evana®





Pharmacy training guide

Managing heavy menstrual bleeding

A pharmacy guide from the makers of Evana®
Heavy Period Relief 500 mg Tablets Tranexamic acid

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Introduction

Overall aim of this training guide

To support you in conducting effective, patient-specific, clinical consultations on heavy menstrual bleeding (HMB), and enable you to appropriately supply Evana Heavy Period Relief 500 mg tablets (tranexamic acid), available without prescription from pharmacies to women who are eligible.

Heavy menstrual bleeding (HMB), or menorrhagia is a common gynaecological problem affecting up to 30% of women of reproductive age. It has a significant impact on a woman's quality of life causing physical, social, and emotional consequences. In addition, HMB is the main cause of iron deficiency anaemia among reproductive women, adding to the symptom burden among those affected.

The Women's Health Strategy for England states women have been told that heavy and painful periods are 'normal' and they will 'grow out of them'. The 'normalisation' of HMB means patients may live with symptoms for several years before seeking healthcare professional advice. Add to this a lack of awareness that HMB can be treated, and it is clear that there is a role for pharmacy to step in and act as a source of advice for those living with HMB.

With the launch of the Pharmacy-only medicine Evana Heavy Period Relief 500 mg tablets, containing the antifibrinolytic tranexamic acid ⁶, the pharmacy team is also able to provide an effective, NICE-recommended firstline non-hormonal treatment option for HMB management.²

The active ingredient in Evana Heavy Period Relief 500 mg tablets has been shown to not only reduce menstrual bleeding by up to $60\%^7$ but also to improve quality of life by up to 83%,8 meaning you can make a real and valuable difference to the lives of your HMB patients*.

* Please be aware that HMB may also affect patients assigned female at birth (AFAB).

Learning objectives

- To understand the definition, symptoms and causes of HMB
- To be aware of the impact HMB has on a patient's quality of life
- To recognise when HMB symptoms require referral
- To know how to manage HMB with over-the-counter (OTC) treatments
- To understand the role and mode of action of tranexamic acid in HMB
- To be able to recommend Evana (tranexamic acid) appropriately
- To be able to offer appropriate advice on the use of Evana (tranexamic acid) in HMB.

Understanding Heavy Menstrual Bleeding (HMB)

HMB affects up to 30% of women of reproductive age¹

What is HMB?

According to NICE, HMB is2:

"Excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms".

How common is HMB?

HMB affects between 5–30% of women¹ and is the underlying reason for 12% of all gynaecology referrals.² It also exerts a significant burden on primary care with 1 in 20 sufferers aged 30–49 years seeking GP advice annually for HMB or menstrual problems.² Yet many of these women may have been living with the impact of HMB for several years before seeking help.⁵

The burden in younger patients may be even higher, as HMB is estimated to affect up to 37% of adolescents, who may not be consulting any healthcare professional for advice.



How is HMB defined?

Women lose, on average, 30–40ml of menstrual blood each cycle¹⁰. For those with HMB this rises to 80ml or more of blood loss per cycle.^{9,10}

However, from a practical perspective, this is not particularly helpful when talking to patients as it may not reflect their experience or the impact of HMB on their quality of life. In addition, HMB can be subjective, with one person's perception of normal bleeding being another person's perception of heavy bleeding.

Given this, an HMB diagnosis is usually based on the patient's personal perception of blood loss and the effect of this on their daily life.8



"You think, oh it can't be that bad, I'm sure it will get better, you know. Oh really, do I want to bother them with this?"⁵ "I just thought this is normal... I have just got to stick with it until the menopause [laughing]. It never really occurred to me to try and seek help" 5

"It was probably four or five years before I kind of did anything, you know, about it"⁵

What are the symptoms of HMB?

There are several different physical symptoms of HMB,¹¹ however, it is also important to ask patients about the impact of HMB on their quality of life.⁹

HMB symptoms¹¹



Needing to change sanitary product (tampon or pad) every 1–2 hours or emptying a menstrual cup more frequently than recommended



Bleeding through bedding or clothes



Doubling up on sanitary products, e.g. pad + tampon



Having to take time off work or from doing daily activities because of a period



Periods that last more than 7 days



Often feeling short of breath or tired¹¹
- these can be symptoms of iron deficiency anaemia^{3,9}



Passing blood clots larger than a 10p coin



Pain may be the primary symptom⁴

What causes HMB?

