Profinal®

Anti-inflammatory, Antirheumatic, Analgesic, Antipyretic Coated-Tablets, Alcohol-free Paediatric Suspension

Composition

Profinal 200
Each sugar coated-tablet contains:
Active ingredient: Ibuprofen 200mg
Excipients: Starch, cellulose, magnesium stearate, sucrose, talc, gelatin, and titanium dioxide.

Profinal 400
Each film coated-tablet contains:
Active ingredient: Ibuprofen 400mg
Excipients: Starch, stearic acid, aerosil, hypromellose, lactose, polyethylene glycol, titanium dioxide, ponceau 4R lake, FD&C red no. 7, and carmoisine red color.

Profinal 600
Each film coated-tablet contains:
Active ingredient: Ibuprofen 600mg
Excipients: Starch, stearic acid, aerosil, magnesium stearate, hypromellose, lactose, titanium dioxide, polyethylene glycol, ponceau 4R lake, FD&C red no. 7, and carmoisine red color.

Profinal Paediatric Suspension
Each teaspoonful (5mL) of the suspension contains:
Active ingredient: Ibuprofen 100mg
Excipients: Sucrose, sodium benzoate, saccharin sodium, sodium EDTA, glycerol, sorbitol, xanthan gum, cellulose, polysorbate, citric acid, FD&C red no. 40, all fruit flavour, strawberry flavour, and purified water.

Properties

Ibuprofen, the active component of **Profinal**, 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.
Ibuprofen is rapidly absorbed from the gastro-intestinal tract, and thus it will give a fast effect. In painful conditions, its effect appears within 30 minutes and lasts for 4 - 6 hours, whereas in case of fever, peak effect is reached in about 2 - 4 hours and its action lasts for 6 - 8 hours, depending on the dose. Ibuprofen is 90 - 99% bound to plasma proteins and has a plasma half-life of about 2 hours. It is rapidly excreted in the urine mainly as metabolites; the elimination half-life is about 1.8 - 2 hours.
Profinal paediatric suspension is a sweet, palatable fruity-flavoured preparation, especially formulated for paediatric use. It is characterised by being extremely well-tolerated.

Indications

Profinal is indicated for its antirheumatic, anti-inflammatory, analgesic, and antipyretic effects in the following conditions:

Adults

- Treatment of acute and chronic rheumatic diseases including rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and juvenile arthritis. It is also used in the treatment of psoriatic arthritis.
- Relief of mild to moderate pain, especially when anti-inflammatory actions may also be desired, e.g., following dental, obstetric, or orthopaedic surgery.
- Relief of musculoskeletal pain due to soft tissue athletic injuries (strains or sprains).
- Treatment of painful nonrheumatic inflammatory conditions such as bursitis, capsulitis, synovitis, or tendinitis.
- Relief of mild to moderate bone pain caused by metastatic neoplastic disease.
- Relief of pain and other symptoms of primary dysmenorrhea.
- Relief of migraine headache or other types of headache, 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.
- Reduction of fever.

Children

Profinal paediatric suspension is mainly recommended for children whenever a rapid effect is required to:

- reduce elevated body temperature.
- relieve from pain.
- relieve from inflammatory conditions.

Dosage

Adults

- ***Antirheumatic:***
  Initial dose: 1200 - 1800mg daily in 3 - 4 divided doses, increased if necessary to a maximum of 2400mg daily.
  Maintenance dose: 600 - 1200mg daily may be adequate.
  Note: Patients with rheumatoid arthritis generally require higher doses than those with osteoarthritis.
- ***Analgesic (mild to moderate pain), antipyretic, antidysmenorrheal:***
  200 - 400mg every 4 - 6 hours; not to exceed 1200mg daily.

Children (over 7 kg bodyweight)

- ***Antirheumatic (juvenile rheumatoid arthritis):***
  30 - 40mg/kg daily in 3 - 4 divided doses.
- ***Antipyretic, Analgesic:***
  20 - 30mg/kg daily in divided doses.
  Alternatively, daily doses may be expressed in term of age and are:

6 - 12 months:	50mg (½ teaspoonful or 2.5mL of the suspension) 3 times daily.
1 - 2 years:	50mg (½ teaspoonful or 2.5mL of the suspension) 3 - 4 times daily.
3 - 7 years:	100mg (1 teaspoonful or 5mL of the suspension) 3 - 4 times daily.
8 - 12 years:	200mg (2 teaspoonfuls or 10mL of the suspension) 3 - 4 times daily.

Notes:

- It is advisable to administer **Profinal** with or after food or milk to reduce the risk of gastro-intestinal effects.
- It is not generally recommended for children weighing less than 7 kg.
- For geriatric use, the suspension form can be used whenever tablets cannot be easily swallowed.

If you miss a dose
If on regular dosing schedule:

- Take the missed dose as soon as you remember.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications

It is contraindicated in patients having a history of hypersensitivity to any ingredient in the preparation.
As with other NSAIDs, ibuprofen is contraindicated in patients with 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. Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma.
In addition, NSAIDs are also contraindicated in patients with active peptic ulceration, and unless otherwise prescribed by the physician it is preferable to avoid them in patients with current or previous gastro-intestinal ulceration or bleeding, and to withdraw them if gastro-intestinal lesions develop.

Precautions

As with other NSAIDs, ibuprofen should be used with caution in patients having renal, hepatic, or cardiac impairment.
Hepatic impairment: Since NSAIDs have generally been reported to increase the risk of gastro-intestinal bleeding and can cause fluid retention, they should be used with caution in patients having hepatic impairment and should be avoided in those 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 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, it is advisable to avoid the use of ibuprofen during pregnancy, unless the potential benefit to the mother outweighs any possible risk to the fetus.
Regular use of NSAIDs during the third trimester of pregnancy 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: No special dosage modifications are required for elderly patients unless renal or hepatic functions are impaired, in which case the dosage should be assessed individually.

Side Effects

Ibuprofen is usually well tolerated. Some minor side effects have occasionally been reported such as skin rashes, dizziness, nausea, heartburn, and abdominal discomfort.
Rarely, asymptomatic thrombocytopenia and gastro-intestinal bleeding and ulceration have been reported.

Overdosage

Symptoms of nausea, vomiting, and tinnitus have been reported after ibuprofen overdosage. More serious toxicity is uncommon, but gastric emptying followed by supportive measures is recommended if the quantity ingested within the previous hour exceed 400mg/kg bodyweight. There is no specific antidote for ibuprofen.

Drug Interactions

In therapeutic doses, no evidence of clinically significant interactions with other commonly used drugs has so far been observed. However, as with other NSAIDs, the following drug interactions have been reported upon concurrent administration of ibuprofen with other drugs:

- The risk of side effects may be increased when used with other NSAIDs, including aspirin; concomitant administration should be avoided.
- The effect of ibuprofen is enhanced by moclobemide.
- Ibuprofen may reduce the excretion of baclofen, lithium, or methotrexate, 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.

Presentations

Profinal 200 tablets: Packs of 20, 100, 250, 500, and 1000 tablets.
Profinal 400 tablets: Packs of 24, 120, 240, and 1000 tablets.
Profinal 600 tablets: Packs of 20, 40, 100, and 250 tablets.
Profinal paediatric suspension: Bottles of 60mL, 110mL, and 135mL.

* *Store at a temperature of 15 - 25°C. Keep the tablets in a dry place, protect the suspension from light.*

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 the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

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

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