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NEW
PHARMACY (P)
PRODUCT

Pharmacy training guide

Managing dysmenorrhoea (period pain)

A pharmacy guide from the makers of Ultravana®
Period Pain Relief 250 mg Gastro-resistant tablets (Naproxen)

Contents

Introduction

Overall aim of this training guide

To support you in conducting effective, patient-specific, clinical consultations on period pain, and enable you to appropriately supply Ultravana Period Pain Relief 250mg gastro-resistant tablets (Naproxen), available without prescription from pharmacies to women who are eligible.

Dysmenorrhoea, or period pain, is common among women of reproductive age, with an estimated prevalence as high as 91%. As with other gynaecological issues, period pain is a condition that exerts a significant adverse effect on female wellbeing and quality of life leading to work/school absenteeism[1].

The Women's Health Strategy for England acknowledges that women have been told that painful periods are 'normal' and that they will 'grow out of them'. In some cases, women feel they are not being listened to by healthcare professionals and feel that their pain is being diminished when they try to discuss their period pain[2].

Given the high prevalence of dysmenorrhoea[1] there is a real opportunity for pharmacy to raise awareness of the condition and its management and to become period pain champions for their patients.

The launch of the Pharmacy-only gastro-resistant tablet Ultravana Period Pain Relief for dysmenorrhoea in women aged 15–50 years, containing the non-steroidal anti-inflammatory drug (NSAID) naproxen 250 mg[3], provides an opportunity for pharmacy to step into this gap in their patient's pain management with a long-lasting treatment option[4,5,6]. In addition, naproxen is a NICE-recommended first-line treatment for dysmenorrhoea[1] and has been shown in a Cochrane review to be highly effective[7].

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

Learning objectives

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

Understanding *Dysmenorrhoea*

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Dysmennorhoea affects 71% of women of reproductive age[10]

What is dysmenorrhoea?

According to NICE, Dysmenorrhoea, or period pain, is[1]: "a cramping pain usually in the lower abdomen that occurs shortly before the onset of menstruation and persists for up to 72 hours".

There are two types of dysmenorrhoea[1]:

- **Primary –** caused by menstruation, with no other underlying cause.
- **Secondary –** caused by an underlying gynaecological issue, such as fibroids.

While most patients will experience primary dysmenorrhoea, few patients seek medical advice for period pain[1] it is therefore important to be alert to the potential for secondary dysmenorrhoea as the underlying causes may warrant further investigation.

How common is dysmenorrhoea?

Dysmenorrhoea is the most common menstrual problem[9]. Prevalence varies widely according to data, with estimates ranging from 16–91%[1]. However, a more recent systematic analysis of 37 studies estimated the overall prevalence as being 71%[10].

"There was a certain element of 'this is just part of life, just get on with it'"[8]

"Someone told me I could suffer from endometriosis, but that I don't 'check all the boxes'. So, because I 'only' have a painful period. It's probably just that I'm unlucky, right?"[8]

What are the symptoms of dysmenorrhoea?

The symptoms of dysmenorrhoea can differ, depending on whether it is primary or secondary in nature.

Dysmenorrhoea symptoms[1,10,11]

	Primary dysmenorrhoea	Secondary dysmenorrhoea
 First presentation	6–12 months after periods first appear, once menstrual cycle is regular	Begins several years after the onset of painless periods, usually five years after
 Onset of pain	Just before menstruation begins	May be present throughout the menstrual cycle but is exacerbated by menstruation
 Pain location	Lower abdominal pain that may also be felt in the back and inner thigh	Lower abdominal pain that may also be felt in the back and inner thigh
 Pain severity	Mild-to-moderate in most cases but 2–29% of women experience severe pain	Pain may be worse during menstrual cycle and worsens with time
 Pain duration	Can last for up to 72 hours, diminishing as the period progresses	Can persist beyond menstruation
 Non-pain symptoms	• Fatigue • Irritability/emotional changes • Dizziness • Bloating • Breast tenderness • Vomiting/nausea • Diarrhoea • Headache • Lower back pain	• Pain during sexual intercourse • Heavy menstrual bleeding • Bleeding between periods or after sex • Abnormal vaginal discharge • Pelvic or abdominal mass • Rectal pain and bleeding

What causes dysmenorrhoea?

Primary dysmenorrhoea with no underlying cause is believed to be due to an increase or imbalance in the amount of prostaglandins released by the lining of the uterus (endometrium) during menstruation[7]. Prostaglandin release is triggered by a drop in the amount of progesterone during the normal menstrual cycle[12].

This release of prostaglandins prompts:

- Uterine contractions
- Reduced blood flow
- Uterine hypoxia (lack of oxygen)
- Hypersensitisation of the peripheral nerves[7,13]

Uterine hypoxia is the cause of the cramping pains in primary dysmenorrhoea[13]. Further, the tissue breakdown that happens during menstruation causes elevated prostaglandin levels[12].

Secondary dysmenorrhoea is caused by underlying gynaecological pathologies, such as[1]:

- Adenomyosis
- Endometriosis
- Endometrial polyps
- Fibroids
- Gynaecological cancers
- Pelvic inflammatory disease.

It can also arise because of intrauterine device (IUD) insertion[1].

What are the risk factors for dysmenorrhoea?

There are several different factors that can either increase or decrease the risk of dysmenorrhoea or cause increased pain severity[1,9].

