National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. **Name of the Medicinal Product**

NKOYO IBUPROFEN TABLET 200 MG (Ibuprofen Tablets BP 200 mg)

2. Quality and Quantitative Composition

Ingredient	Reference	Qty / Tablet in mg	Uses
Ibuprofen	BP	200	Active
Dibasic calcium Phospahte	BP	16	Binder
Starch	BP	22.5	Binder
Sodium Benzaote	BP	0.5996	Presevative
PVPK 30	BP	1.5	Binder
Starch for paste	BP	10	Binder
Purifed water	BP	16.33	Vechicle
Lubrication			
Magnesium Sterate	BP	2	Disintegrants
Talcum	BP	6.399	Lubricants
Colloidal silicon dioxide	BP	1.0	Binder
Starch dried	BP	4.493	Lubricants
		280.8216	

* 11 kg of starch (dried)is added in formula to compensate drying loss

3. Pharmaceutical Form

Sugar coated Tablets

Description: Ibuprofen Tablets Red coloured, circular shaped sugar coated tablets printed "IBU 200" on one side of each tablets. .

4. Clinical Particulars

4.1 Therapeutic indications

NKOYO IBUPROFEN 200 mg sugar coated tablets are indicated for the treatment of the following Rheumatic or muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of cold and influenza..

4.2 Posology and method of administration

To be taken orally preferably with or after food

Adults the elderly and children over 12 years:

One or two tablets (200-400 mg) up to three times a day. The dose should not be repeated more frequently than every 4 hours and no more than 1200 mg should be taken in any 24 hour period.

Children 8- 12 years :

200 mg up to 4 times a day

If the child's symptoms persist for more than 3 days, consult a doctor.

4.3 Contraindications:

Hypersensitivity to Ibuprofen or to any of the tablet constituents

Ibuprofen is contraindicated in patients, who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, or urticaria) in response to aspirin or other non steroidal anti-inflammatory drugs.

Current or previous peptic ulceration.

Severe heart failure.

4.4 Special warning and precautions for use

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

The elderly are at risk of the serious consequences of adverse reactions. Caution is required in patients with renal, cardiac or hepatic impairment since renal function may deteriorate.

Caution (discussion with doctor or pharmacist) is required prior to starting treatment inpatients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg daily) is associated with an increased risk of myocardial infarction.

The label will state:

Do not use if you have ever had a stomach ulcer or are allergic to ibuprofen or aspirin. If you are allergic to or are taking any other painkiller, are pregnant or suffer from asthma, speak to your doctor before taking ibuprofen. Do not exceed the stated dose. Keep out of reach of children. If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interactions

Concurrent aspirin or other NSAID's may result in an increased incidence of adverse reactions.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of *ex-vivo* data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use .
NSAIDs may enhance the effects of anticoagulants and diminish the effect of antihypertensives or diuretics.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal studies, ibuprofen should be avoided during pregnancy. The onset of labour may be delayed and the duration of labour increased. Ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machine

Dizziness or headaches are possible undesirable effects after taking NSAID's, and may affect the patient's ability to drive or operate machinery.

4.8 Undesirable effects

Gastro-intestinal: abdominal pain, nausea and dyspepsia. Occasionally peptic ulcer and gastro-intestinal haemorrhage.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis, erythema multiforme and exfoliative dermatitis).

Haematological: thrombocytopenia.

Renal: papillary necrosis, which can lead to renal failure.

Others: rarely hepatic dysfunction, headache, dizziness, hearing disturbances. Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke)

4.9 Overdose

Symptoms include headache, vomiting, drowsiness and hypotension. Gastric lavage and correction of severe electrolyte abnormalities should be considered.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Ibuprofen has analgesic, anti-inflammatory and antipyretic properties. Ibuprofen inhibits prostaglandin synthesis.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400 mg was taken within 8 hours before or within 30 minutes after immediate release aspirin dosing (81 mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic Properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. Thesetimes may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety Data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

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6. Pharmaceutical Particulars

6.1 List of excipients

Dibasic calcium Phosphate

Starch

Sodium Benzoate

PVPK 30

Magnesium Sterate

Stearic Acid

Purified Talcum

Colloidal Silicon dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30 °C,

Protect from light.

Keep all medicines out of reach of childrens

6.5 Nature and contents of container

1000 Tablets in Jar

6.6 Special Precaution for disposal

No special requirements

7. APPLICANT/MANUFACTURER

NAFDAC REG.NO: 04-4495

MANUFACTURED BY:
MAXHEAL PHARMACEUTICALS (INDIA) LTD
J-7, M.I.D.C.Tarapur Industrial Area,
Boisar-401506, Dist. Palghar, India