Although there are several different causes of HMB, in about half of cases no underlying reason can be identified.

Underlying conditions that can cause HMB⁹



Gynaecological conditions

Uterine fibroids
Endometrial polyps
Endometriosis and adenomyosis
Polycystic ovary syndrome
Pelvic inflammatory disease



Other systemic conditions

Hypothyroidism Diabetes mellitus Hyperprolactinaemia Hepatic disease Renal disease



Coagulation disorders

Von Willebrand disease



Cancer

Of the cervix, uterus or endometrium

Pharmacists should also be aware that certain medications can also cause HMB9:

Anticoagulants, Antiplatelet drugs, Herbal supplements, e.g. gingko, ginseng, soya, Intra-uterine contraceptive devices (sometimes known as the copper coil), Non-steroidal anti-inflammatory drugs (NSAIDs), Oral contraceptives, Selective serotonin reuptake inhibitors.

What is the impact of HMB?

Being able to offer advice and guidance on effective treatment is vital for sufferers as HMB has a profound and debilitating impact on many different aspects of their lives,⁵ including their physical, social, emotional and/or material quality of life.²

HMB is often passed off as being 'normal' and something they will 'grow out of'^{4,5} and it is, therefore, important for pharmacists to be aware of customers who may be trying to manage symptoms silently. A further complication is that women may also feel a social pressure to hide their symptoms in the belief that it is a taboo subject.⁵

Pharmacists, have the potential to identify HMB as patients will try to manage or hide their blood loss by buying extra sanitary products.⁵ The purchase of larger than normal volumes of sanitary products or doubling up on types of sanitary products could, therefore, act as a cue to open a conversation with a customer about HMB. In addition, menstrual pain is another prominent symptom,⁴ therefore, those seeking strong analgesics for this indication could also be asked about HMB and its quality-of-life impact.

HMB's quality of life impact⁵



Avoid social events/ activities



Mood reduction



Reduces libido/affects intimate relationships



Lack of confidence



Anxiety



Embarrassment/ stigma



"Our sex life sort of dwindled because of all of this"⁵

"I was just mortified, it always made me really anxious. I would get very tearful... I think because I was just scared"⁵ "I couldn't go to work some days because I was just flooding... I started to think am I going to lose my job if I carry on like this, it really affected me"⁵

The complications of HMB

The most prevalent complication of HMB is iron deficiency anaemia,⁹ as menstruation is the most common cause of anaemia in premenopausal women.³ Indeed, for some patients, a diagnosis of iron deficiency anaemia can be the prompt for HMB identification.⁵

Common symptoms of iron deficiency anaemia include³:











"My hair was coming out in clumps and then [GP] told me I have got it because you're severely anaemic"⁵

Other iron deficiency anaemia symptoms include:

Weakness, dizziness, pale skin, dry damaged hair and moderate alopecia, irritability, palpitations, itching, sore tongue, tinnitus, abnormal cravings for ice or dirt, changes in the nails, such as becoming spoon shaped or having long ridges.

When should you refer the patient to a doctor?

The following patients with HMB should be referred to their doctor for further investigation if they^{9,11}:

- Have severe pain during their period
- · Experience bleeding between periods or after sex
- · Experience pain when having sex, micturition or passing stools
- · Have a pelvic mass with unexplained bleeding or weight loss
- Are over 55 years of age and experiencing post-menopausal bleeding
- Have ascites (abnormal fluid collection in the abdomen) and/or pelvic or abdominal mass
- Have iron deficiency anaemia that is not responding to iron supplementation
- Have HMB that is not improving with OTC treatments.

Understanding Evana®

Evana® contains tranexamic acid, recommended by NICE as a first-line non-hormonal treatment option for HMB²

How can HMB be managed?

Patients can be reassured that they don't need to suffer in silence when there is a range of effective HMB treatments available.