Dysmenorrhoea risk factors [1,9]

Increased risk of dysmenorrhoea [1,9]

Starting periods at a younger age

Have not given birth

Family history of dysmenorrhoea

Heavy menstrual bleeding

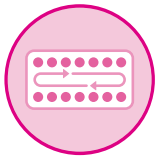
Stress

Decreased risk of dysmenorrhoea [9]

Older age (improves in the third decade)[14]

Have given birth

High fruit and vegetable intake



Oral hormonal contraception

What is the impact of dysmenorrhoea?

Dysmenorrhoea has a significant impact on a woman's quality of life[1,15], with a greater disease burden than any other gynaecological condition[9]. This affects a patient throughout their life course as dysmenorrhoea is an episodic ongoing condition that can hinder the ability to achieve educationally or in their career, social relationships, emotional well-being and starting a family[12].

Impact of dysmenorrhoea[12]

Quality of life[1,12,15]

The impact is similar to other chronic conditions, such as cystic fibrosis[12]

Relationships[12,16]

One study found more than 20% of young women reported poor relationships due to their dysmenorrhoea[12]

Work/studying/ social activities[12,16]

More than 70% of women reported these were affected, with 16% saying dysmenorrhoea had a serious impact[12]

Absenteeism

The main reason for repeated work or school absenteeism in young women[17], resulting in a significant economic cost due to reduced productivity[9]

It is important for the pharmacy team to be aware that much of the impact of dysmenorrhoea may be hidden.

- The Women's Health Strategy for England found period pain was perceived as being 'normal' and a condition they would 'grow out of'[2]
- There is a stigma and embarrassment around periods that is exacerbated by this 'normalisation' and, therefore, it is not a legitimate health concern[2,8]
- Yet, it has been shown that dysmenorrhoea can result in enhanced central nervous system sensitivity to pain, not restricted to the menstrual cycle, and has been linked to an increased likelihood of developing other chronic pain conditions, such as fibromyalgia[1,12,18].

It is, therefore, important for women to take their dysmenorrhoea seriously, not just for the immediate term in validating their condition[8] but also in terms of chronic pain issues that necessitate the early and adequate treatment of period pain[18].

"When it's on TV, even when it's like being publicly talked about ... it's still kind of a secret"[8]

"You don't talk about it, you don't complain... you don't bring it up with anybody... it's... a secret kind of shameful thing for most of society"[8]

When should you refer the patient to a doctor?

Patients presenting with the following symptoms that suggest secondary dysmenorrhoea should be referred to their doctor for further investigation[1,19].

- Chronic pelvic pain occurring before menstruation
- Deep pain during intercourse
- Rectal pain or bleeding
- Heavy menstrual bleeding (may or may not be accompanied by lower abdominal pain), bleeding or spotting between periods, or after intercourse, abnormal or postmenopausal bleeding
- Longer, heavier periods and more irregular periods
- Abnormal vaginal bleeding or discharge – mucoid, blood-stained, or purulent
- Pelvic mass
- Pelvic/lower abdominal pain and tenderness or abdominal distension
- Loss of appetite/early satiety
- Increased urinary urgency and frequency or pain when urinating or passing stools
- Dyspepsia and nausea
- Fever (if there is an acute infection)
- Pain after intra-uterine device (IUD) insertion 3–6 months earlier.

Patients who complain of dysmenorrhoea or pelvic pain that is more severe than usual, which is not eased by analgesics, should be referred to a doctor urgently[19].

Understanding Ultravana®

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Ultravana® contains the NSAID naproxen, recommended by NICE as a first-line analgesic for dysmenorrhoea[1]

Managing dysmenorrhoea

Oral analgesics are the only OTC pharmacological options available for dysmenorrhoea management, according to NICE guidance[1]. There are several oral analgesics available:[1,20]

- **NSAIDs** such as naproxen, ibuprofen and aspirin are NICE's first-line recommended dysmenorrhoea treatment.
- **Paracetamol** is a second-line treatment and should be used where NSAIDs are contraindicated or not tolerated. Paracetamol can be used in combination with an NSAID if there is insufficient pain relief.

Where a patient's pain is unable to be managed with OTC analgesics, they should be referred to their doctor for prescription options with a hormonal contraception, an alternative first-line treatment[1].

The differences between the oral analgesics used in dysmenorrhoea

Paracetamol and NSAIDs are the only analgesics recommended by NICE for dysmenorrhoea[1]. They have different modes of action[20] which is of critical importance when it comes to effectively alleviating period pain.

