

Profinal XP

Fast and effective relief from pain Film-coated Caplets

Composition

Each film-coated caplet contains:

Active ingredients:	Ibuprofen	400 mg
	Caffeine	65 mg

Excipients: Starch, povidone, colloidal silicone dioxide, sodium starch glycolate, glyceryl behenate, microcrystalline cellulose, hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide, and talc.

Properties

Profinal XP provides "extra" pain relieving property by virtue of its components, which combat pain symptoms in different ways. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) having marked anti-inflammatory, antirheumatic, analgesic, and antipyretic properties. It is postulated to act by inhibiting prostaglandins biosynthesis which are known to have a major role in inducing inflammation, pain, and fever. Caffeine potentiates the effect of ibuprofen and expedites its onset of action.

Both ingredients are well absorbed from gastrointestinal tract. Ibuprofen is 90-99% bound to plasma proteins, whereas caffeine is 36%. They are rapidly excreted in the urine mainly as metabolites; the elimination half-life of ibuprofen is about 2 - 4 hours, whereas for caffeine is 4 - 5 hours.

Indications

Profinal XP is used to get a rapid relief in the following conditions:

- migraine headache or other types of headaches, when taken at the first sign of onset.

It can also be used prophylactically to prevent recurrence of such headaches, and may also be taken prior to and during menstruation to prevent migraine associated with menstruation.

- mild to moderate pain, especially when anti-inflammatory actions may also be desired, e.g., following dental, obstetric, or orthopaedic surgery.
- musculoskeletal pain due to soft tissue athletic injuries (sprains or strains).
- mild to moderate bone pain caused by metastatic neoplastic disease.
- pain and other symptoms of primary dysmenorrhoea.

Dosage

The recommended dose is 1 caplet 3 times daily.

It is advisable to administer **Profinal XP** with or after food or milk to reduce the risk of gastrointestinal effects.

Not recommended for children below 12 years of age.

Contraindications

It is contraindicated in patients having a history of hypersensitivity to any ingredient in the preparation. It is also contraindicated in those having a history of hypersensitivity to aspirin or any other NSAIDs, including patients in whom attacks of asthma, angioedema, urticaria, or rhinitis have been precipitated due to administration of these agents.

As with other preparations containing NSAIDs, **Profinal XP** should not be given to patients with active peptic ulceration, and unless otherwise prescribed by the physician it is preferable to avoid them in patients with current or previous gastrointestinal ulceration or bleeding, and to withdraw them if gastrointestinal lesions develop.

Precautions

Excessive consumption of tea or coffee together with **Profinal XP** should be avoided as this may make the patient tense and irritable.

As with other preparations containing NSAIDs, it should be used with caution in patients having renal, hepatic, or cardiac impairment.

Hepatic impairment: It should be used with caution in patients having hepatic impairment, since NSAIDs have generally been reported to increase the risk of gastrointestinal bleeding and can cause fluid retention. It should be avoided in patients having severe liver disease.

Renal impairment: Since NSAIDs have generally been reported to cause sodium and water retention and may cause deterioration in renal function

that may possibly progress to renal failure, these agents should be given at the lowest effective dose in patients with mild renal impairment and that renal function should be carefully monitored; they should be avoided if possible in patients with moderate to severe renal impairment.

Pregnancy: As with other NSAIDs, ibuprofen is better to be avoided during pregnancy, unless potential benefit to the mother outweighs possible risk to the fetus.

Regular use of NSAIDs during the third trimester of pregnancy should be avoided, since it may result in closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. The onset of labour may be delayed and its duration increased.

Lactation: Ibuprofen appears in breast milk in an amount which is considered too small to be harmful to a breast-fed infant.

Elderly: Elderly patients are more susceptible to the adverse effects of NSAIDs, and since they are more likely to have an age-related renal function impairment, ibuprofen should be used with caution in these patients and may need to be given in reduced doses.

Side Effects

Profinal XP is usually well tolerated when therapeutic doses are not exceeded. Some minor side effects have occasionally been reported such as skin rashes, dizziness, nausea, heartburn, and abdominal discomfort.

Rarely, asymptomatic thrombocytopenia, gastro-intestinal bleeding and ulceration, angioedema, bronchospasm, tinnitus, nervousness, toxic epidermal necrolysis, and papillary necrosis have been reported.

Overdosage

Symptoms of nausea, vomiting, and tinnitus have been reported after ibuprofen overdosage. Gastric emptying is recommended if the quantity ingested within the previous hour exceed 400mg/kg body weight. There is no specific antidote for ibuprofen.

Drug Interactions

Due to the presence of ibuprofen in the preparation, the following drug interactions have been reported upon concurrent administration with other drugs:

- The effect of ibuprofen is enhanced by moclobemide (antidepressant).
- Ibuprofen may reduce the excretion of baclofen (muscle relaxant), lithium, or methotrexate (cytotoxic), increasing thereby their plasma concentrations and consequently the risk of toxicity.
- Ibuprofen may increase plasma concentrations of cardiac glycosides.
- Ibuprofen may possibly enhance the anticoagulant effect of acenocoumarol, warfarin, and possibly phenindione.
- The risk of nephrotoxicity may be increased if NSAIDs are given with ACE inhibitors, ciclosporin, tacrolimus, or diuretics.
- The risk of gastrointestinal bleeding and ulceration may be increased when NSAIDs are concurrently used with corticosteroids.

Presentation

Profinal XP film-coated caplets: Pack of 20 caplets.

* Store at a temperature of 15 - 25°C.

THIS IS A MEDICAMENT

- Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Ministers,
Union of Arab Pharmacists

Any information ? Call Toll Free No. (971) 800-4994



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