Approved Professional Information for Medicines for Human Use:

IBUSOR 200 and IBUSOR 400

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

IBUSOR 200 mg film-coated tablets

IBUSOR 400 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

IBUSOR 200 tablets:

Each film coated tablet contains 200 mg ibuprofen.

Sugar-free.

IBUSOR 400 tablets:

Each film coated tablet contains 400 mg ibuprofen.

Sugar-free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pink coloured, circular, biconvex, film- coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

IBUSOR 200 and IBUSOR 400 are indicated for treatment of:

- rheumatoid arthritis
- juvenile rheumatoid arthritis or Still’s disease
- ankylosing spondylitis

- osteo-arthritis
- acute gouty arthritis
- non-articular rheumatism including fibrositis
- non-rheumatic inflammatory conditions such as capsulitis (frozen shoulder), bursitis, tendonitis, tenosynovitis and low back pain
- relief of mild to moderate pain such as dysmenorrhoea, dental, post-episiotomy and post-partum pain
- soft tissue injuries such as sprains and strains
- pyrexia.

4.2 Posology and method of administration

Posology

Adults:

The recommended dosage of IBUSOR 200 and IBUSOR 400 is 600 mg 6 - 8 hourly.

The total daily dose of IBUSOR 200 and IBUSOR 400 should not exceed 2400 mg.

Pain:

Initial dose 5 mg/kg of bodyweight. A second dose of 5 mg/kg may be given after 2 hours if pain is not controlled. Thereafter 5 mg/kg every 4 - 6 hours.

DO NOT EXCEED 20 mg/kg of bodyweight per day.

Fever:

5 mg/kg of bodyweight every 4 - 6 hours.

DO NOT EXCEED 20 mg/kg of bodyweight per day.

Paediatric population

This formulation is not suitable for children under 12 years of age (see section 4.3).

Method of administration

IBUSOR is for oral use.

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur, IBUSOR should be given with food or milk.

4.3 Contraindications

- Hypersensitivity to ibuprofen or any of the excipients listed in section 6.1.
- Heart failure.
- Peptic ulcer disease or gastrointestinal bleeding.
- History of gastrointestinal bleeding, ulceration or perforation (PUBs) related to previous NSAIDs.
- Active or history of recurrent ulcer/haemorrhage/perforations.
- Patients sensitive to aspirin or another nonsteroidal anti-inflammatory medicines (NSAIDs).
- History of severe allergic reactions such as anaphylaxis or angioedema, induced by aspirin or other NSAIDs because of the possibility of cross-sensitivity due to structural relationships which exist among NSAIDs, acute allergic reactions are likely to occur in patients who have exhibited allergic reactions to these compounds.
- Aspirin-induced nasal polyps associated with bronchospasm.
- Patients with renal failure.
- Children under 12 years of age.
- The use of IBUSOR around 20 weeks gestation or later in pregnancy may cause a rare but serious foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment (see section 4.4 and 4.6).
- Third trimester of pregnancy and during labour (see section 4.6).
- Safety in lactation has not been established.

4.4 Special warnings and precautions for use

Masking of symptoms of underlying infections

The antipyretic, analgesic and anti-inflammatory action of ibuprofen may mask symptoms of the occurrence or worsening of infection. This 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 bacteria complications to varicella. When IBUSOR tablets is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a health care provider if symptoms persist or worsen.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2, and GI and cardiovascular risks below).

Concomitant use with other NSAIDs

The use of IBUSOR with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors, should be avoided due to the increased risk of ulceration or bleeding (see section 4.5).

Medication overuse headache

The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of analgesic medication. Patients with medication overuse headache should not be treated by increasing the dose of the analgesic. In such cases the use of analgesics should be discontinued.

Concomitant alcohol

The concomitant consumption of excessive alcohol with NSAIDs, including ibuprofen may increase the risk of adverse effects on the gastrointestinal tract, such as GI haemorrhage or the central nervous system, possibly due to an additive effect.

Elderly

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

Gastrointestinal bleeding, ulceration and perforation

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 serious GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly.

Patients with a history of gastrointestinal disease, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal 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 agents such as aspirin (see section 4.5).

When GI bleeding or ulceration occurs in patients receiving IBUSOR, the treatment should be withdrawn.

