

## Patient Information Leaflet

# Feminax<sup>®</sup> Express



## 342mg Tablets Ibuprofen Lysine

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

### IN THIS LEAFLET

1. What is Feminax<sup>®</sup> Express for?
2. Before you take Feminax<sup>®</sup> Express
3. How to take Feminax<sup>®</sup> Express
4. Possible side effects
5. Storing Feminax<sup>®</sup> Express
6. Further information

### 1. WHAT IS FEMINAX<sup>®</sup> EXPRESS FOR

This medicine contains ibuprofen lysine which is the lysine salt of ibuprofen. Ibuprofen is one of a group of non-steroidal anti-inflammatory drugs (known as NSAIDs) which work to reduce pain, fever and swelling.

This medicine is used to relieve:

- rheumatic and muscular pain, backache
- neuralgia (nerve pain)
- headache, migraine
- dental pain, period pain
- fever (high temperature)
- the symptoms of colds and flu

### 2. BEFORE YOU TAKE FEMINAX<sup>®</sup> EXPRESS

**Do not take this medicine if you:**

- have or have had a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen, to any of the ingredients (listed in section 6), or to aspirin or other painkillers (an allergic reaction may be recognised as shortness of breath, runny nose, skin rash or itching)
- have kidney or heart failure or severe liver failure
- are taking aspirin with a daily dose above 75mg
- are in the last 3 months of pregnancy

**Talk to your doctor or pharmacist before taking ibuprofen tablets if you:**

- are elderly because you may be at more risk of having serious side effects, particularly stomach problems
- have or have suffered from asthma, diabetes, high cholesterol or have allergies
- have liver or kidney problems
- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body.
- have, have previously had, or are at risk of heart

problems, high blood pressure or stroke. Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (10 days). If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

### If you are taking other medicines

You must not take these tablets if you are taking certain other medicines - see section 2 'Do not take this medicine if you'.

Talk to your pharmacist or doctor before you take the tablets if you are taking any regular medication, especially:

- aspirin at low dose as an anti-platelet agent medicine (i.e. 75mg or below daily), as taking ibuprofen may reduce the effect of the aspirin or cause stomach problems
- other medicines for thinning the blood (anti-coagulants) e.g. warfarin
- anti-platelet agents e.g. ticlopidine
- two or more NSAID painkillers, including cyclooxygenase-2 selective inhibitors
- medicines for high blood pressure (ACE-inhibitors such as captopril, beta-blockers and angiotensin II antagonists) and water tablets (diuretics)
- antidepressants called selective-serotonin reuptake inhibitors (SSRIs) e.g. fluoxetine
- corticosteroids (for skin problems and allergies e.g. cortisol)
- methotrexate (a medicine for cancer)
- cardiac glycosides (medicines used to treat heart failure e.g. digoxin)
- ciclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
- mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
- lithium (for depression or mental problems)
- zidovudine (a medicine to treat viruses)
- quinolone antibiotics (medicines used to treat bacterial infections e.g. ciprofloxacin).

### Pregnancy and Breastfeeding

Do not take this medicine if you are in the last 3 months of pregnancy. Talk to your doctor before taking ibuprofen tablets if you are in the first 6 months of pregnancy or are breastfeeding. These tablets belong to a group of medicines, which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that the tablets, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

### 3. HOW TO TAKE FEMINAX<sup>®</sup> EXPRESS

Age	Dose and how often to take
Adults, the elderly and children over 12 years	Initial dose 1 or 2 tablets to be taken with water, then if necessary 1 or 2 tablets every 4 hours. Do not take more often than every 4 hours. Do not take more than 6 tablets in any 24 hour period.

### Do not give to children under 12 years

The tablets are intended for short-term use only. Use them for the shortest time needed to relieve symptoms. Always use the lowest dose that relieves your symptoms. Do not take these tablets for longer than 10 days unless your doctor tells you to.

Talk to a doctor or pharmacist if you do not get better or get worse, or if new symptoms occur.

### If you take too many tablets:

Talk to a doctor straight away, or go to your nearest hospital casualty department. Take the carton and this leaflet with you.

### 4. POSSIBLE SIDE EFFECTS

Most people take these tablets without any problems, but they can have side effects, like all medicines.

To reduce the chance of side effects, especially if you are elderly, use the lowest effective dose for the shortest possible time.

**STOP TAKING the tablets and contact your doctor immediately if you develop any of the following symptoms at any time while taking your medicine:**

### Allergic reactions:

The following reactions may mean you are having an allergic reaction to this medicine:

- asthma, worsening of asthma, unexplained wheezing or shortness of breath
- swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing)
- rapid heart rate, low blood pressure, collapse
- also, there may be skin reaction (including hives, rash and itching) – very rarely these can be severe with blistering and peeling skin

### Stomach and bowel problems including:

- stomach discomfort or pain, nausea, indigestion or heartburn, stomach ulcers or perforation, mouth ulcers
- stomach bleeding which can result in vomit with blood or dark particles (like coffee grounds), black tarry stools or blood passed in your stools
- worsening of bowel problems (ulcerative colitis or Crohn's disease)

### Blood disorders which can cause:

- unexplained or unusual bruising or bleeding
- sore throat or mouth ulcers

- fever (high temperature)
- extreme paleness or weakness and exhaustion

### Heart and circulation effects:

Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack (myocardial infarction), high blood pressure, heart failure, swelling due to fluid build-up (oedema) or stroke.

**Other side effects** that may occur include those listed below. If you experience any of these symptoms, or have any other unusual symptoms or concerns with your medicine, stop taking the tablets and see your doctor.

**Other stomach and intestine effects** including diarrhoea, flatulence, constipation and vomiting.

**Liver problems** that might be indicated by yellowing of the skin and eyes (jaundice) and/or pale coloured stools and dark urine.

**Kidney problems** that might be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs) – very rarely kidney failure.

**Nervous system problems** including headache and aseptic meningitis (which can have symptoms such as severe headache, stiff neck, disorientation, fever and eye sensitivity to light in those with existing auto-immune disorders such as lupus).

### 5. STORING FEMINAX<sup>®</sup> EXPRESS

Do not use after the expiry date shown on the pack. Store in the original container.

**Keep all medicines out of the reach and sight of children.**

### 6. FURTHER INFORMATION

**What is in this medicine:**

**The active ingredient is:** Ibuprofen 200 mg (as ibuprofen lysine) per coated tablet.

**The other ingredients are:** Crospovidone, copovidone, microcrystalline cellulose, magnesium stearate, Opadry II White (contains polyvinyl alcohol, titanium dioxide E171, macrogol and talc).

**What this medicine looks like and contents of the pack:** Each tablet is a film-coated white tablet, embossed with 'IBL' on one side.

This pack contains 8 or 12 or 16 tablets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer:

Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, United Kingdom.

### Distributed by:

Bayer plc, Consumer Care Division, Newbury, Berkshire, RG 14 1JA

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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



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