

FLARIN®

200 mg SOFT CAPSULES IBUPROFEN

PFLA/PIU/021

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this product.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Flarin 200 mg Soft Capsules are and what they are used for
2. What you need to know before you take Flarin 200 mg Soft Capsules
3. How to take Flarin 200 mg Soft Capsules
4. Possible side effects
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6. Contents of the pack and other information.

1 WHAT FLARIN 200 mg SOFT CAPSULES ARE AND WHAT THEY ARE USED FOR

This medicine contains ibuprofen, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

Your capsules are used for the relief from rheumatic or muscular pain, also for the relief of pain of non-serious arthritic conditions (caused by swelling, stiffness and inflammation of joints), joint pain, back pain, neuralgia (sharp pain along nerves), migraine, headache, dental pain, period pain, feverishness, cold and flu symptoms.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLARIN 200 mg SOFT CAPSULES

Do not take these capsules if you:

- are allergic to ibuprofen or any of the other ingredients of this product, aspirin or other related painkillers (see end of section 2 and section 6)
- have had a worsening of asthma, allergic rash or itchy, runny nose when taking similar medicines
- have ever had a stomach ulcer, perforation or bleeding
- ever had stomach bleeding or a perforation due to NSAIDs
- are already taking other drugs that belong to the NSAIDs group
- are taking aspirin at doses of above 75 mg daily
- are in the last 3 months of pregnancy
- suffer from severe heart, liver or kidney disease
- are under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- have an infection - please see heading "Infections" below
- are elderly, as you may be more likely to suffer from side effects
- have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
- are allergic to any other painkiller
- suffer from systemic lupus erythematosus (a chronic rheumatic disease)
- suffer from an allergy
- suffer from inflammation of the intestines (ulcerative colitis, Crohn's disease)
- are on low-dose aspirin (up to 75 mg daily)
- are a smoker
- are in the first 6 months of pregnancy
- are 12-18 years old and have not been drinking fluids or have lost fluids due to continuous vomiting or diarrhoea, as there is a risk of kidney damage.

If symptoms persist or worsen, or if new symptoms occur, consult your doctor.

Infections: Flarin 200mg Soft Capsules may hide signs of infections such as fever and pain. It is therefore possible that Flarin 200mg Soft Capsules may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses.

Do not exceed the recommended dose or duration of treatment.

If you are taking Flarin 200mg Soft Capsules for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Flarin 200 mg Soft Capsules and contact immediately your doctor or medical emergencies if you notice any of these signs.

You should discuss your treatment with your doctor or pharmacist before taking Flarin 200 mg Soft Capsules if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA")
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Skin reactions: Serious skin reactions have been reported in association with Flarin 200 mg Soft Capsules treatment. You should stop taking Flarin 200 mg Soft Capsules and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Flarin 200 mg Soft Capsules and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Flarin 200 mg Soft Capsules

Talk to your doctor or pharmacist if you have been taking, have recently taken or might take any other medicines. Flarin 200 mg Soft Capsules may affect or be affected by some other medicines. For example:

- any other painkillers (or other NSAIDs)
- corticosteroids (anti-inflammatory) which can increase the risk of side effects in the stomach including bleeding
- serotonin reuptake inhibitors and lithium (for treatment of depression – bipolar disease and mania)
- cardiac glycosides (treatment of heart failure and cardiac arrhythmia)
- methotrexate (anti-cancer and psoriasis)
- zidovudine (HIV/AIDS infection)
- ciclosporin (prevent rejection after organ transplant)
- mifepristone (emergency contraceptive). Do not take this medicine for 8-12 days after mifepristone administration as it can reduce its effect
- tacrolimus (prevent rejection after organ transplant, treatment of skin diseases)
- quinolone (antibiotics)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines to help you pass water (diuretics).

Some other medicines may also affect or be affected by the treatment of Flarin 200 mg Soft Capsules. You should therefore always seek the advice of your doctor or pharmacist before you use Flarin 200 mg Soft Capsules with other medicines.

Pregnancy and breast-feeding

Do not take Flarin 200 mg Soft Capsules if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Flarin 200 mg Soft Capsules during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Flarin 200 mg Soft Capsules can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Ask your doctor or pharmacist for advice before taking any medicine if you are breast-feeding.

Female fertility

Flarin 200 mg Soft Capsules belong to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking this medicine. It is unlikely that if you only take Flarin 200 mg Soft Capsules occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

Driving and using machines

Flarin 200 mg Soft Capsules are unlikely to cause any effect on your ability to drive or use machines.

Important information about some of the ingredients of Flarin 200 mg Soft Capsules.

- Contains sorbitol (E420). Sorbitol is a source of fructose. If you have been told that you have an intolerance to some sugars or you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before taking this medicine
- May contain trace amounts of soya lecithin (E322). If you are allergic to peanut or soya, do not use this medicinal product.

