FEMINAX ULTRA 250MG GASTRO-RESISTANT TABLETS
PL 16028/0145

UKPAR

TABLE OF CONTENTS

Lay Summary Page 2
Scientific discussion Page 3
Steps taken for assessment Page 10
Steps taken after authorisation – summary Page 11
Summary of Product Characteristics Page 12
Product Information Leaflet Page 27
Labelling Page 29
LAY SUMMARY

The MHRA granted Galpharm Healthcare Limited a Marketing Authorisation (licence) for the medicinal product Feminax Ultra 250mg Gastro-Resistant Tablets on 24th February 2010. This product, to be available as a pharmacy medicine, contains naproxen and is used to treat period pain (also called menstrual pain or dysmenorrhoea).

Naproxen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce pain and inflammation. Other medicines in this group include ibuprofen and aspirin.

This application is a duplicate of a previously granted application for Naproxen 250mg Enteric-Coated Tablets (PL 00289/0699), for which a marketing authorisation was granted to Teva UK Limited on 12th September 2007.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Feminax Ultra 250mg Gastro-Resistant Tablets outweigh the risks, hence a Marketing Authorisation has been granted.
FEMINAX ULTRA 250MG GASTRO-RESISTANT TABLETS
PL 16028/0145

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ............................... Page 4
Pharmaceutical assessment ............... Page 5
Preclinical assessment ..................... Page 8
Clinical assessment ....................... Page 9
Overall conclusions and risk benefit assessment ............................... Page 10
INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Feminax Ultra 250mg Gastro-Resistant Tablets (PL 16028/0145) to Galpharm Healthcare Limited on 24th February 2010. The product is available as a pharmacy medicine (P) for the treatment of primary dysmenorrhea in women aged 15 to 50 years.

This product contains the active substance naproxen. Naproxen acts as a non-steroidal anti-inflammatory, reducing the levels of prostaglandins.

The application was submitted as a simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Naproxen 250mg Enteric-Coated Tablets (PL 00289/0699), for which a marketing authorisation was granted to Teva UK Limited on 12th September 2007.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 16028/0145
PROPRIETARY NAME: Feminax Ultra 250mg Gastro-Resistant Tablets
ACTIVE(S): Naproxen
COMPANY NAME: Galpharm Healthcare Limited
LEGAL STATUS: P

1. INTRODUCTION
This was a simple, piggy back application for Feminax Ultra 250mg Gastro-Resistant Tablets submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Galpharm Healthcare Limited, Hugh House, Upper Cliffe Road, Dodworth Business Park, Dodworth, Barnsley, South Yorkshire, S75 3SP, United Kingdom.

The application cross-refers to Naproxen 250mg Enteric-Coated Tablets (PL 00289/0699), for which a marketing authorisation was granted to Teva UK Limited on 12th September 2007. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed name of the product is Feminax Ultra 250mg Gastro-Resistant Tablets. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains naproxen, equivalent to 250mg. It is to be stored in blister strips in packs of 3, 6, 8 or 9 tablets.

The proposed shelf-life (36 months) and storage conditions (Do not store above 25°C. Store in the original package) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available as a pharmacy medicine (P).

2.4 Marketing authorisation holder/Contact Persons/Company
Galpharm Healthcare Limited, Hugh House, Upper Cliffe Road, Dodworth Business Park, Dodworth, Barnsley, South Yorkshire, S75 3SP, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.
2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
No materials of animal or human origin are included in the product. This is consistent with the cross reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application is acceptable. A Marketing Authorisation should be granted.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
This application is identical to the previously granted application for Naproxen 250mg Enteric-Coated Tablets (PL 00289/0699).

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with those for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with naproxen is considered to have demonstrated the therapeutic value of the compound. The risk:benefit is, therefore, considered to be positive.
## STEPS TAKEN FOR ASSESSMENT

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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation applications on 25/11/2009.</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the applications valid on 06/12/2009.</td>
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**FEMINAX ULTRA 250MG GASTRO-RESISTANT TABLETS**  
PL 16028/0145

**STEPS TAKEN AFTER ASSESSMENT**

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Feminax® Ultra 250mg Gastro-Resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 250 mg of Naproxen. For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM
Gastro-Resistant Tablet
White, round, biconvex enteric-coated tablets, overprinted in black 3N3.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Indicated for the treatment of primary dysmenorrhoea in women aged 15 to 50 years.