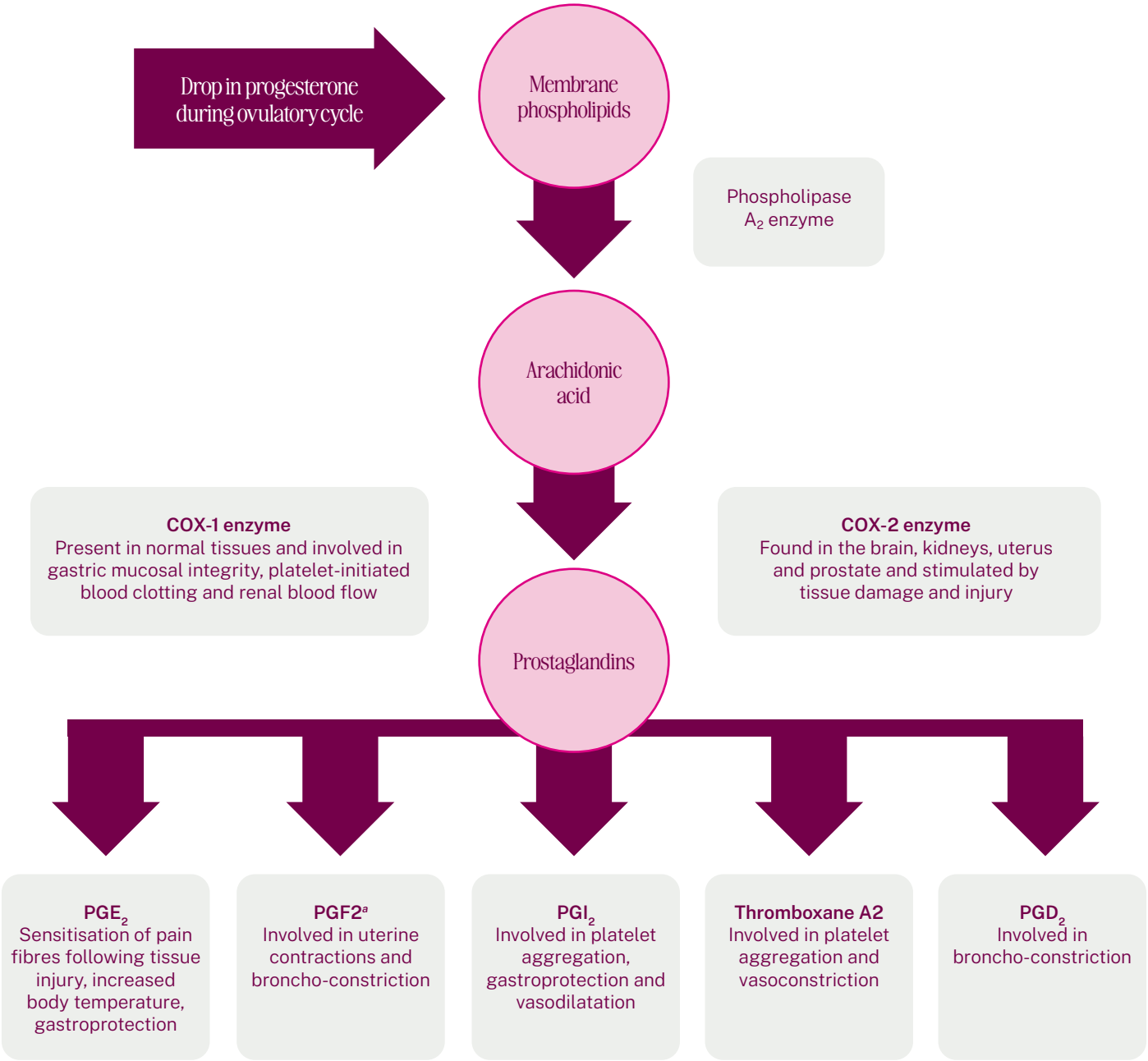
	NSAIDs	Paracetamol
Mode of Action	Reversibly inhibit the enzymes cyclo-oxygenase-1 (COX-1) and cyclo-oxygenase-2 (COX-2) involved in prostaglandin production[21]. COX-2 prostaglandins mediate pain, inflammation and fever[20]. COX-1 prostaglandins have protective roles on gastric mucosal integrity, platelet-initiated blood clotting and renal blood flow[20,21].	The mode of action is not fully known but is believed to inhibit COX enzymes in the central nervous system (CNS)[20].
Tolerability	NSAIDs contraindications include: • active gastrointestinal (GI) bleeding or • previous NSAID associated GI bleeding • active GI ulcer or • history of recurrent GI haemorrhage or ulceration • severe heart failure • renal/hepatic impairment • varicella infection • history of hypersensitivity reactions to NSAIDs • pregnant women in the third trimester[6]. The risk of adverse effects can be minimised by using the lowest effective dose for the shortest time. Naproxen and low-dose ibuprofen have the most favourable cardiovascular and GI safety profile[6].	Although there are no contraindications for paracetamol, and adverse effects are rare, there is risk of hepatotoxicity and accidental overdose[20]. Patients at risk include those with: • chronic alcohol consumption • malnutrition and dehydration • a body weight <50 kg • severe hepatic disease • older age or frailty • use of liver enzyme-inducing drugs[20].

Ultravana® use for dysmenorrhoea

Ultravana contains the NSAID naproxen 250 mg (in a gastro resistant tablet) for the treatment of primary dysmenorrhoea in women aged 15 to 50 years[3]. Patients with dysmenorrhoea can experience pain for up to 72 hours[1]. Ultravana provides long-lasting pain relief [4,5,6].

Naproxen acts by inhibiting both the COX-1 and COX-2 enzymes to reduce pain and fever and exert an anti-inflammatory action[19] - see Figure 1. The COX enzymes act on arachidonic acid, which is released by the endometrium during menstruation[7,12] with tissue breakdown during this time also contributing to prostaglandin release[12,22].

Figure 1: Naproxen's mode of action in dysmenorrhoea[12,22]



How effective is Ultravana® in managing dysmenorrhoea?

The most recent Cochrane review of NSAIDs in dysmenorrhoea concluded[7]:

"NSAIDs appear to be a very effective treatment for dysmenorrhoea…there is insufficient evidence to determine which (if any) individual NSAID is the safest and most effective for the treatment of dysmenorrhoea".

Given this, patient preference is important as an NSAID recommendation cannot be made based on efficacy or safety alone. Determining how critical long-lasting relief is to the patient experiencing dysmenorrhoea is essential. As Ultravana contains naproxen[4,5,6], it can provide long-lasting relief to help them get through the day or night.