Non-hormonal treatment options for HMB2:

- The anti-fibrinolytic tranexamic acid, which is available OTC
- An NSAID these have been shown to cut menstrual bleeding by up to 50%.¹² However, pharmacists should be aware that NSAIDs are not indicated for the treatment of HMB.⁹

Hormonal treatment options for HMB (available on prescription) ^{2,9}:

- A levonorgestrel intrauterine system is the firstline hormonal treatment choice
- Combined hormonal contraception
- Cyclical oral progestogen (norethisterone) this can suppress menstruation which can be of particular benefit to those with HMB.

Where these treatments are unsuccessful, surgical interventions may be a suitable option.^{2,9}

What is Evana® Heavy Period Relief 500 mg Tablets?

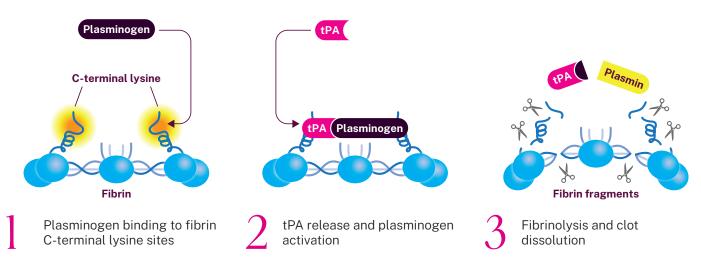
Evana is a pharmacy-only treatment that contains 500 mg tranexamic acid for the reduction of HMB over several cycles. The active ingredient in Evana is recommended by NICE as a first-line non-hormonal treatment option for HMB. Indeed, it contains the ONLY active ingredient licensed for OTC use in HMB management.



How does Evana® work in HMB?

Women with HMB have been found to have increased fibrinolytic activity in their menstrual blood. This causes accelerated degradation of the fibrin clot that forms to induce haemostasis see Figure 1. This increased fibrinolytic activity results in increased blood loss when the endometrium is shed during menstruation.

Figure 1: What happens in fibrinolysis¹⁴

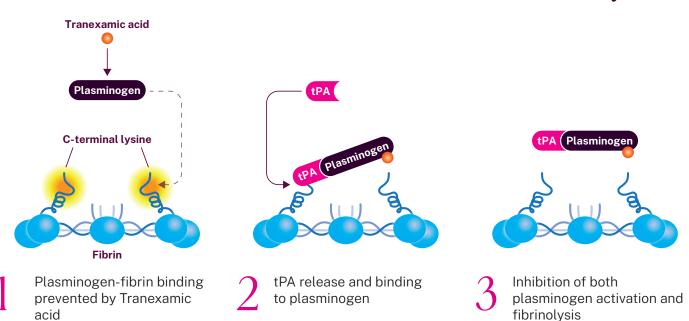


The tranexamic acid in Evana is an anti-fibrinolytic agent, which is a potent competitive inhibitor of the activation of plasminogen to plasmin.⁶ see Figure 2. Tranexamic acid reversibly blocks lysine binding sites on plasminogen, which prevents plasmin interacting with lysine residues on the fibrin polymer.

This blocking results in a deceleration in subsequent fibrin degradation, leading to a slowing in clot dissolution and, therefore, menstrual bleeding.^{8,10}

Figure 2:

How tranexamic acid works to inhibit fibrinolysis¹⁴



How effective is Evana® in managing HMB?

Data show that the active ingredient in Evana can reduce menstrual bleeding by up to 60%.7 Most women will see a significant reduction in HMB within the first cycle of use15 but for a small proportion it may take several cycles for Evana to significantly reduce HMB.^{6,15} For example, in one study, after the first cycle of tranexamic acid use, 87% of women perceived a decreased or strongly decreased volume of menstrual bleeding, rising to 94% of users after the third cycle of use.15

Benefits and effectiveness of tranexamic acid

Benefits on menstrual bleeding



O 94%



80%

of women experienced decreased volume of bleeding*15

of women were satisfied with tranexamic acid treatment*15

Benefits on quality of life



83%



3 67%



46%

of women had improved had an improved social life¹⁶ leakage/flooding¹⁶

had an improved sex life¹⁶

Additional customer benefits



Non-hormonal option²



No impact on fertility¹⁷

*After the third menstrual cycle with tranexamic acid treatment.