NSAIDs should be given with care to patients with a history of ulcerative colitis or Crohn's disease as these conditions may be exacerbated (see section 4.8)

Respiratory disorders and hypersensitivity reactions

IBUSOR should not be administered to patients suffering from, or with a previous history of, bronchial asthma, chronic rhinitis or allergic diseases since NSAIDs have been reported to precipitate bronchospasm, urticaria or angioedema in such patients.

Cardiac, renal and hepatic impairment

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. The habitual concomitant intake of various similar painkillers further increases this risk. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. For these patients, use

the lowest effective dose, for the shortest possible duration and monitor renal function especially in long-term treated patients (see also section 4.3).

Cardiovascular and cerebrovascular effects

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2 400 mg/ day) may be associated with a small increased risk of arterial thrombotic events such as myocardial infarction or stroke. Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1 200 mg/day) is associated with an increased risk of arterial thrombotic events.

Careful consideration should 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.

Cases of Kounis syndrome have been reported in patients treated with Ibuprofen. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

Renal effects

Caution should be used when initiating treatment with ibuprofen in patients with considerable dehydration. There is a risk of renal impairment especially in dehydrated children, adolescents and the elderly.

Severe hypokalaemia and renal tubular acidosis have been reported due to prolonged use of ibuprofen at higher than recommended doses. This risk is increased with the use of codeine/ibuprofen as patients may become dependent on the codeine component (see warning on Opioid use disorder, section 4.8 and section 4.9). Presenting signs and symptoms included reduced level of consciousness and generalised weakness. Ibuprofen induced renal tubular acidosis should be considered in patients with unexplained hypokalaemia and metabolic acidosis.

Long-term administration of ibuprofen has resulted in renal papillary necrosis and other renal pathologic changes. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may cause renal failure. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pre-treatment state.

SLE and mixed connective tissue disease

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis (see below and section 4.8).

Cutaneous and soft tissues infections

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). Most of these reactions occurred within the first month. If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately, and an alternative treatment considered (as appropriate).

Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as IBUSOR. 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. Eosinophillia 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 IBUSOR and evaluate the patient immediately.

In exceptional cases, varicella can be at the origin of serious cutaneous and soft tissues infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of Ibuprofen in case of varicella.

Haematological effects

Ibuprofen, like other NSAIDs, can interfere with platelet aggregation and prolong bleeding time in normal subjects.

Aseptic meningitis

Aseptic meningitis has been observed on rare occasions in patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have an underlying chronic disease.

Changes in vision

IBUSOR 200 and IBUSOR 400 should be discontinued in patients who experience blurred or diminished vision, or changes in colour vision.

Opioid use disorder (abuse and dependence)

Tolerance, physical and psychological dependence and opioid use disorder (OUD) may develop upon repeated administration of opioids such as codeine. Abuse or intentional misuse of codeine may result in overdose and/or death.

Serious clinical outcomes, including fatalities, have been reported in association with abuse and dependence with codeine/ibuprofen combinations, particularly when taken for prolonged periods at higher than recommended doses. These have included reports of gastrointestinal perforations, gastrointestinal haemorrhages, severe anaemia, renal failure, renal tubular acidosis and severe

hypokalaemia associated with the ibuprofen component.

Patients should be informed about the risks and signs of OUD as well as serious clinical outcomes. If these signs occur, patients should be advised to contact their doctor.

Withdrawal symptoms, such as restlessness and irritability may occur once the medicine is stopped.

4.5 Interaction with other medicines and other forms of interaction

- Anticoagulants such as warfarin – Enhancement of anticoagulant effect and the possibility of gastrointestinal ulceration or bleeding (see section 4.4).
- Alcohol, corticosteroids, anti-platelet medicine (clopidogrel, ticlopidine), bisphosphonates, pentoxyfylline – Increased risk of gastrointestinal bleeding and ulceration (see section 4.4).
- Selective serotonin reuptake inhibitors (SSRIs) – Increased risk of gastrointestinal bleeding with NSAIDs (see section 4.4).
- Antidiabetic agents like sulfonylureas – Hypoglycaemic effects of these medicines may be increased.
- Lithium – Increase in the steady-state concentration of lithium.
- Methotrexate – Increased and prolonged methotrexate plasma concentration and an increased risk of methotrexate toxicity.
- Nephrotoxic medicines e.g. cyclosporin and tacrolimus – Increased risk of nephrotoxicity.
- Antihypertensives, beta-blockers and diuretics – Reduction or reversal of the antihypertensive effect may occur. Diuretics can also increase the risk of nephrotoxicity of NSAIDs.
- Cardiac glycosides – NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels e.g increase in serum digoxin concentrations.
- Bone marrow depressants – The leucopenic and/or thrombocytopenic effects of these medicines may be increased.
- Cholestyramine – The concomitant administration of ibuprofen and cholestyramine may reduce the absorption of ibuprofen in the gastrointestinal tract. However, the clinical significance is unknown.
- Mifepristone – A decrease in the efficacy of the medicinal product can theoretically occur due