4.2 Posology and method of administration
For oral administration.
To be taken preferably with or after food swallowed whole with water.
Adolescents (post puberty) and adult females between the ages of 15 and 50:
On the first day 2 tablets (500 mg) should be taken initially and then one tablet (250 mg) after 6 to 8 hours if needed.
On the second and third day, if needed, one tablet (250mg) should be taken every 6 to 8 hours. Not more than 3 tablets to be taken per day. The maximum duration of continuous treatment in any one cycle (period) is 3 days.

4.3 Contraindications
Naproxen is contra-indicated in patients with a history of, or active peptic ulceration and active gastrointestinal bleeding.
Naproxen is contra-indicated in patients with a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
Naproxen is contra-indicated for patients with known hypersensitivity to naproxen, naproxen sodium formulations or any of the excipients.
Naproxen should not be given to patients in whom aspirin or other non-steroidal anti-inflammatory/analgesic drugs induce the syndrome of asthma, rhinitis or urticaria.
Naproxen should not be given to patients with severe heart failure.

4.4 Special warnings and precautions for use
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see warnings on GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects
Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.
Clinical trial and epidemiological data suggest that use of coxibs and some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Although data suggest that the use
of naproxen (1000mg daily) may be associated with a lower risk, some risk cannot be excluded. There are insufficient data regarding the effects of low dose naproxen 250mg – 750mg daily to draw firm conclusions on possible thrombotic risks.

Gastrointestinal effects
GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

Although naproxen is usually well tolerated, there have been reported incidences of gastro-intestinal bleeding. Therefore, patients with a history of gastro-intestinal disease should not take naproxen without being closely monitored by their doctor.

Patients with a history of GI toxicity should report any unusual abdominal symptoms. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin (see section 4.5).

If GI bleeding or ulceration occurs in patients receiving the product, the treatment should be withdrawn.

Serious gastro-intestinal adverse reactions may occur at any time in patients on therapy with non-steroidal anti-inflammatory drugs. The duration of therapy does not seem to change the risk of occurrence. Studies to date have not identified any subset of patients not at risk of developing peptic ulcer and bleeding. However, elderly and debilitated patients tolerate gastro-intestinal ulceration or bleeding less well than others. Most of the serious gastro-intestinal events associated with non-steroidal anti-inflammatory drugs occurred in this patient population.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn’s disease) as their condition may be exacerbated (see section 4.8).

The anti-inflammatory and antipyretic activities of Naproxen may reduce inflammation and fever, thereby diminishing their utility as diagnostic signs.

In patients with a history of bronchial asthma or allergic disease, administration of naproxen may elicit bronchospasm.

Naproxen decreases platelet aggregation and prolongs bleeding time.

The use of NSAIDs may result in a deterioration of renal function.

Patients with impaired renal function, or cardiac impairment should only use naproxen with great caution and under their doctor’s supervision who will monitor serum creatinine and/or creatinine clearance. When the baseline creatinine clearance is less than 20 ml/min naproxen is not recommended.

When renal blood flow is compromised, patients should have renal function assessed before and during naproxen therapy. A reduction in daily dosage should be considered to avoid the possibility of excessive accumulation of naproxen metabolites in these patients.

Patients with impaired liver function should only take naproxen under the supervision of their doctor. When liver function is impaired, the plasma concentration of unbound naproxen is increased. The significance of this is unknown but caution is advised when high doses are required.

Haematological
Patients who have coagulation disorders or patients who are receiving drug therapy that interferes with haemostasis should be carefully observed if naproxen-containing products are administered.

Patients at high risk of bleeding or those on full anti-coagulation therapy (e.g. dicoumarol derivatives) can be at increased risk of bleeding if given naproxen-containing products.
Anaphylactic (anaphylactoid) reactions
In susceptible individuals hypersensitivity reactions may occur. Anaphylactic (anaphylactoid) reactions may occur both in patients with and without a history of hypersensitivity or exposure to aspirin, other non-steroidal anti-inflammatory drugs or naproxen-containing products. They may also occur in individuals with a history of angioedema, bronchospastic reactivity (e.g. asthma), rhinitis and nasal polyps.