Who can take Evana®?

Evana can be recommended:

• For women aged 18–45 years with HMB who have regular menstrual cycles (21–35 days duration) where the length of their cycle does not vary by more than 3 days from month to month.⁶

How to take Evana® for HMB?

Evana should only be taken once heavy menstrual bleeding has started, for a maximum of 4 days. The recommended dosage is⁶:

- · Two tablets to be taken 3 times a day (e.g., morning, afternoon, and evening), as long as needed
- If menstrual bleeding isn't reduced, an extra 2 tablets can be taken at night, –but no more than 8 tablets (4 g) should be taken per day
- Evana can be used for as long as the woman's periods remain regular and heavy⁶
- However, if the patient has taken Evana as directed for three menstrual cycles and there has been no reduction in their HMB, then they should seek further advice from their doctor.⁶ Their doctor may recommend an alternative non-hormonal treatment, such as the off-licence use of an NSAID, or a hormonal option, with levonorgestrel intrauterine system (LNG-IUS) and combined hormonal contraceptives or cyclical oral progestogen.²

Who cannot take Evana®?

The following patients cannot take Evana⁶:

- · Under 18 years of age
- With irregular menstrual bleeding more than 3 days variability per 21-35 day cycle
- · Taking oral contraceptives, as this can increase the risk of thrombosis
- · Taking warfarin or other anticoagulants
- Mild-to-moderate renal insufficiency or severe renal impairment
- · Active thromboembolic disease, or a previous thromboembolic event and a family history of thrombophilia
- Blood in the urine (haematuria)
- · Fibrinolytic conditions following disseminated intravascular coagulation
- · History of convulsions
- Hypersensitivity to tranexamic acid or any of the tablet excipients. These are Calcium hydrogen phosphate, croscarmellose sodium, povidone, talc, and magnesium stearate
- · Pregnant women.

Who needs to take care when considering Evana®?

Evana may need to be used with caution in certain patients. You can advise the following patients on the suitability of Evana for their HMB or recommend that they speak to their doctor before taking Evana⁶.

- Over 45 years of age
- Obese patients (Body Mass Index (BMI) of 30 or above)
- · Diabetics
- Those with polycystic ovary syndrome
- · History of endometrial cancer in a first-degree relative (e.g., mother, grandmother, aunt, or sister)
- Those taking unopposed oestrogen or tamoxifen, or fibrinolytic medicines such as streptokinase
- Breastfeeding women a small amount passes into breastmilk but an antifibrinolytic effect in the infant is unlikely.

Evana® side effects

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

Side effects with Evana may include⁶:

- Gastrointestinal discomfort, such as nausea, vomiting and diarrhoea, are the most common adverse effects (may affect up to 1 in 10 people), however, these resolve when the dosage is reduced
- Uncommon (may affect up to 1 in 100 people): allergic skin reactions
- Very rare (may affect up to 1 in 10,000 people): hypersensitivity reactions including anaphylaxis
- Frequency not known: thromboembolic events, retinal/artery occlusion, impaired colour vision or other visual disturbances have been reported.

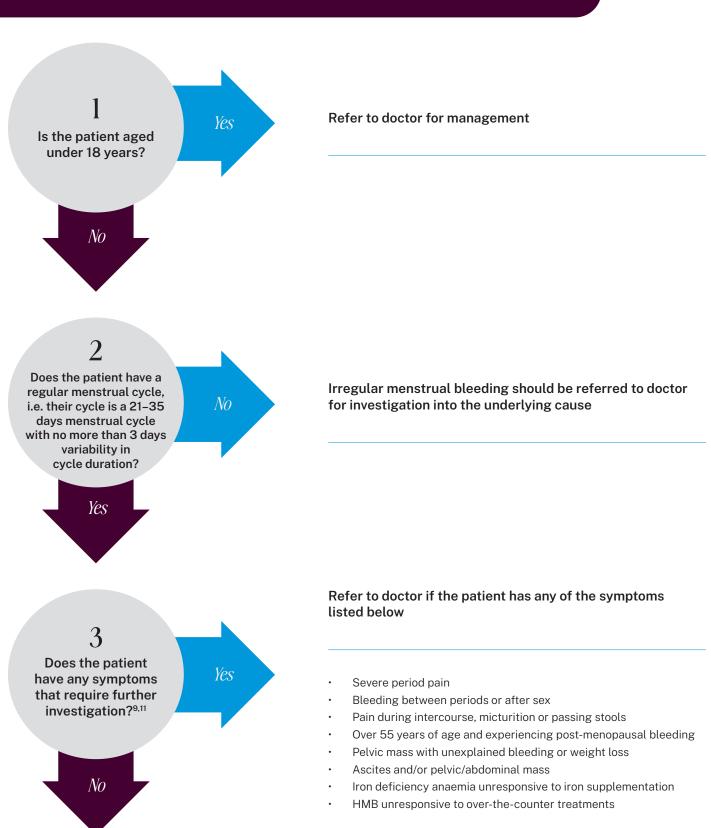
Seizures can occur, particularly in cases of misuse. The patient should be advised to stop taking Evana if they experience any visual disturbances.⁶