to the antiprostaglandin properties of NSAIDs. Limited evidence suggests that coadministration of NSAIDs on the day of prostaglandin administration does not adversely influence the effects of mifepristone or the prostaglandin on cervical ripening or uterine contractility and does not reduce the clinical efficacy of medicinal termination of pregnancy.

- Other analgesics and cyclooxygenase-2 selective inhibitors – Avoid concomitant use of two or more NSAIDs, includingCox-2 inhibitors, as this may increase the risk of adverse effects (see section 4.4).
- Aspirin (Acetylsalicylic acid) – As with other products containing NSAIDs, concomitant administration of ibuprofen and aspirin 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 aspirin 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 cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional use (see section 5.1).
- Quinolone antibiotics – Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
- Zidovudine – Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
- Aminoglycosides – NSAIDs may decrease the excretion of aminoglycosides.
- Herbal extracts – Ginkgo biloba may potentiate the risk of bleeding with NSAIDs.
- CYP2C9 Inhibitors – Concomitant administration of ibuprofen with CYP2C9 inhibitors may increase the exposure to ibuprofen (CYP2C9 substrate). In a study with voriconazole and fluconazole (CYP2C9 inhibitors), an increased S(+)-ibuprofen exposure by approximately 80 to 100 % has been shown. Reduction of the ibuprofen dose should be considered when potent

CYP2C9 inhibitors are administered concomitantly, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.

4.6 Fertility, pregnancy and lactation

Pregnancy

- Pregnant women should not use IBUSOR at 20 weeks or later because it may cause foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment (see section 4.3).
- Additionally, it should be avoided at 30 weeks and later in pregnancy as it may result in premature closure of the foetal ductus arteriosus in uterus and possibly in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed, or its onset increased (see section 4.3).

Breastfeeding

Safety and efficacy in lactation have not been established (see section 4.3).

Fertility

Impaired female fertility

The use of IBUSOR may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of IBUSOR should be considered.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

a) Tabulated list of adverse reactions

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and postmarket spontaneous reports with ibuprofen.

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Frequency Not Known**
Infections and infestations		Rhinitis, aseptic meningitis (see section 4.4)	
Blood and lymphatic system disorders		Agranulocytosis, thrombocytopenia, leukopenia, anaemias (aplastic and haemolytic), neutropenia, eosinophilia	
Immune system disorders		Hypersensitivity, anaphylactic reactions	
Metabolism and nutrition disorders			Hypokalaemia*
Psychiatric disorders		Insomnia, anxiety, depression, confusional state	
Nervous system	Headache, dizziness	Paraesthesia, somnolence, optic neuritis	Nervousness, drowsiness

disorders			
Eye disorders		Visual impairment, toxic optic neuropathy	Blurred vision, changes in visual colour perception, toxic amblyopia
Ear and labyrinth disorders		Hearing impaired, tinnitus, vertigo	
Cardiac disorders		Cardiac failure, myocardial infarction (also see section 4.4)	Tachycardia, flushing, Kounis Syndrome
Vascular disorders		Hypertension	
Respiratory, thoracic and mediastinal disorders		Asthma, bronchospasm, dyspnoea	
Gastrointestinal disorders	Dyspepsia, diarrhoea, nausea, vomiting, abdominal cramps and discomfort, flatulence, constipation, melaena, haematemesis, gastrointestinal haemorrhage	Gastritis, duodenal ulcer, gastric ulcer, mouth ulceration, gastrointestinal perforation, pancreatitis	Exacerbation of Colitis and Crohn´s disease
Hepatobiliary disorders		Hepatitis, jaundice, hepatic function abnormal, hepatic failure	

Skin and subcutaneous tissue disorders	Rash	Urticaria, pruritus, purpura, angioedema, photosensitivity reaction, severe cutaneous adverse reactions (SCARs) (including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), acute generalised exanthematous pustulosis (AGEP)
Renal and urinary disorders		Nephrotoxicity in various forms e.g. Tubulointerstitial nephritis, nephrotic syndrome and renal failure	Impairment of renal function, acute reversible renal impairment, renal tubular acidosis*
General disorders and administration site conditions	Fatigue	Oedema	

b) Description of selected adverse reactions

Gastrointestinal disorders:

The most frequently observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (see section 4.4). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, gastrointestinal haemorrhage and exacerbation of colitis and Crohn's disease (see section 4.4) have been reported following ibuprofen

administration. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed.

