

FLARIN®

200 mg SOFT CAPSULES IBUPROFEN

PFLA/PLU/015

FRONT TO REAR

28 mm

29 mm

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FRONT TO REAR

29 mm

FRONT TO REAR

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
5. How to store Flarin 200 mg Soft Capsules
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 (or have had) two or more episodes of 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, 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.

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. See section 4.

Very rare reports of potentially life threatening skin rashes (Stevens Johnson Syndrome, toxic epidermal necrolysis) have been reported with the use of ibuprofen. Patients are at a higher risk of such reactions during the first month of therapy. **STOP TAKING** Flarin and seek medical assistance from your doctor or pharmacist if you notice a skin rash, lesions or any other signs of allergic reaction (see 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

Ask your doctor or pharmacist before taking this medicine if you are in the first 6 months of pregnancy. **DO NOT TAKE** the capsules if you are in the last 3 months of pregnancy. 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. If you have an intolerance to some sugars, contact your doctor before taking this product.
- Brilliant blue (E133) and Allura red (E129) may cause allergic reactions.

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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, Flarin 200 mg Soft Capsules 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.
- severe forms of skin reactions including rash, itching, hives, redness, blistering and peeling of the skin (Stevens Johnson syndrome).

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.

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:

- 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.
- 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]).
- Kidney failure, liver problems.

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, purified water, Brilliant blue (E133) and Allura red (E129). Hard fat and glycerol monolinoleate are lipids.

Ink ingredients: Titanium dioxide, isopropyl alcohol, propylene glycol, hypromellose.

(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
Central Point, 45 Beech Street,
London EC2Y 8AD

Manufacturer:

Wasdell Packaging Ltd.
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If you have any queries or comments about your medicine or any other infirst Limited products, ring our UK customer line 0808 281 0143.