This long-lasting benefit has been seen in a study comparing a single dose of naproxen 440 mg (please note this is lower than the initial Ultravana dose of 500 mg[3]) against the maximum dose of paracetamol 1000 mg in dental pain. This study found naproxen had superior total pain relief over 12 hours, compared with paracetamol[23].
-See Figure 2

In addition, another single dose study in dental pain using the same 440 mg naproxen dose compared with maximum OTC dose ibuprofen (400 mg) also found the former provided significantly longer pain relief[5].
-See Figure 3

Figure 2: Mean pain relief over 12 hours with naproxen 440 mg vs paracetamol 1000 mg [23]

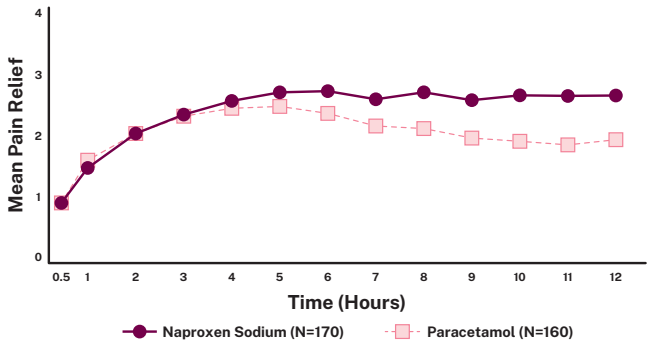
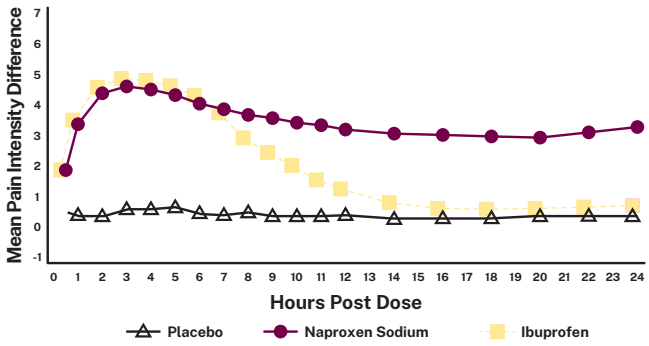


Figure 3: Mean pain relief over 24 hours with naproxen 440 mg vs ibuprofen 400 mg [5]



Why is the Ultravana® formulation important?

Ultravana is available in a gastro-resistant formulation that does not disintegrate in the stomach. Instead, it disintegrates once it reaches the small intestine. As such, the delayed absorption seen with enteric-coated tablet formulations aims to minimise the risk of adverse GI effects seen with NSAIDs and is of value in patients where gastric dissolution is undesirable[3].

Who can take Ultravana®?

Ultravana can be recommended:

- For women aged 15 to 50 years with primary dysmenorrhoea.

How to take Ultravana® for Dysmenorrhoea?

Ultravana should only be taken for a maximum of 3 days per menstrual cycle. The recommended dosage is[3]:

- Day 1: Two tablets to be taken initially and then one tablet, after 6-8 hours if required.
- Days 2 and 3: One tablet to be taken every 6-8 hours, if required.

Do not take more than 3 tablets (750 mg) per day.

Patients should be advised to take Ultravana whole with water, with or after food. Ultravana is not to be broken or crushed[3].

Who cannot take Ultravana®?

The following patients cannot take Ultravana:

- Those under the age of 15 years or over 50 years
- With a history of, or active, peptic ulceration and active gastrointestinal (GI) bleeding (two or more distinct episodes of proven ulceration or bleeding)
- With a history of GI bleeding or perforation, related to previous NSAID therapy
- Those who have experienced asthma, rhinitis, nasal polyps, angioedema or urticaria with aspirin or other NSAIDs as there is the potential for cross-sensitivity reactions. Severe anaphylactic-like reactions to naproxen have been reported in such patients[3]. This is known as aspirin-exacerbated respiratory disease with a prevalence of 7% in general adult asthmatics and 15% in those with severe asthma[24]. If an asthmatic has not previously had a reaction to aspirin or other NSAIDs, then Ultravana can be recommended[3,24]
- With severe heart failure, hepatic or renal failure
- During the last trimester of pregnancy
- Known hypersensitivity to naproxen or any of the other tablet excipients[3]
- Ultravana should not be taken with other NSAIDs due to the increased risk of side effects[3].

Who needs to take care when considering Ultravana®?

Caution should be exercised when considering whether to recommend Ultravana for patients with the following conditions[3]:

- **Respiratory problems** as bronchospasm can occur in those with a history of bronchial asthma or allergic disease. Always ask about asthma before recommending Ultravana and advise patients to stop using if asthma worsens[24]. However, most asthmatics do not react to NSAIDs and Ultravana is only contra-indicated in those who have experienced an asthmatic or allergic reaction to aspirin or other NSAIDs[3,24]
- **Cardiovascular or hepatic impairment or renal failure** NSAIDs can cause a dose-dependent reduction in prostaglandin formation, resulting in renal failure. Those most at risk are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and older patients and renal function should be monitored. It should be noted that naproxen and low-dose ibuprofen are the NSAIDs with the most favourable cardiovascular safety profile[25]
- **History of hypertension and/or mild-to-moderate heart failure.** Patients with uncontrolled hypertension, congestive heart failure, established ischaemic disease, peripheral arterial disease and/or cerebrovascular disease should only take Ultravana under doctor supervision
- **GI conditions.** NSAIDs are sometimes associated with GI adverse effects. Ultravana should also be used with caution in those with a history of GI disease, such as Crohn's disease and ulcerative colitis, as their condition may be exacerbated.
- **Coagulation disorders** or those who are taking medication that interferes with coagulation
- **Systemic lupus erythematosus** and mixed connective tissue disorders are at increased risk of aseptic meningitis
- Those who are **breastfeeding**.