Immune system disorders:

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 asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, very rarely, erythema multiforme, bullous dermatoses (including Stevens- Johnson syndrome and toxic epidermal necrolysis).

**Renal tubular acidosis and hypokalaemia:*

Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses due to dependence on the codeine component.

Cardiac disorders and vascular disorders:

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical studies suggest that use of ibuprofen, particularly at high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events such as myocardial infarction or stroke (see section 4.4).

Infections and infestations:

Rhinitis and aseptic meningitis (especially in patients with existing autoimmune disorders, such as systemic lupus erythematosus and mixed connective tissue disease) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (see section 4.4).
Exacerbation of infection-related inflammations coinciding with the use of NSAIDs has been described. 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.

Skin and subcutaneous tissue disorders:

In exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection (see also "Infections and infestations").

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. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via medsafety@shanur.co.za

4.9 Overdose

Toxicity

Signs and symptoms of toxicity have generally not been observed at doses below 100 mg/kg in children or adults. However, supportive care may be needed in some cases. Children have been observed to manifest signs and symptoms of toxicity after ingestion of 400 mg/kg or greater.

Signs and symptoms

Most patients who have ingested significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours.

The most frequently reported symptoms of overdosage are epigastric pain, nausea, vomiting, lethargy and drowsiness. Central nervous system (CNS) effects include headache, tinnitus, dizziness, convulsion, and loss of consciousness. Nystagmus, metabolic acidosis, hypothermia, renal effects, gastrointestinal bleeding, coma, apnoea, diarrhoea and depression of the CNS and respiratory system have also been rarely reported. 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. Disorientation, excitation, fainting and cardiovascular toxicity, including hypotension, bradycardia and tachycardia have been reported. In cases of significant overdose, renal failure and liver damage are possible. Large overdoses are generally well tolerated when no other medicines are being taken.

Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see section 4.4 and section 4.8).

Exacerbation of asthma is possible in asthmatics.

Treatment

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Electrolytes may be corrected by intravenous infusions if necessary.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 3.1 Antirheumatics (Anti-Inflammatory agents)

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

ATC Code: M01AE01

Mechanism of action

Ibuprofen has analgesic, antipyretic and anti-inflammatory activities.

5.2 Pharmacokinetic properties

Well-absorbed after oral administration and peak concentrations are observed after 1 to 2 hours. The onset of action for pain relief is 30 minutes and the time for peak effect for fever is 2 to 4 hours. The half-life of ibuprofen is about 2 hours. Ibuprofen is extensively bound to plasma-proteins. More than 90 % of an ingested dose is excreted in the urine as metabolites or their conjugates. Ibuprofen passes slowly into the synovial spaces, remaining there in higher concentrations, as the plasma concentration of ibuprofen declines.

Ibuprofen inhibits platelets aggregation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Pregelatinised starch

Maize/corn starch

Colloidal silicon dioxide

Magnesium stearate

Film coating (Instacoat: A05R03239 - Pink):

Titanium dioxide

HPMC 2910-Hypromellose

Polyethylene glycol

Polysorbate 80

Lake erythrosine

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

IBUSOR 200:

In patient ready pack pouches (PRP's) - 24 months.

In HDPE containers – 48 months.

IBUSOR 400:

24 months.

6.4 Special precautions for storage

Store in a dry place, at or below 25 °C. Protect from light.

6.5 Nature and contents of container

15 or 84 tablets in silver bioxilary oriented polypropylene patient ready packs.

100 tablets in clear transparent PVC/aluminium foil blister strips (10 x 10).

100 tablets in milky-white high-density polyethylene containers.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Shanur Healthcare (Pty) Ltd

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8. REGISTRATION NUMBERS

IBUSOR 200 film-coated tablets: 37/3.1/0479

IBUSOR 400 film-coated tablets: 37/3.1/0480

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 November 2005

10. DATE OF REVISION OF THE TEXT

07 February 2025