

PRODUCT MONOGRAPH

FLOCTAFENINE

Floctafenine Tablets

200 mg and 400 mg

THERAPEUTIC CLASSIFICATION

Anti-inflammatory, Analgesic

INFORMATION FOR THE PATIENT

FLOCTAFENINE, which has been prescribed to you by your doctor, is one of a large group of non-steroidal anti-inflammatory drugs (also called NSAIDs) and is used to relieve mild to moderate acute pain in conditions such as muscle or joint strains or damage, or after a tooth extraction. FLOCTAFENINE helps to relieve pain and swelling by reducing the production of certain substances (prostaglandins) and by helping to control inflammation. NSAIDS promote suppression of the inflammation and the tissue damaging effects resulting from inflammation. This medicine will help you only as long as you continue to take it.

You should take FLOCTAFENINE only as directed by your doctor. Do not take more of it, do not take it more often and do not take it for a longer period of time than your doctor or dentist has ordered. Taking too much of any of these medicines may increase the chance of unwanted effects, especially if you are an elderly patient.

Be sure to take FLOCTAFENINE regularly as prescribed. During treatment, your doctor may decide to adjust the dosage according to your response to the medication.

STOMACH UPSET IS ONE OF THE COMMON PROBLEMS WITH NSAIDs:

To lessen stomach upset, take this medicine immediately after a meal or with food, with a glass of water. Also, you should remain standing or sitting upright (i.e. do not lie down) for about 15-30 minutes after taking the medicine. This helps to prevent irritation that may lead to trouble swallowing. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor.

Do not take ASA (acetylsalicylic acid), ASA-containing compounds or other drugs used to relieve symptoms of arthritis while taking FLOCTAFENINE unless directed to do so by your physician.

Always remember: the risks of taking this medication must be weighed against the benefits it will have. Before taking this medication, tell your doctor and pharmacists if you:

- or a family member are allergic to or have had a reaction to FLOCTAFENINE or other anti-inflammatory drugs (such as acetylsalicylic acid (ASA), diclofenac, diflunisal, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, mefenamic acid, piroxicam, tiaprofenic acid, tolmetin, nabumetone or tenoxicam) manifesting itself by increased sinusitis, hives, the initiating or worsening of asthma or anaphylaxis (sudden collapse);
- or a family member has had asthma, nasal polyps, chronic sinusitis or chronic urticaria (hives);
- have a history of stomach upset, peptic ulcer or any other active inflammatory disease of the gastrointestinal tract, liver or kidney diseases;
- have blood or urine abnormalities;

- have high blood pressure;
- have diabetes;
- are on any special diet, such as a low-sodium or low-sugar diet.
- are pregnant or intend to become pregnant while taking this medication;
- are breast feeding or intend to breast feed while taking this medication;
- are taking any other medication (either prescription or non-prescription) such as other NSAIDs, high blood pressure medication, blood thinners, corticosteroids, methotrexate, cyclosporin, lithium, phenytoin;
- have any other medical problem(s) such as alcohol abuse, bleeding problems, etc.

FLOCTAFENINE should not be used by children, except as recommended by a doctor.

Long-term use of FLOCTAFENINE is not recommended.

WHILE TAKING THIS MEDICATION:

- tell any other doctor, dentist or pharmacist that you consult or see, that you are taking this medication;
- some NSAIDs may cause drowsiness or fatigue in some people taking them. Be cautious about driving or participating in activities that require alertness if you are drowsy, dizzy or lightheaded after taking this medication;
- check with your doctor if you are not getting any relief or if any problems develop;

- report any untoward reactions to your doctor. This is very important as it will aid in the early detection and prevention of potential complications.
- stomach problems may be more likely to occur if you drink alcoholic beverages. Therefore, do not drink alcoholic beverages while taking this medication;
- check with your doctor immediately if you experience unexpected weakness while taking this medication, or if you vomit any blood or have dark or bloody stools;
- some people may become more sensitive to sunlight than they are normally. Exposure to sunlight or sunlamps, even for brief periods of time, may cause sunburn, blisters on the skin, skin rash, redness, itching or discoloration; or vision changes. If you have a reaction from the sun, check with your doctor;
- check with your doctor immediately if chills, fever, muscle aches or pains, or other flu-like symptoms occur, especially if they occur shortly before, or together with, a skin rash. Very rarely, these effects may be the first signs of a serious reaction to this medication;
- YOUR REGULAR MEDICAL CHECKUPS ARE ESSENTIAL.

SIDE EFFECTS OF THIS MEDICATION

Along with its beneficial effects, FLOCTAFENINE like other NSAID drugs, may cause some undesirable reactions.

Elderly, frail or debilitated patients often seem to experience more frequent or more severe side effects.

Although not all of these side effects are common, when they do occur they may require medical attention.

CHECK WITH YOUR DOCTOR IMMEDIATELY IF ANY OF THE FOLLOWING ARE NOTED:

- bloody or black tarry stools;
- rapid heartbeat;
- shortness of breath, wheezing, any trouble in breathing, or tightness in the chest;
- skin rash, hives or swelling, itching;
- abnormalities of taste, dry mouth;
- vomiting or persistent indigestion, nausea, stomach pain, stomach cramps, gas, constipation or diarrhea;
- yellow discoloration of the skin or eyes;
- any change in the amount of or colour of your urine (dark red or brown);
- any pain or difficulty experienced while urinating, and/or strong smelling urine;
- headache;
- insomnia;
- swelling of the feet or lower legs;
- malaise, fatigue, drowsiness, loss of appetite;

- blurred vision or any visual disturbance;
- mental confusion, depression, dizziness, lightheadedness;
- nervousness, irritability;
- hearing problems (ringing in your ears);
- abnormal liver function.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

DOSING

The usual adult dose of FLOCTAFENINE is one 200 or 400 mg tablet every 6 to 8 hours as required. You should not take more than 1200 mg in a day unless directed by your doctor or dentist. The tablets should be taken after a meal or food, with a glass of water.

STORAGE

FLOCTAFENINE tablets should be stored at room temperature (15 to 30°C) and protected from light.

FLOCTAFENINE IS NOT RECOMMENDED FOR USE IN CHILDREN SINCE SAFETY AND EFFECTIVENESS HAVE NOT BEEN ESTABLISHED.

DO NOT KEEP OUTDATED MEDICINE OR MEDICINE NO LONGER NEEDED.

KEEP OUT OF THE REACH OF CHILDREN.

THIS MEDICATION HAS BEEN PRESCRIBED FOR YOUR MEDICAL PROBLEM. DO NOT
GIVE IT TO ANYONE ELSE.

IF YOU REQUIRE MORE INFORMATION ON THIS DRUG, CONSULT YOUR DOCTOR OR
PHARMACIST.