not give to children and adolescents under 18 years of age.

Elderly

- Evana Heavy Period Relief is not for use in the elderly.

Using Evana Heavy Period Relief every month

Evana Heavy Period Relief may be used every month as long as it continues to reduce your bleeding AND there are no changes in your bleeding pattern.

If Evana Heavy Period Relief is not working

Talk to your pharmacist or doctor if:

- your bleeding has not been reduced by Evana Heavy Period Relief after using it for 3 periods in a row.
- Evana Heavy Period Relief seems to have stopped working.

If you take more Evana Heavy Period Relief than you should

If you have taken too much contact a doctor or go to your nearest Accident & Emergency Department (Casualty) taking this leaflet and pack with you.

If you forget to take Evana Heavy Period Relief

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

If you have any further questions on the use of this medicine talk to your pharmacist or doctor.

4. Possible side effects

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

Stop taking this medicine and get medical advice immediately, if you experience any of the following 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 talk to your pharmacist or doctor as soon as possible if you experience any of the following symptoms:

Very rare (may affect up to 1 in 10,000 people)

- allergic reactions including swelling of the face, lips, tongue, or throat which may cause difficulty in swallowing or breathing.

Frequency not known (cannot be estimated from the available data)

- 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.

Other side effects:

Common (may affect up to 1 in 10 people)

- feeling sick
- being sick
- diarrhoea.

Uncommon (may affect up to 1 in 100 people)

- itchy, red or swollen skin (allergic skin reactions).

Frequency not known (cannot be estimated from the available data)

- Seizures or fits.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Evana Heavy Period Relief

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 store above 25°C.

Store in the original package.

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 other information

What Evana Heavy Period Relief contains

The active substance is: Each tablet contains 500mg of tranexamic acid.

The other ingredients are: calcium hydrogen phosphate anhydrous, croscarmellose sodium, povidone, talc and magnesium stearate.

What Evana Heavy Period Relief looks like and contents of the pack

The tablets are white to off-white and capsule shaped.

They are engraved with "TXA 26" on one side, and are plain on the other side.

They are available in packs of 18.

Marketing Authorisation Holder

Manx Healthcare Ltd, Taylor Group House, Wedgnock Lane, Warwick, CV34 5YA, UK.

Manufacturer

Laboratorios Alcalá Farma S.L. Avenida de Madrid, 82, Alcalá de Henares, 28802 Madrid, Spain.

Distributor

Maxwellia Ltd, Alderley Park, Alderley Edge, SK10 4TG, UK.

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