Understanding the *pharmacy* supply of Evana®

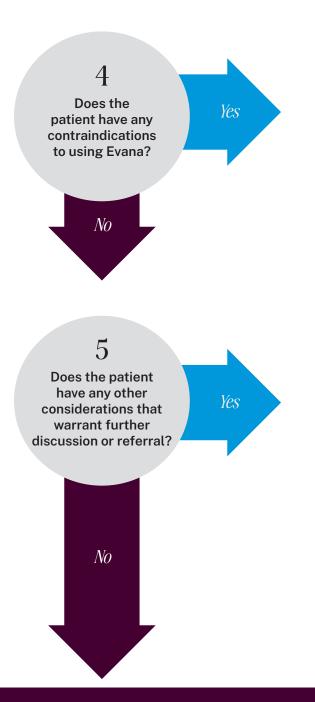
Evana® is only available from pharmacies

The following Evana Pharmacy Supply Model acts as a reminder of the various factors to consider when making a treatment recommendation.

The Evana Pharmacy Supply Model⁶ | Patient with heavy menstrual bleeding



Please see next page



Do not recommend Evana if the patient has any of the below contraindications

- Taking oral contraceptives
- · Taking warfarin or other anticoagulants
- Mild-to-moderate renal insufficiency or severe renal impairment
- Active thromboembolic disease, or a previous thromboembolic event and a family history of thrombophilia
- · Blood in the urine (haematuria)
- Fibrinolytic conditions following disseminated intravascular coagulation
- History of convulsions
- Hypersensitivity to tranexamic acid or the other tablet excipients
- Pregnancy.

Discuss the suitability of Evana or advise the patient to speak to their doctor before taking Evana if any of the following apply

- Over 45 years of age
- · Obese (Body Mass Index (BMI) of 30 or above)
- Diabetic
- Have polycystic ovary syndrome
- History of endometrial cancer in a first-degree relative (e.g., mother, grandmother, aunt, or sister)
- Breastfeeding
- Taking unopposed oestrogen or tamoxifen
- · Taking fibrinolytics e.g., streptokinase.

Evana® can be recommended for heavy menstrual bleeding⁶

Evana should only be taken once heavy menstrual bleeding has started, for a maximum of 4 days.

Two tablets to be taken 3 times a day (e.g., morning, afternoon, and evening), as long as needed.

If menstrual bleeding isn't reduced, an extra 2 tablets can be taken at night, - but no more than 8 tablets (4 g) should be taken per day.

How to have a conversation with women with HMB

Pharmacy teams can play a key role in identifying and helping women with HMB

It is important to recognise that due to the perceived normality of HMB, some women will not raise the issue and the pharmacy team should be alert to cues that could act as a prompt to open the conversation:

- Buying large quantities of sanitary products
- Doubling up on sanitary products, e.g. heavy flow tampons and pads
- · Requests for strong analgesics to manage period pain
- If the patient has signs or symptoms of iron deficiency anaemia.

Ways to start a conversation based on these prompts could include:

"How are you feeling today?"

"Is there anything you're worried about that we can help with?"

"Is everything OK or do you have any questions about the products you are buying?"