Anaphylactoid reactions, like anaphylaxis, may have a fatal outcome.

Serious skin reactions, some of them fatal, including Exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see section 4.8). The product should be discontinued at the first appearance of skin rash, mucosal lesion, or any other sign of hypersensitivity.

Steroids
Patients taking steroids should not take naproxen except under the supervision of their doctor. If steroid dosage is eliminated or reduced during therapy, the steroid dosage should be reduced slowly and the patients must be observed closely for any evidence of adverse effects, including adrenal insufficiency and exacerbation of symptoms of arthritis.

Ocular effects
Studies have not shown any changes in the eye attributable to naproxen administration. Rarely, adverse ocular disorders including papillitis, retrobulbar optic neuritis and papilledema, have been reported in users of NSAIDs including naproxen, although a cause-and-effect relationship cannot be established; accordingly, patients who develop visual disturbances during treatment with naproxen-containing products should have an ophthalmological examination.

Combination with other NSAIDs
The combination of naproxen-containing products and other NSAIDs including ibuprofen, cyclooxygenase-2 selective inhibitors or aspirin is not recommended, because of the cumulative risks of inducing serious NSAID-related adverse events.

This product should be taken, except on the advice of a doctor, by women who first experience pain more than a year after starting menstruation.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The label will include:

| Read the enclosed leaflet before taking this product.  
| Do not take if you: 
| - have or have ever had a stomach ulcer, perforation or bleeding 
| - are allergic to naproxen or any other ingredient of the product, aspirin, ibuprofen or other related painkillers 
| - are taking other NSAID painkillers, or aspirin 
| Speak to a pharmacist or your doctor before taking this product if 
| - you have asthma, liver, heart, kidney or bowel problems 
| - there is a chance you may be pregnant 
| If symptoms persist or worsen, consult your doctor. |

4.5 Interaction with other medicinal products and other forms of interaction
Naproxen should not be taken with other medication except on the advice of a doctor, pharmacist or nurse.

Concomitant administration of antacid, colestyramine or food may delay the absorption of naproxen but does not affect its extent.

Care should be taken in patients treated with any of the following drugs as interactions have been reported in some patients.
Anti-hypertensives: reduced anti-hypertensive effect.

Naproxen and other non-steroidal anti-inflammatory drugs may increase the risk of renal impairment associated with the use of ACE-inhibitors.

Diuretics: reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium: Decreased elimination of lithium.

Methotrexate: Decreased elimination of methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Other analgesics: Avoid concomitant use of two or more NSAIDs. See section 4.4 Special Warnings and Special Precautions for use.

Corticosteroids: Increased risk of GI ulceration or bleeding. See section 4.4 Special Warnings and Special Precautions for use.

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin. See section 4.4 Special Warnings and Special Precautions for use.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4)

Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Naproxen is highly bound to plasma proteins and if anti-coagulants, hydantoins or highly protein-bound sulphonamides are given simultaneously, overdosage of these drugs may result.

Co-administration of probenecid inhibits the renal tubule secretion of naproxen, so raising its plasma concentration and prolonging its half-life.

It is suggested that naproxen is withdrawn 48 hours before adrenal function tests as it may interfere with some tests for 17-ketogenic steroids. Naproxen may interfere with some assays of urinary 5-hydroxy-indoleacetic acid.

4.6 Pregnancy and lactation

Naproxen should not be used during pregnancy or lactation except on the advice of a doctor.

Whilst no teratogenic effects have been demonstrated in animal toxicology studies, the use of naproxen during pregnancy should if possible be avoided. Congenital abnormalities have been reported in association with naproxen administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (a closure of ductus arteriosus), use in late pregnancy should be avoided. In the limited studies so far available, naproxen appears in the breast milk in very low concentrations and is unlikely to adversely affect the breast-fed infant. However, the use of naproxen should be avoided in patients who are breast feeding.
4.7 Effects on ability to drive and use machines
Dizziness, drowsiness, vertigo, insomnia, depression or visual disturbances are possible undesirable effects after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects
Gastro-intestinal: the most commonly-observed adverse events are gastrointestinal in nature.

Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (See section 4.4). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis exacerbation of colitis and Crohn’s disease (See section 4.4 - Special warnings and precautions for use) have been reported following administration. Less frequently, gastritis has been observed.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis, erythema multiforme and Stevens-Johnson Syndrome).

Cardiovascular: Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of coxibs and some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Eosinophilic pneumonitis and aseptic meningitis have also been reported.

Other adverse events reported less commonly include:

Renal: Nephrotoxicity in various forms, including glomerular nephritis, interstitial nephritis, nephrotic syndrome, haematuria and renal failure.

Hepatic: Abnormal liver function, hepatitis and jaundice.

Neurological and special senses: Visual disturbances, optic neuritis, headaches, paraesthesia, depression, confusion, hallucinations, tinnitus, hearing impairment, vertigo, dizziness, convulsions, insomnia, inability to concentrate, cognitive dysfunction, malaise, fatigue and drowsiness.

Haematological: Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia, hyperkalaemia and haemolytic anaemia.

Dermatological: Photosensitivity, alopecia.

Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (very rare).

4.9 Overdose
Human experiences of overdosage with naproxen may result in drowsiness, heartburn, indigestion, nausea or vomiting. The stomach may be emptied by inducing emesis or aspiration and lavage. Activated charcoal may reduce the absorption of naproxen. (See section 5.2 Pharmacokinetic properties). Further treatment is symptomatic.

Haemodialysis does not decrease the plasma concentration of naproxen because of the high degree of protein binding. However, haemodialysis may still be appropriate for a patient with renal failure who has taken naproxen.

Correction of severe electrolyte abnormalities should be considered.
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Naproxen is a propionic acid derivative. It acts as an anti-inflammatory agent, analgesic and has anti-pyretic activity in man. By its action on cyclo-oxygenase it inhibits prostaglandin synthesis. However, the exact mechanism of its anti-inflammatory action is not known.

ATC Code: M01A E02 (anti-inflammatory and antirheumatic products, non-steroids, propionic acid derivatives).

5.2 Pharmacokinetic properties
Animal studies suggest that prompt administration of activated charcoal would reduce the absorption of naproxen.

Following oral administration, naproxen is fully absorbed from the gastro-intestinal tract. Depending on food intake, peak plasma concentrations are reached 2 to 4 hours after ingestion. More than 99% is bound to plasma proteins. The plasma half-life is between 12 and 15 hours. Excretion in urine accounts for approximately 95% of the dose. Naproxen crosses the placental barrier and is excreted in breast milk.

When naproxen is administered in the enteric-coated form, the peak plasma levels are delayed when compared with the standard tablets. However, the mean areas under the plasma concentration time curves, and hence bioavailability, are equivalent. The tablets do not disintegrate until they reach the small intestine, where dissolution is rapid and complete. This delay in absorption makes Naproxen EC of value for patients in whom gastric dissolution is undesirable.

5.3 Preclinical safety data
Preclinical information has not been included because the safety profile of naproxen has been established after many years of clinical use. Please refer to section 4.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Tablet contains:
Lactose Monohydrate,
Maize Starch,
Polyvidone,
Sodium Starch Glycollate (type A),
Magnesium Stearate (E572).

Coating contains:
Lactose Monohydrate:
Hydroxypropyl methylcellulose (E464),
Colloidal silicon dioxide,
Polyethylene glycol,
Polyvinyl acetate phthalate,
Purified stearic acid (E570),
Purified talc (E553(b)),
Sodium alginate (E401),
Sodium bicarbonate (E500),
Triethyl citrate,
Titanium Dioxide (E171).

Printing Ink:
Shellac (E904),
Soya lecithin (E322),
Antifoam agent,
Black iron oxide (E172).

6.2 Incompatibilities
Not applicable.
6.3 Shelf life
36 months.

6.4 Special precautions for storage
Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container
Blister strips in packs of 3, 6, 8 or 9 tablets.