Ultravana® possible side effects

Like all medicines, and as an NSAID, Ultravana can cause side effects, although not everybody gets them. These side effects can be minimised by using the lowest effective dose for the shortest duration needed to control symptoms[3]

- **GI side effects** are the most commonly reported effects, such as nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, heartburn and epigastric distress. Prescription dose naproxen is associated with an intermediate GI risk, while OTC dose ibuprofen has the lowest risk[6]
- **Blood and lymphatic system disorders,** such as agranulocytosis, neutropenia, thrombocytopenia, aplastic anaemia, and haemolytic anaemia
- **Cardiac disorders,** such as oedema, palpitations, heart failure and congestive heart failure. Naproxen and low-dose ibuprofen are the NSAIDs with the most favourable cardiovascular safety profile[25]
- **Ear and labyrinth disorders,** e.g. tinnitus, hearing impairment and vertigo
- **Eye disorders,** e.g. visual disturbances, this requires ophthalmologist investigation
- **General disorders,** e.g. thirst, fever, fatigue, and malaise
- **Hepatobiliary disorders,** e.g. abnormal liver function, fatal hepatitis, and jaundice
- **Immune system disorders,** such as hypersensitivity reactions
- **Metabolic and nutrition disorders,** e.g. hyperkalaemia
- **Musculoskeletal and connective tissue disorders,** such as myalgia and muscle weakness
- **Nervous system disorders,** such as convulsions, dizziness, headaches, drowsiness, lack of concentration
- **Psychiatric disorders,** e.g. insomnia, depression, confusion, hallucinations, and dream abnormalities
- **Renal and urinary disorders,** such as glomerular or interstitial nephritis or renal failure
- **Reproductive disorders** – female infertility
- **Respiratory, thoracic, and mediastinal disorders,** such as asthma, shortness of breath and pulmonary oedema
- **Skin and subcutaneous tissue disorders,** e.g. Stevens-Johnson syndrome, skin rashes, urticaria, pruritus, sweating, alopecia
- **Vascular disorders,** e.g. hypertension and vasculitis.

Ultravana® interactions with other medicines

Ultravana interactions with the following medications have been reported[3].

Ultravana® drug-drug interactions[3]

Medication	Interaction
Other NSAIDs	Increased risk of adverse events
Antacid or colestyramine	Can delay naproxen absorption
Anti-coagulants	Can enhance the effect of anticoagulants, such as warfarin
Anti-hypertensives	Reduced anti-hypertensive effects. NSAIDs can also increase the risk of renal impairment seen with ACE-inhibitors
Anti-platelet agents	Increased risk of GI bleeding
Cardiac glycosides	Can exacerbate cardiac failure and increase plasma glycoside levels
Ciclosporin	Increased risk of nephrotoxicity
Corticosteroids	Increased risk of GI ulceration or bleeding
Diuretics	Decreased diuretic effect
Lithium	Increased plasma lithium concentrations
Methotrexate	Decreased methotrexate elimination, leading to possible toxicity
Mifepristone	Can reduce the effect of mifepristone, therefore should not be used for 8–12 days after mifepristone use
Quinolone antibiotics	May have an increased risk of convulsions with concomitant use
Selective serotonin reuptake inhibitors	Increased risk of GI bleeding
Sulphonylureas	Can cause overdosage of sulphonylureas, sulphonamides or hydantoin, therefore, dose adjustment of these medications may be required
Tacrolimus	Increased risk of nephrotoxicity
Zidovudine	Increased risk of haematological toxicity

Understanding the *pharmacy* supply of Ultravana®

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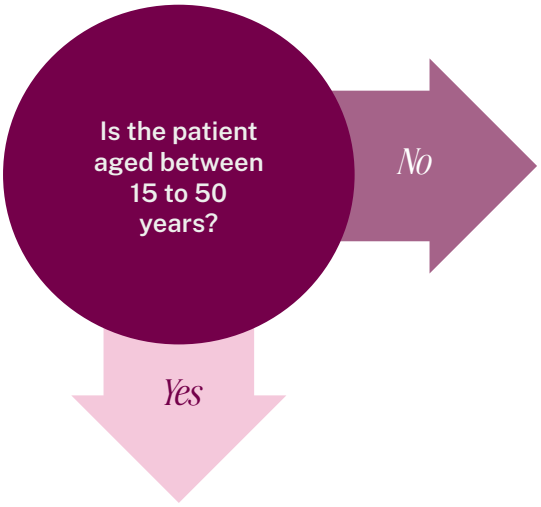
Ultravana® is only available from pharmacies

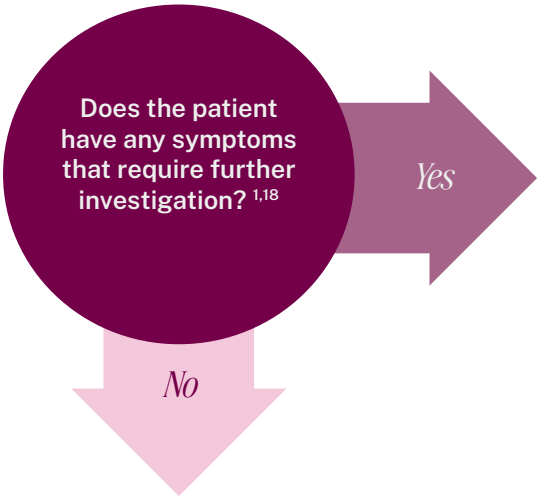
Analgesics are among the most common pharmacy request; therefore, the pharmacy team is already familiar with the OTC recommendation of NSAIDs. Many of the contraindications, precautions and interactions apply across the NSAID class and, therefore, also apply to Ultravana. As such, you and your team will already be accustomed at taking these considerations into account before making an appropriate analgesic recommendation.

