SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

GO PAIN IBUPROFEN 200, 200 mg film-coated tablets

GO PAIN IBUPROFEN 400, 400 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

GO PAIN IBUPROFEN 200: Each tablet contains ibuprofen 200 mg.

GO PAIN IBUPROFEN 400: Each tablet contains ibuprofen 400 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets

GO PAIN IBUPROFEN 200: White to off-white round shape, film- coated tablets with "G 2" debossing on one side and plain on the other side.

GO PAIN IBUPROFEN 400: White to off-white oval shape, film-coated tablets with "I 6" debossing on one side & plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GO PAIN IBUPROFEN is indicated for the relief of headache and back pain of musculoskeletal origin, feverishness, muscular aches and pain, menstrual pain, dental pain and for the relief of pain associated with migraine.

4.2 Posology and method of administration

Posology

Adults and children over 12 years

The initial dose is 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) taken with water, then, if necessary, 200 mg ibuprofen (one GO PAIN IBUPROFEN 200 tablet) or 400 mg ibuprofen (one GO PAIN IBUPROFEN 400 tablet) every four hours.

Migraine

Take 400 mg ibuprofen (two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet) three times a day.

Period pain

The recommended dosage of ibuprofen is 1 200 mg daily in divided doses, that is take two GO PAIN IBUPROFEN 200 tablets or one GO PAIN IBUPROFEN 400 tablet three times a day.

Do not exceed 1 200 mg ibuprofen (six GO PAIN IBUPROFEN 200 tablets or three GO PAIN IBUPROFEN 400 tablets) in any 24 hours.

If symptoms persist for more than 7 days or worsen or new symptoms occur, consult your doctor.

Use the lowest effective dose for the shortest possible duration of treatment.

Paediatric population

Not to be given to children under 12 years.

Method of administration

For oral administration and short-term use only.

4.3 Contraindications

- Hypersensitivity to ibuprofen or to any of the excipients listed in section 6.1.
- Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Heart failure.
- Severe renal failure or hepatic failure (see section 4.4).
- History of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous NSAIDs, including GO PAIN IBUPROFEN.
- Active or history of recurrent ulcer, haemorrhage or perforations.
- Third trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

General

GO PAIN IBUPROFEN should not be given to patients with bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration. Asthma sufferers should only take GO PAIN IBUPROFEN after consulting a doctor. Caution is advised in those patients who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin should not be given GO PAIN IBUPROFEN.

DRESS syndrome

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as GO PAIN IBUPROFEN. Some of these events have been fatal or life threatening. DRESS typically, although not exclusively, presents with fever, rash,

lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue GO PAIN IBUPROFEN and evaluate the patient immediately.

Respiratory

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

Other NSAIDs

Using GO PAIN IBUPROFEN concomitantly with other non-steroidal anti-inflammatory drugs (NSAIDs) including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

SLE and mixed connective tissue disease

Systemic lupus erythematosus (SLE) as well as those with mixed connective tissue disease – there is an increased risk of aseptic meningitis (see section 4.8). Clinical trial and epidemiological data suggest that the use of ibuprofen, particularly at high doses (2 400 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. ≤ 1 200 mg daily) is associated with an increased risk of myocardial infarction.

Renal

Renal impairment as renal function may further deteriorate (see sections 4.3 and 4.8).

There is a risk of renal impairment in dehydrated children and adolescents.

Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Hepatic

Hepatic dysfunction (see sections 4.3 and 4.8).

Cardiovascular and cerebrovascular effects

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with ibuprofen as in GO PAIN IBUPROFEN therapy. In view of GO PAIN IBUPROFEN's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Impaired female fertility

There is limited evidence that medicines which inhibit cyclo-oxygenase/ prostaglandin synthesis (such as GO PAIN IBUPROFEN) may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

Gastrointestinal

NSAIDs should be given with care to patients with a history of gastrointestinal (GI) disease (ulcerative colitis, hiatus hernia, Crohn's disease, gastro-oesophageal reflux disease, angiodysplasia) as these conditions may be exacerbated (see section 4.8).

GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcers and in the elderly.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet medicines such as aspirin (see section 4.5).
When GI bleeding or ulceration occurs in patients receiving GO PAIN IBUPROFEN, the treatment should be withdrawn.

Severe skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. GO PAIN IBUPROFEN should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Masking of symptoms of underlying infections

GO PAIN IBUPROFEN can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When GO PAIN IBUPROFEN is administered for pain or fever in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Elderly

The elderly have an increased frequency of adverse reactions to NSAIDs including GO PAIN IBUPROFEN, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

4.5 Interactions with other medicines and other forms of interaction

GO PAIN IBUPROFEN should be avoided in combination with

Aspirin (acetylsalicylic acid)

Unless low-dose aspirin (not above 75 mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.4). 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 GO PAIN IBUPROFEN use and no clinically relevant effect is considered to be likely for occasional GO PAIN IBUPROFEN use.

NSAIDs

Use of two or more NSAIDs concomitantly could result in an increase in side effects.

GO PAIN IBUPROFEN should be used with caution in combination with

Corticosteroids

Increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).

Antihypertensives and diuretics

NSAIDs may diminish the effects of these medicines. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ACE inhibitor or Angiotensin II antagonist and medicines that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking

a coxib concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated, and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Anti-coagulants

GO PAIN IBUPROFEN may enhance the effects of anti-coagulants such as warfarin.

Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs)

Increased risk of gastrointestinal bleeding.

Cardiac glycosides

GO PAIN IBUPROFEN may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium

There is evidence for potential increase in plasma levels of lithium.

Methotrexate

There is evidence for the potential increase in plasma levels of methotrexate.

Ciclosporin

Increased risk of nephrotoxicity.

