SUMMARY OF PRODUCT CHARACTERISTICS IBUCOS 200 MG FILM COATED TABLET

1. **Name of the Medicinal Product**

   Ibucos 200 mg film coated Tablets

2. **Qualitative and Quantitative Composition**

   Each film coated Tablet contains 200 mg of Ibuprofen.

   For the full list of excipients, see section 6.1.

3. **Pharmaceutical Form**

   Film coated Tablets

   Pink, circular, biconvex, film coated tablet, plain on one side and a break line on the other side.

4. **Clinical Particulars**

4.1 Therapeutic Indications

P

For the relief of pain of non-serious arthritic conditions and for the relief of rheumatic or muscular pain, backache, neuralgia, headache including migraine headache, dental pain, dysmenorrhoea, feverishness and the symptoms of colds and influenza.

GSL

For the relief of rheumatic or muscular pain, backache, neuralgia, headache including migraine headache, dental pain, dysmenorrhoea, feverishness and the symptoms of colds and influenza.

4.2 Posology and Method of administration

P and GSL:

For oral administration and short-term use only.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Adults, the elderly and children over 12 years:

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.

One to two (200-400 mg) tablets to be taken up to three times a day, as required.

Leave at least four hours between doses and do not take more than 6 tablets (1200mg) in any 24 hour period.

Adolescents (12-18 years old):

If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Children under 12 years:

Not suitable for children under 12 years.

4.3 Contraindications

P and GSL

Hypersensitivity to ibuprofen or any of the excipients in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria), in response to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Severe heart failure (NYHA Class IV), renal failure or hepatic failure.

Last trimester of pregnancy.

Children under 12 years.

4.4 Special warnings and precautions for use

P and GSL

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory:

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

Other NSAIDs:

The use of ibuprofen with concomitant NSAIDs including cyclo-oxygenase-2 selective inhibitors should be avoided.

SLE and mixed connective tissue disease:

Systemic lupus erythematosus and mixed connective tissue disease - increased risk of aseptic meningitis.

Renal:

Renal impairment as renal function may further deteriorate.

There is a risk of renal impairment in dehydrated adolescents.

Hepatic:

Hepatic dysfunction.

Cardiovascular and cerebrovascular effects:

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

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) 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/day) is associated with an increased risk of arterial thrombotic events.

Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided.

Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Impaired female fertility:

There is limited evidence that drugs which inhibit cyclo-oxygense/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

Gastrointestinal:

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:

Acetylsalicylic acid: Unless low-dose aspirin (not above 75mg daily) has been advised by a doctor. Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardio protective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.

Other NSAIDS including cyclo-oxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects.

Ibuprofen should be used with caution in combination with:

Anticoagulants: NSAIDS may enhance the effects of anti-coagulants, such as warfarin.

Antihypertensive and diuretics: NSAIDs may diminish the effect of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding

Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium: There is evidence for potential increases in plasma levels of lithium.

Methotrexate: There is a potential for an increase in plasma methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

4.6 Pregnancy and lactation

Pregnancy

P and GSL

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen should, if possible, be avoided during the first 6 months of pregnancy.

During the 3rd trimester, ibuprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child.

Lactation

P and GSL

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Infections and infestations:

Very rare: Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of non-steroidal anti-inflammatory drugs has been described. This is possibly associated with the mechanism of action of the non-steroidal anti-inflammatory drugs. If signs of an infection occur or get worse during use of Ibuprofen the patient is therefore recommended to go to a doctor without delay. It is to be investigated whether there is an indication for anti-infective/antibiotic therapy.

Haematological:

Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

Immune System:

Not known: In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed.

Hypersensitivity reactions:

Uncommon: Hypersensitivity reactions with urticaria and pruritus.

Very rare: severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock).

Not known: Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea. Exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Nervous System:

Uncommon: Headache.

Very rare: Aseptic meningitis – single cases have been reported very rarely.

Cardiovascular and Cerebrovascular:

Not known: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Gastrointestinal:

The most commonly-observed adverse events are gastrointestinal in nature.
Uncommon: Abdominal pain, nausea, dyspepsia.

Rare: Diarrhoea, flatulence, constipation and vomiting

4.9 Overdose

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

5 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic classification: Anti-inflammatory and antirheumatic products, nonsteroidal; propionic acid derivatives. ATC code: M01AE01

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. 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. These times 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.

6 Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline cellulose BP
Maize starch BP
Aerosil BP
Potassium sorbate BP
Magnesium stearate BP
Stearic acid BP
Sodium lauryl sulphate BP
Purified Talc BP
COATING
Hypromellose BP 5 cps
Macrogol 300 BP
Isopropyl alcohol BP
Dichloromethane BP
Purified Talc BP
Titanium dioxide BP
Erythrosine lake color
Carnauba wax
Hard paraffin
Chloroform BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store in a dry place below 30˚C. Protect from Light.

6.5 Nature and contents of container

Tablets are provided in PVC/Aluminium blisters and HDPE containers.

6.6 Instructions for use, handling and disposal

No special requirements.

7 Registrant

Cosmos Limited

8 Manufacturer

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