The following Ultravana Pharmacy Supply Model acts as a reminder of the various considerations when making a treatment recommendation.

The Ultravana® Pharmacy Supply Model [3] | Patient with dysmenorrhoea



Refer to doctor



Refer to doctor if the patient has any of the symptoms listed below

- Periods have become more painful, heavy or irregular
- Pain on urinating, passing stools or increased urgency or frequency
- Chronic pelvic pain occurring before menstruation
- Heavy menstrual bleeding or bleeding between periods
- Pain during intercourse or bleeding after intercourse
- Rectal pain or bleeding
- Lower abdominal pain/tenderness often accompanied by heavy menstrual bleeding
- Pelvic mass/pain
- Abnormal vaginal bleeding and discharge
- Fever, if there is acute infection
- Abdominal distension
- Loss of appetite/early satiety
- Abnormal postmenopausal bleeding
- Dyspepsia and nausea
- Pain after IUD insertion 3–6 months earlier

Please see next page

Does the patient have any contraindications?

Yes

Do not recommend Ultravana or other NSAIDs if the patient has any of the below contraindications

- Active or history of peptic ulceration
- Active GI bleeding (> 2 episodes of proven ulceration or bleeding)
- History of GI bleeding or perforation, related to previous NSAID therapy
- Severe renal or hepatic failure
- Severe heart failure
- Last trimester of pregnancy
- Hypersensitivity to naproxen or the other tablet excipients
- Aspirin or NSAID sensitivity*

*Since the potential exists for cross-sensitivity reactions, Ultravana should not be given to patients in whom aspirin or other NSAIDs/analgesic drugs induce asthma, rhinitis, nasal polyps or urticaria. Severe, fatal anaphylactic-like reactions to naproxen have been reported in such patients[3].

No

Are there other issues that warrant caution?

Do they have or have had a history of bronchial asthma or allergic disease?

Yes

Bronchospasm may be precipitated

Do they have platelet aggregation issues, have a coagulation disorder, or taking concomitant anti-coagulation therapy, e.g. warfarin?

Yes

Decreases platelet aggregation and prolongs bleeding times

Do they have a history of inflammatory bowel disease, e.g. ulcerative colitis, or Crohn's disease

Yes

These conditions may be exacerbated

Have they had any visual disturbances when using naproxen?

Yes

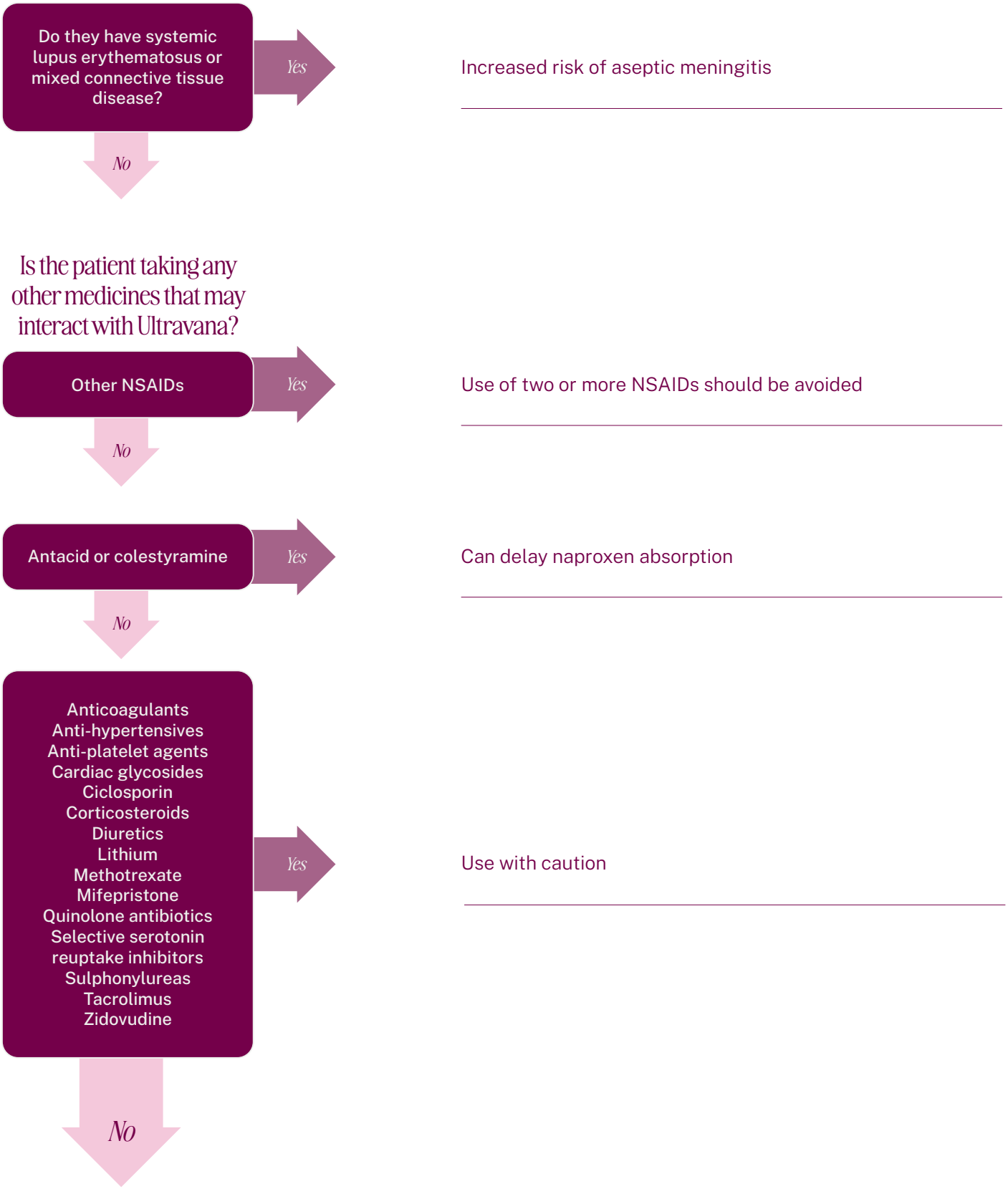
Refer to ophthalmologist for examination