Mifepristone

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

Tacrolimus

Possible increased risk of nephrotoxicity when GO PAIN IBUPROFEN is given with tacrolimus.

Zidovudine

Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthrosis and haematoma in HIV-positive haemophiliacs receiving concurrent treatment with zidovudine and GO PAIN IBUPROFEN.

Quinolone antibiotics

GO PAIN IBUPROFEN can increase the risk of convulsions associated with quinolone antibiotics. Patients taking GO PAIN IBUPROFEN and quinolones may have an increased risk of developing convulsions.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

GO PAIN IBUPROFEN may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

Pregnancy

GO PAIN IBUPROFEN is contraindicated during the third trimester of pregnancy (see section 4.3).

First trimester

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies raise concern about an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1 %, up to approximately 1,5 %. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

Second and third trimester

During the third trimester of pregnancy, prostaglandin synthesis inhibitors, may expose the foetus to: cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction, which may progress to renal failure with oligohydramnios.

At the end of pregnancy, the mother and the neonate may be exposed to possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses; inhibition of uterine contractions resulting in delayed or prolonged labour.

Breastfeeding

Patients using GO PAIN IBUPROFEN should not breastfeed their infants.

4.7 Effects on ability to drive and use machines

GO PAIN IBUPROFEN has negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

The list of the following adverse events relates to those experienced with ibuprofen at OTC doses for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse events may occur.

The adverse events observed most often are gastrointestinal in nature. Adverse events are mostly dose-dependent, in particular, the risk of occurrence of gastrointestinal bleeding is dependent on the dosage range and duration of treatment.

b. Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Adverse reactions**
Blood and lymphatic system disorders	Less frequent	Haemopoietic disorders including anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis [1.]
Immune system disorders	Less frequent	Hypersensitivity reactions consisting of urticaria and pruritus [2,3] Severe hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia, and hypotension (anaphylaxis, angioedema or severe shock) [3]
	Frequency unknown	Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea
Metabolism and nutrition disorders	Frequency unknown	Decreased appetite, hypokalaemia
Nervous system disorders	Less frequent	Headache, aseptic meningitis [4]
Cardiac disorders	Frequency unknown	Cardiac failure and oedema [5]

System Organ Class	Frequency	Adverse reactions
Vascular disorders	Frequency unknown	Hypertension
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Provocation of bronchospasm in patients with asthma
Gastrointestinal disorders	Less frequent	Abdominal pain, nausea, dyspepsia, diarrhoea, flatulence, constipation, vomiting, peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, melaena, haematemesis, ulcerative stomatitis, gastritis.
	Frequency unknown	Exacerbation of colitis and Crohn's disease
Hepato-biliary disorders	Less frequent	Hepatotoxicity, abnormalities in liver function tests.
Skin and subcutaneous tissue disorders	Less frequent	Skin rash, bullous reactions, including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal syndrome
	Frequency unknown	DRESS syndrome (see section 4.4), acute generalised exanthematous pustulosis (AGEP), photosensitivity reactions
Renal and urinary disorders	Less frequent	Cystitis, haematuria, acute renal failure, interstitial nephritis, nephrotic syndrome, papillary necrosis [6.]
	Frequency unknown	Renal insufficiency, uretic colic, dysuria, renal tubular acidosis
Investigations	Less frequent	Decreased haemoglobin levels

c. Description of selected adverse reactions

1 First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

2 Hypersensitivity reactions may occur less frequently and include fever and rashes. 2 Other side effects include nervousness, tinnitus, depression, drowsiness, insomnia, and blurred vision and other visual field defects.

3 Ibuprofen can provoke bronchospasm in patients with asthma.

4 Other side-effects include blurred vision, changes in visual colour perception, and toxic amblyopia.

5 Cardiovascular side-effects include: dizziness, nervousness, tinnitus, depression, drowsiness and insomnia.

6 Papillary necrosis, especially in long term use, is associated with increased serum urea and oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

In addition, side-effects can also be reported to info@pharmacorp.co.za

4.9 Overdose

Symptoms

In adults, the dose response effect is less clear cut than in children where ingestion of more than 500 mg/ kg may cause symptoms. The half-life in overdose is 1,5 to 3 hours.

Nausea, vomiting, epigastric pain, or more rarely diarrhoea may develop. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in

the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Electrolytes may be corrected by intravenous infusion, if necessary. There is no specific antidote to GO PAIN IBUPROFEN.

Management should be symptomatic and supportive. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for bronchospasm.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesic

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, nonsteroidal; propionic acid derivatives.

ATC code: M01AE01

Ibuprofen is a non-steroidal compound, with analgesic, anti-inflammatory and antipyretic actives.

5.2 Pharmacokinetic properties

When taken with food, peak levels are observed after 1 to 2 hours. The half-life of Ibuprofen is about 2 hours. Excretion is via the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Cellulose, microcrystalline

Colloidal silicon dioxide

Croscarmellose sodium

Magnesium stearate

Povidone (K-90)

Starch, pregelatinised (maize)

Sodium lauryl sulphate

Film coating

Aquarius® BKP18066 Cool Vanilla

Ingredients

Hypromellose 2910 3CPS

Hypromellose 2910 6CPS

Hypromellose 2910 50CPS

Hydroxy propyl cellulose EF

Polyethylene glycol 400

Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 ºC.

6.5 Nature and contents of container

GO PAIN IBUPROFEN 200: Blister packs of 24 tablets.

GO PAIN IBUPROFEN 400: Blister packs of 12 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

8. REGISTRATION NUMBERS

GO PAIN IBUPROFEN 200: 57/2.7/0492

GO PAIN IBUPROFEN 400: 57/2.7/0493

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03 February 2026

10. DATE OF REVISION OF THE TEXT