3 HOW TO TAKE FLARIN 200 mg SOFT CAPSULES

This medicine is for oral administration and short-term use only.

Swallow the capsules whole with water. Do not chew.

Adults, the elderly and children over 12 years:

Take one or two capsules (200 mg – 400 mg), up to three times a day as required.

Leave at least 4 hours between doses and **do not** take more than 1200 mg (6 capsules) in any 24 hour period.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If you are over 18 years of age, **do not** take this medicine for longer than 10 days unless your doctor tells you to.

If you are aged between 12 and 18 years and this medicinal product is required for more than 3 days, or if symptoms worsen you should contact your doctor.

If symptoms persist or worsen consult your doctor, who may instruct you to continue taking the medicine.

Not suitable for children under 12 years.

If you take more Flarin 200 mg Soft Capsules than you should:

If you have taken more Flarin 200 mg Soft Capsules than you should, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take Flarin 200 mg Soft Capsules:

Do not take a double dose to make up for a forgotten dose.

If you have any question on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

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

If you experience any of the following side effects, or anything unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

If you suffer from any of the following, at any time, during your treatment STOP TAKING the medicine and get medical help straight away:

- pass blood in your faeces (stools/ motions)
- pass black tarry stools or motions
- vomit any blood or dark particles that look like coffee grounds
- severe hypersensitivity reactions – signs could include swelling of the face, tongue and throat, causing difficulty in swallowing or breathing; breathing problems e.g. unexplained wheezing, shortness of breath, worsening of asthma, accelerated heart rate, low blood pressure, severe shock
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- fluid retention e.g. swollen ankles (this may be a sign of kidney problems)
- yellowing of the eyes and/or skin (jaundice). This may be a sign of liver problems.

STOP taking the medicine and tell your doctor if you experience:

- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach problems
- problems in blood cell production: the first signs are tiredness and lethargy (lack of energy), shortness of breath, pale skin, fever, sore throat, mouth ulcers, flu-like symptoms, unexplained bleeding and bruising
- liver, kidney problems or difficulty urinating.

Flarin 200 mg Soft Capsules, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Uncommon: may affect up to 1 in 100 people

- hypersensitivity reactions such as urticaria (hives) and pruritus (itchy skin)
- abdominal pain, nausea (feeling sick) and dyspepsia (indigestion)
- headache
- various skin rashes.

Rare: may affect up to 1 in 1,000 people

- diarrhoea, flatulence (wind), constipation and vomiting.

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

- peptic ulcer, perforation or gastrointestinal haemorrhage, melaena (black tarry stools), vomit of blood or dark particles, ulcerative stomatitis (inflammation of the mouth), gastritis (inflammation of the stomach lining), worsening of existing bowel disease (ulcerative colitis or Crohn's disease)
- meningitis symptoms such as fever and chills, severe headache, nausea and vomiting and stiff neck (in patients with inflammatory disease of connective tissue in the skin or joints [systemic lupus erythematosus]).

Not known: frequency cannot be estimated from the available data

- cardiac failure (heart problem), hypertension (high blood pressure), oedema (fluid retention)
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- a red scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Flarin 200 mg Soft Capsules if you develop these symptoms and seek medical attention immediately. See also section 2
- skin becomes sensitive to light.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Medicines such as Flarin 200 mg Soft Capsules may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Reporting of side effects

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

5 HOW TO STORE FLARIN 200 mg SOFT CAPSULES

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. The expiry date refers to the last day of that month.

Keep the capsules in the original pack. Do not store above 25°C.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Flarin 200 mg Soft Capsules contain:

The **active** ingredient is: ibuprofen 200 mg. The **other** ingredients are: Hard fat, glycerol monolinoleate, macrogol 400, gelatin, sorbitol (E420), purified water, brilliant blue (E133) and carmine (E120). Hard fat and glycerol monolinoleate are lipids.

Ink ingredients: Titanium dioxide (E171), propylene glycol, polyvinyl acetate phthalate, macrogol 400.

Also may contain trace amounts of soya lecithin (E322) and medium chain triglycerides.

(see **also end of Section 2** "Important information about some of the ingredients of "Flarin 200 mg Soft Capsules").

What Flarin 200 mg Soft Capsules look like and contents of the pack

Each Flarin 200 mg Soft Capsule is an oval red and blue capsule printed in white with 'Flarin'.

This product is available in packs of 4, 10, 12, 16, 30, 48, 54 and 60 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Infirst Limited
20 Little Britain
London
EC1A 7DH

Manufacturer

Wasdell Packaging Ltd
Units 1, 2, 3, 5, 6, 7 & 8
Euroway Industrial Estate,
Swindon, SN5 8YW

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Pharma Laetus	XX
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