Do they have uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease, impaired kidney, or liver function?

Yes

Discuss the suitability of Ultravana or advise the patient to speak to their doctor before taking

Please see next page



Ultravana® can be recommended for primary dysmenorrhoea[3]

How to have a *conversation* with women with Dysmenorrhoea

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Pharmacy teams can play a key role in identifying and helping patients with dysmenorrhoea

There are two key priorities when it comes to managing dysmenorrhoea in the pharmacy:

1. The first is that the patient feels their condition is recognised as being a legitimate health concern and is not dismissed as being 'normal'.
2. The second reason is that, as dysmenorrhoea has been associated with an increased future risk of developing chronic pain conditions[1,12,18] early and effective pain management is important[18].

Due to the stigma and embarrassment that some patients can feel about their dysmenorrhoea[2] it may be useful to explore what type of pain the patient is experiencing and be alert to visual cues:

- Requesting strong analgesics – if these are paracetamol-opioid combinations as paracetamol is a second-line NICE analgesic recommendation and opioids are not recommended. Switching a patient to an NSAID as a NICE first-line analgesic, such as Ultravana where appropriate, could make a significant difference to a patient's dysmenorrhoea management[1]
- Buying sanitary products, particularly if they are buying large quantities or doubling up on both tampons and towels, as this could indicate they have heavy periods (menorrhagia). If they experience heavy periods, it is important to make them aware that NICE-recommended tranexamic acid is also available OTC for the management of menorrhagia[26]. Tranexamic acid products such as Evana Heavy Period Relief 500 mg tablets can be used in the treatment of menorrhagia in combination with Ultravana for any associated period pain.

Advising patients on Ultravana®

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

1 Dose[3]	• On the first day of dysmenorrhoea: take 2 x 250 mg tablets initially and then 1 x 250 mg tablet after 6–8 hours, if required • On days 2 and 3: take 1 x 250 mg tablet every 6–8 hours, if required
2 Diet[3]	• Take whole with water, with or after food. Ultravana is not to be broken or crushed
3 Duration[3]	• Maximum continuous use of 3 days per menstrual cycle

Self-care for dysmenorrhoea

In addition to recommending a suitable dysmenorrhoea treatment, such as Ultravana you can also offer advice on self-care measures that can also help ease the patient's pain

Heat

Such as a hot water bottle or heat patch, can also help to reduce pain[1]

TENS machines

Can also help to reduce pain[1]

Increase physical activity

There is some evidence that exercising for 45–60 minutes at a time at least three times a week can reduce period pain by around a quarter[13]

Relaxation exercises

Can help with the cramping pains of dysmenorrhoea[27]

Some patients may ask about dietary interventions and supplements that can help with dysmenorrhoea. In a Cochrane review there was some evidence that vitamin B1, fish oil, zinc sulphate, ginger, valerian, fenugreek and zataria may have potential benefit[27].

Useful sources of information

Patients can be signposted to useful sources of information for more advice on managing dysmenorrhoea.

Dysmenorrhoea

Pelvic Pain Support Network:
https://www.pelvicpain.org.uk

NHS. Period pain:
https://www.nhs.uk/conditions/period-pain/

Endometriosis

Endometriosis UK:
https://www.endometriosis-uk.org.

Pre-menstrual syndrome

National Association for Premenstrual Syndromes:
https://www.pms.org.uk.

Understanding *Dysmenorrhoea* in pharmacy practice

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

Case Study 1

Who is the patient?	What are the symptoms?	How long have the symptoms been present?	Action taken?	Medication being taken?
33-year-old, wanting a long-lasting pain reliever. They also buy multiple period products.	Lower abdominal pain, lower back pain, nausea and headaches.	For as long as they can remember having periods, they have had period pain.	Usually takes paracetamol when the pain is bad but is finding it ineffective this month.	No other medication being taken.

- The patient's symptoms suggest they have primary dysmenorrhoea
- Their usual treatment of paracetamol is a second-line recommendation in the NICE guidelines, which also does not recommend the use of opioids[1]
- Instead, NICE guidance recommends NSAIDs, such as naproxen or ibuprofen, as the first-line treatment choice for period pain[1]
- A supply of Ultravana can be made[3]
- From a self-care perspective advise them that exercise, heat, TENS machines and relaxation can be beneficial[1,13,27].

Case Study 2

Who is the patient?	What are the symptoms?	How long have the symptoms been present?	Action taken?	Medication being taken?
25-year old patient collecting their usual inhalers for mild asthma. They also buy some tampons and request a paracetamol + codeine analgesic.	Cramping lower abdominal pains, low back pain, headache and fatigue. Avoids exercise as they feel too tired.	They get period pain most months but some months worse than others so they want a 'strong' pain reliever.	Usually takes paracetamol but is finding it ineffective this month.	Steroid inhaler and occasional reliever inhaler.