The key priority in helping women with HMB is to take their concerns seriously, and to listen and provide reassurance.⁴

Firstly, in validating their condition is worthy of intervention and management. HMB is a common gynaecological complaint, so sufferers often don't feel it needs to be investigated or treated as they believe it's normal. 4.5

Secondly, if they are concerned that their symptoms are a sign of a serious cancer condition, they can be reassured that the risk is negligible. Check that the patient does not have any symptoms that warrant referral, such as pelvic mass or unexplained weight loss.

Thirdly, that there are effective and well-tolerated treatment options, such as Evana, that can help reduce menstrual blood loss by up to 60%.

Advising patients on Evana®

Once you have established, using the Pharmacy Supply Model, that Evana is an appropriate treatment for your HMB patient there are several key points to advise the patient on.

1 Dose

- Start Evana only once heavy bleeding has started⁶
- Take 2 tablets 3 x daily i.e. 6 tablets (3 g) for a maximum of 4 days⁶
- The dose can be increased to a maximum of 4 x daily i.e., 8 tablets (4 g) if menstrual bleeding is very heavy.⁶

2 Duration

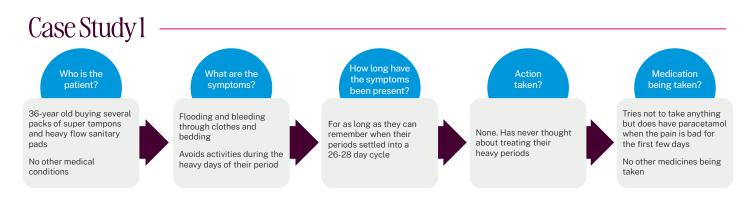
- It may take using Evana for three menstrual cycles before they experience the full benefit on their blood flow⁶
- If Evana is successful in reducing blood flow, it can continue to be used for as long as periods remain regular and heavy, following a review of the Pharmacy Supply Model
- If there is no reduction in menstrual blood flow after three menstrual cycles, Evana should be stopped and the patient should see their GP.6

3
Deficiency

- Be alert and ask about symptoms of iron deficiency anaemia, as this is common among patients with HMB.³ These include fatigue, breathlessness, headache, restless leg syndrome and cognitive dysfunction⁹
- Advise the patient that iron supplements can be purchased from pharmacy and that if iron deficiency symptoms do not improve then they should see their doctor for further advice.

Understanding *HWB* in pharmacy practice

The following case studies are designed to help your pharmacy team identify and support patients with HMB.



- The patient has HMB and a regular menstrual cycle with two days of variability
- · $\,\,\,$ Advise the patient to try Evana for three cycles to see if it is effective in reducing their HMB $^{
 m 6}$
- NICE guidance recommends NSAIDs, such as naproxen or ibuprofen, as the first-line treatment choice for period pain,¹⁹ therefore recommend a switch from paracetamol.

Case Study 2 What are the Medication the symptoms being taken? patient? symptoms? Headache, dizziness and is pale and tired, despite Has had heavy periods Takes 'strong' analgesics being inactive due to their for the past few years since coming off the oral (paracetamol + codeine) None. Their mum heavy periods to try to manage their had heavy periods so contraceptive pill Changes sanitary products they expect it will be 25-year old headache several times a every hour for the first day, several times a week The other symptoms have something that gets couple of days of their better after they have been for the past few No other medicines being period months but they seem to children be getting worse Has a 28-29 day menstrual cycle

- The patient has symptoms consistent with iron deficiency anaemia, likely due to their HMB
- As they have a regular menstrual cycle with one day of variability, Evana can be recommended⁶
- Advise the patient to take Evana for three cycles to see if it is effective in reducing their HMB⁶
- NICE guidance recommends iron deficiency anaemia is treated with a daily tablet of oral ferrous sulfate, ferrous fumarate or ferrous gluconate that is continued for 3 months after the iron deficiency is corrected.³ Advise the patient that iron supplements can be purchased from pharmacy and that if their iron deficiency symptoms do not improve then they should see the doctor for further advice⁹
- Also advise the patient to monitor their analgesic intake as taking analgesics for 15 days or more per month can cause medication overuse headache.²⁰ In addition, advise the patient that codeine-containing analgesics should be taken for a maximum of 3 days, due to the risk of addiction.²¹

Case Study 3



- The patient has HMB symptoms but the change in frequency and severity warrant further investigation from their doctor
- Evana is not a suitable treatment option as they are under 18 years of age and have an irregular menstrual cycle with a less than a 21-35-day cycle and more than 3 days of individual variability⁶
- Naproxen can be recommended as an alternative NSAID to ibuprofen¹⁹ for long-lasting period pain relief.

