PATIENT INFORMATION LEAFLET OF IBUCOS 200 MG FILM COATED TABLET

Read all of this leaflet carefully before you start taking this medicine. It contains important information about your treatment and illness. If you have any further questions, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again.
If any of the side effects mentioned in the leaflet gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

1. IDENTIFICATION OF THE FINISHED PHARMACEUTICAL PRODUCT

Form/Presentation
Product name: Ibucos 200 mg film coated Tablets,
Presentation: Pink, circular, biconvex, film coated tablet, plain on one side and a break line on the other side.
Qualitative and quantitative composition.

Active substance	**Excipients**
Ibuprofen	

PHARMACO-THERAPEUTIC CLASS:
Ibuprofen is an NSAID and non-selective COX inhibitor used to treat mild-moderate pain, fever, and inflammation.

2. CLINICAL PARTICULARS

2.1 *Therapeutic indications*

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.
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2.2 *Posology and method of administration*

Always take this medicine exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.
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.

Method of administration
Tablets should be swallowed whole with a glass of water. To be taken with or without food.

Dosage for special populations
Elderly (≥ 65 years)
No dosage adjustments are necessary.
Pediatrics
Not suitable for children under 12 years.

3. Contraindications
Do not take Ibucos tablet in case any of the following apply to you:
-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 nonsteroidal 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.
If you are unsure whether any of the above apply to you, please contact your doctor or pharmacist for further guidance.

4. *Special warnings and Precautions for use*

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).
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.

5. *Interaction with other medicinal products and other forms of interaction*
Ibuprofen should be avoided in combination with:
Acetylsalicylic acid:
Concomitant administration of ibuprofen and
acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.
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.
6. *Additional information on special populations*
Refer to section 2 on dosage and administration for special population.

7. *Fertility, pregnancy and lactation*
Pregnancy
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
In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

8. *Effects on ability to drive and use machines*
Not known.

9. *Undesirable effects*
Like all medicines, Ibucos tablets can cause side effects, although not everybody gets them. If any of the side effects indicated in the leaflet gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.
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.
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.

10. *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.

11. PHARMACEUTICAL PARTICULARS

11.1 *Shelf life*

3 Years

11.2 STORAGE CONDITIONS

Store in a dry place below 30˚C. Protect from light.
Keep all medicines out of the reach and sight of children.
Do not use after the expiry date which is stated on the carton.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

12. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Cosmos Limited
Rangwe Road; Off Lunga Lunga, Industrial Area
P.O Box 41433, GPO 00100-Nairobi
Kenya
Telephone: 020-2519603/4/5, 020-8042200/2/3/4/5
Telefax: N/A
E-mail: admin@cosmos-pharm.com

13: LOCAL TECHNICAL REPRESENTATIVE ADDRESS

For any information about this pharmaceutical product, please contact the local representative as stated below:
Sun Enterprises S.A.R.L
Depot Pharmaceutique B.P 1952,
Quarter Commercial, Kigali
Rwanda

14. DATE OF REVISION OF THE LEAFLET

OCTOBER 2024