6.6 Special precautions for disposal
Not applicable

7 MARKETING AUTHORISATION HOLDER
Galpharm Healthcare Limited
Hugh House
Upper Cliffe Road
Dodworth Business Park
Dodworth
Barnsley
South Yorkshire
S75 3SP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 16028/0145

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
24/02/2010

10 DATE OF REVISION OF THE TEXT
24/02/2010
PATIENT INFORMATION LEAFLET

Feminax® Ultra 250 mg Gastro-resistant tablets

Naproxen (250 mg)

This leaflet contains important information about Feminax® Ultra 250 mg Gastro-resistant tablets (tolerance to see Feminax® Ultra from now on). Please read it carefully before you take these tablets.

WHAT IS FEMINAX® ULTRA FOR?

These tablets contain 250 mg of naproxen. This medicine is used to treat period pain (also called menstrual pain or dysmenorrhea)• Naproxen belongs to a group of medicines called Non-steroidal Anti-Inflammatory Drugs (also called NSAIDs).• Other medicines in this group include布洛芬和阿司匹林.

WHO SHOULD TAKE FEMINAX® ULTRA?

Only take this medicine if you are between 15 and 50 years old. Ask your doctor, pharmacist or nurse if you need more information.

THINGS TO KNOW BEFORE TAKING FEMINAX® ULTRA

Do not take this medicine if you have, or have ever had a stomach ulcers
• or other serious stomach problems
• This includes any stomach pain that did not go away and any bleeding in the stomach
• If you have ever had anything like this then you should not take this tablets.

Do not take this medicine if you have severe heart failure
• Do not take this medicine if you are already taking aspirin, low dose aspirin or any other non-steroidal anti-inflammatory drug (NSAID) like diclofenac. This includes cyclo-oxygenase-2 selective inhibitors (COX2) like celecoxib.

Do not take this medicine if you have had an allergic reaction to:
• Naproxen, aspirin, ibuprofen, or another non-steroidal anti-inflammatory drug (NSAID).
• Any other medicine in these tablets (see the list in the What’s in these tablets section, at the end of this leaflet).
• Allergic reactions can include wheezing, itchy runny nose, rash or swelling of the skin.

Do not take this medicine unless your doctor says you can, if:
• You are breast feeding, or there is a chance you may be pregnant.
• You started to have period pain more than a year after your first period.

Do not take this medicine unless your doctor says you can, if you have these illnesses:
• Head problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker).
• Kidney or liver problems.
• A blood clotting problem.
• Asthma or any allergic illness which makes it hard to breathe.
• Stomach ulcers or any ulcers or stomach acid or Crohn’s disease.

Medicines containing naproxen may be associated with a small increased risk of heart attack, heart failure, stroke or death. The risk is higher for people with high blood pressure, diabetes or high cholesterol or are a smoker.

Important information about some of the ingredients of this medicine
• This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines: These tablets may make you dizzy, sleepy or cause vertigo, loss of concentration, difficulty sleeping or visual problems. Do not drive or use machines if this happens to you.

Talk to your doctor or pharmacist first, if you are taking any of these other medicines:
• Codeine - a medicine used after organ transplants
• Ibuprofen - a medicine for pain
• Steroids also called corticosteroids - like prednisolone
• Cyclo-oxygenase-1 inhibitors (COX1) or non-steroidal anti-inflammatory drug (NSAID) like coxib.
• Lithium - a medicine for depression
• Methotrexate - a medicine for cancer and other illnesses
• Piroxicam - a medicine for pain
• Warfarin - a medicine for blood clotting
• Water tablets (diuretics)
• Medicines for high blood pressure (anti-hypertensives)
• Medicines for your heart (digoxin or clopidogrel)
• Medicines to stop blood clots (anticoagulants such as warfarin or heparin)
• Phenylbutazine - a medicine for pain
• Mefenamic acid - a medicine for pain
• Low dose aspirin - a medicine for “thinning the blood”
• Anti-depressants of the selective serotonin reuptake inhibitor (SSRI) type like fluoxetine.

HOW TO TAKE FEMINAX® ULTRA

First day:
• When the pain starts, take two tablets
• Then after 6 to 8 hours, take one tablet that day if you need it.