Case Study 4 Who is the What are the Medication Action the symptoms patient? symptoms? taken? being taken? been present? Heavy periods that they Six months ago they saw are finding hard to manage Combined oral Has had heavy periods for their GP, who prescribed contraceptive with a one 31-year old as they have to take a

a combined oral

contraceptive

The patient has diagnosed HMB and is being treated with a combined oral contraceptive

couple of days off work

each month

Evana is not a suitable treatment option as its use is contraindicated in those taking oral contraceptives because of the increased risk of thrombosis⁶

the past 10 years

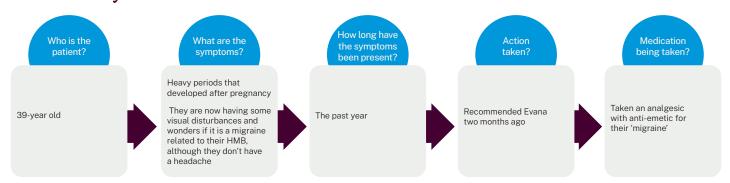
Refer patient to their GP or if the NHS pharmacy contraceptive service is in place, the pharmacist may be able to resolve this and liaise with the GP.

Case Study 5 low long have What are the Medication being taken? Recommended Evana three months ago but Heavy periods that they Has had heavy periods for has not noticed any No other medication 28-year old have previously consulted the past three years difference in their being taken a pharmacist about menstrual flow so would like a repeat purchase

- The patient has been taking Evana for the past three cycles and has not noticed any reduction in her menstrual bleeding
- On this basis, a further sale is inappropriate, and the woman should be referred to her doctor for further management advice.6

week withdrawal bleed

Case Study 6



- The patient has been taking Evana for the past two cycles and is now experiencing visual disturbances
- This is likely to be related to their Evana use, frather than a migraine and the patient should be advised to stop taking the product and consult their doctor for further guidance on HMB management.

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Essential Information

Evana® Heavy Period Relief 500 mg Tablets (Tranexamic acid) - PL 14251/0300. Indications: Reduction of heavy menstrual bleeding over several cycles in women with regular, 21-35 day cycles with no more than 3 day variation. Posology: Two tablets to be taken, 3 times a day at the onset of heavy menstrual bleeding, for a maximum of 4 consecutive days. Maximum daily dose of 8 tablets. **Contraindications:** Hypersensitivity to the active substance or any of the excipients, severe renal impairment, mild to moderate renal insufficiency, active thromboembolic disease, previous thromboembolic event and a family history of thrombophilia, haematuria, irregular menstrual bleeding, those taking warfarin, anticoagulants or oral contraceptives, pregnancy, fibrinolytic conditions following DIC, or history of convulsions. Precautions: Women aged over 45, those who are diabetic or obese, polycystic ovary syndrome, a family history of endometrial cancer, and those receiving unopposed oestrogen or tamoxifen, breastfeeding. Side effects: Common (≥1/100 to <1/10): Nausea, vomiting, diarrhoea. Uncommon (≥1/1,000 to <1/100): Allergic skin reactions. Very rare (<1/10,000): Hypersensitivity reactions including anaphylaxis. Frequency unknown: thromboembolic events, retinal/ artery occlusion, impaired colour vision or visual disturbances, seizures. MA holder: Manx Healthcare Ltd, Taylor Group House, Wedgnock Lane, CV34 5YA, UK. Classification: P. RRP: 18 tablets: £14.95. Date: January 2024 - For full information see: evanaperiods.com/hcp/evana/spc.

Reporting of suspected adverse reactions

Healthcare professionals should report any suspected adverse reactions 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.



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