- The patient's symptoms suggest they have primary dysmenorrhoea
- Their usual treatment of paracetamol is a second-line recommendation in the NICE guidelines, which also does not recommend the use of opioids[1]
- Instead, NICE guidance recommends NSAIDs, such as naproxen or ibuprofen, as the first-line treatment choice for period pain[1] but before recommending a switch from paracetamol it is important to ask about their asthma
- If they have experienced an asthmatic reaction after taking aspirin or an NSAID, then an NSAID, such as Ultravana is contraindicated and a supply cannot be made[3]
- If they haven't had a previous reaction to aspirin or other NSAIDs, then Ultravana can be supplied[24]
- From a self-care perspective advise them that exercise, heat, TENS machines and relaxation can be beneficial[1,13,27].

Case Study 3

Who is the patient?	What are the symptoms?	How long have the symptoms been present?	Action taken?	Medication being taken?
14-year old patient wanting a long-lasting pain reliever.	Lower abdominal pain, headache, bloating and diarrhoea.	They started getting periods about a year a go and has only started having pains once they became more regular over the past 6 months.	They have borrowed some analgesics from a friend but doesn't know what they were called.	No other medication being taken.

- The patient's symptoms suggest they have primary dysmenorrhoea
- While NICE guidance recommends NSAIDs, such as naproxen or ibuprofen, as the first-line treatment choice for period pain[1]. As Ultravana can only be recommended for those 15 years and over, a supply cannot be made[3]
- Ibuprofen can be recommended as an alternative NICE-recommended first-choice treatment[1]
- From a self-care perspective recommend exercise heat, such as a hot water bottle, and relaxation exercises[1,13,27].

Case Study 4

Who is the patient?	What are the symptoms?	How long have the symptoms been present?	Action taken?	Medication being taken?
48-year old patient wanting a 'good' pain reliever. Also requests an oral vaginal thrush treatment.	Pelvic pain. On questioning they also experience pain during intercourse, bleeding between periods and have a smelly discharge.	The pain and bleeding between periods has been for a few months. The discharge developed over the past couple of weeks.	Has treated the discharge with a topical thrush treatment but it was ineffective.	They get regular heartburn that is managed with a proton pump inhibitor.

- The patient's symptoms suggest they have secondary dysmenorrhoea[1]
- As such, an Ultravana supply cannot be made and they should be referred to their doctor as a matter of urgency. Analgesics and vaginal thrush treatment are inappropriate for OTC sale in this case.

Case Study 5

Who is the patient?	What are the symptoms?	How long have the symptoms been present?	Action taken?	Medication being taken?
37-year old patient seeking long-lasting pain relief.	Severe lower abdominal pain. Their periods have become heavier and they sometimes have spotting between periods.	Has developed over the past 2 months, but has never really had period pain before.	None, they have been trying to manage by changing their diet and increasing their vitamin and mineral intake.	They had an IUD inserted about 6 months ago.

- The patient's symptoms suggest they have secondary dysmenorrhoea caused by their IUD[1]
- They require GP referral for further investigation
- Ultravana cannot be supplied for the relief of secondary dysmenorrhoea, however, heat, such as a hot water bottle, may be of benefit in the interim[1].

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Essential Information

Ultravana® Period Pain Relief 250mg Gastro-resistant tablets (Naproxen) PL 20075/0619. **Indication:** Treatment of primary dysmenorrhoea in women aged 15-50 years. **Posology**: Day one: two tablets (500mg) to be taken, followed by one tablet (250mg) every 6-8 hours, if needed. Days 2 and 3: one tablet (250mg) to be taken every 6-8 hours. Maximum daily dose of 3 tablets (750mg), for a maximum of 3 days continuous use in any one cycle. **Contraindications:** hypersensitivity to the active substance or any of the excipients, patients with a history of, or active peptic ulcers and active gastrointestinal (GI) bleeding, history of GI bleeding or perforation related to previous NSAID therapy, aspirin or NSAID sensitivity, patients with severe heart, hepatic or renal failure, or those in the third trimester of pregnancy. **Precautions:** Not recommended in the elderly, in the first 6 months of pregnancy, when breast-feeding or in women attempting to conceive. Caution in patients with bronchial asthma or allergic disease, cardiac impairment, hypertension, impaired renal function, liver dysfunction, peripheral arterial or cerebrovascular disease, history of GI disease (e.g., ulcerative colitis, Crohn's disease), coagulation disorders, and those taking oral corticosteroids, anticoagulants, antiplatelet agents, SSRIs or other NSAIDs. Contains lactose, not for patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption. **Side effects:** Hypersensitivity reactions including non-specific allergic reactions and anaphylaxis, respiratory tract reactivity e.g., asthma, bronchospasm, dyspnoea, various skin reactions e.g., pruritus, urticaria, purpura, angioedema, exfoliative bullous dermatoses (including epidermal necrolysis, erythema multiforme, Stevens-Johnson Syndrome). GI ulceration or haemorrhage, peptic ulceration, or perforation, hyperkalaemia, cardiac and congestive heart failure, myocardial infarction, stroke, renal failure, jaundice, hepatitis, meningitis. **MA Holder:** Accord Healthcare Limited, Sage House, 319 Pinner Road, HA1 4HF, UK. **Classification:** P. **RRP:** 9 tablets £5.95. **Date:** January 2024. For full information see evanaperiods.com/hcp/ultravana/smpc.

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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