Second day:
• Take one tablet every 6 to 6 hours (if needed)

Third day:
• Take one tablet every 6 to 6 hours (if needed)

Do not take more than 3 tablets each day.
Always take the lowest effective dose for you. Do not take more than the recommended dose of up to three tablets in a day. Do not take for longer than three days in any one month (menstrual cycle).

MHRA PAR – Feminax Ultra 250mg Gastro-Resistant Tablets
Taking the tablets:
- Swallow the tablets whole with a drink of water. Do not chew or crush them.
- Take the tablets with or after food.
- Only take the tablets for as long as you need them for the period pain.
- You may not need to take the tablets all the time for all 3 days. If you still have pain after 3 days of treatment, talk to your doctor to see if you need to take them for longer.
- If you have to stop taking the tablets, do so as soon as the pain is under control.

SIDE EFFECTS THAT MIGHT HAPPEN WHILE TAKING FEMINAX ULTRA

Like all medicines, these tablets can cause side effects, although not everyone gets them. If you have any side effect, you should seek advice from your doctor, pharmacist or other healthcare professional. In addition, you can help to make sure that medicines remain as safe as possible by recording any unwanted side effects on the internet at www.yellowcard.gov.uk. Alternatively, you can call Raacophone 0800 100 3355 (available between 10 am – 2 pm Monday to Friday) or fill in a paper form available from your local pharmacy.

If any of the following happen to you, stop taking the tablets and tell a doctor, pharmacist or nurse immediately:
- Skin rash, including swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing).
- Jaundice (yellowing of the skin or whites of the eyes, and/or pale colored stools and dark urine).
- Fits (convulsions), altered vision, pins and needles or numbness, confusion, hallucinations, dizziness and vomiting, hearing problems.

If you have any of the following while taking this medicine, stop taking it and tell your doctor:
- Raising of the blood vessels and a build-up of fluid which may cause swelling ankles.
- Kidney or liver problems: these will show up in blood or urine tests.
- Nervous system: headaches, depression, insomnia, ringing in the ears, weakness, dizziness, inability to concentrate, mental slowing, a general feeling of being unwell or fogginess or a dislike of light.
- Blood problems: these may cause unusual tiredness or weakness, unusual bleeding or unexplained bruising, fever or chills, sore throat, ulcers in your mouth or throat.
- Sensitivity of the skin to light.

Other side effects:
- High blood pressure and heart failure may be reported with NSAI use.
- Medicines which contain NSAI are known to may cause an effect known as conjunctivitis (mucous membranes of the eyes and nose). In some cases, this effect may be life-threatening. Any patient taking this medicine should be monitored closely.
- Allergic reactions like asthma, wheezing or difficulty breathing. This may be severe.
- Blood in the urine, more or less urine than normal or cloudy urine.
- Pain around the kidneys (lower side of your back).
- Severe blisters and burning of the skin, nose and mouth (Stevens-Johnson syndrome).
- Skin problems including rashes, itching, rashes or rashes of a bruiselike rash. There may also be thinning and scaling of the skin.

How to store FEMINAX Ultra:
- Keep these tablets in their original packaging and do not store above 25°C.
- Store your medicine in a safe place, out of the reach of children.
- This medicine is for you only. Do not give it to anyone else.
- Return all unused medicines to your pharmacist for safe disposal.

WHAT IS IN THESE TABLETS?

Each white round coated tablet contains 250 mg of naproxen, which is the active medicine. The tablets come in a box of 9 tablets. The tablet is gastro-resistant (also known as enteric coated). This means that it is covered with a coating which stops the tablet dissolving in the stomach, so that the naproxen is released further down in your gut.

The tablets also have inactive ingredients: food starch, polysorbate, sodium starch glycolate and magnesium stearate. Also, the coating contains colloidal silicon dioxide, polyethylene glycol, titanium dioxide, magnesium stearate, sodium, calcium, sorbitol, carbon black, and dicalcium phosphate.

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REMEMBER

This leaflet does not contain all the information about these tablets. Please ask your doctor, nurse or pharmacist if you have any questions.

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