Approved Patient Information Leaflet for Medicines for Human Use:

IBUSOR 200 and IBUSOR 400

SCHEDULING STATUS: S3

IBUSOR 200 mg film-coated tablets

IBUSOR 400 mg film-coated tablets

Ibuprofen

Sugar free

Read all of this leaflet carefully before you start taking IBUSOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- IBUSOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What IBUSOR is and what it is used for
2. What you need to know before you take IBUSOR
3. How to take IBUSOR
4. Possible side effects
5. How to store IBUSOR
6. Contents of the pack and other information

1. What IBUSOR is and what it is used for

IBUSOR contains the active substance called ibuprofen which belongs to the group of medicines called anti-inflammatory pain killers (also called nonsteroidal anti-inflammatory drugs NSAIDs).

IBUSOR has pain relieving, fever reducing and anti-inflammatory actions.

IBUSOR is used for:

- rheumatoid arthritis (chronic disease of the system, mainly inflammation of joints)
- idiopathic juvenile arthritis (Still's disease) of children
- ankylosing spondylitis (immobility of a joint due to disease)
- osteo-arthritis (a non-inflammatory change to a less active form of joints)
- arthritis due to gout
- non-articular (non-joint) rheumatism including fibrositis (inflammation with pain and stiffness)
- non-rheumatic inflammatory conditions such as capsulitis (frozen shoulder), bursitis (inflammation of sac like cavity filled with a liquid in the tissues), tendonitis (inflammation of the tendons), tenosynovitis (inflammation of the membranes of the tendon) and low back pain
- relief of mild to moderate pain such as painful menstruation, dental, after prevention of tearing during delivery and pain after childbirth
- soft tissue injuries such as sprains and strains
- fever.

2. What you need to know before you take IBUSOR

Do not take IBUSOR

- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of IBUSOR (listed in section 6).
- if you have heart failure.
- if you have active or recurrent stomach ulcer disease or gastro-intestinal bleeding.
- If you have a history of gastro-intestinal bleeding, ulcers or perforation related to previous anti-inflammatory pain killers (NSAIDs).
- If you are sensitive to aspirin or another nonsteroidal anti-inflammatory medicine.
- If you have a history of severe allergic reaction such as anaphylaxis or angioedema (allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing), induced by aspirin or other NSAIDs.
- If you have aspirin-induced nasal protruding growths associated with bronchospasm.
- If you have asthma which has symptoms of breathlessness, wheezing, a cough sometimes

brought on by exercise, and a feeling of tightness in the chest.

- If you have or ever had any history of kidney disease which has symptoms of little or no urine, drowsiness, nausea, vomiting, breathlessness (renal failure).
- if you are under 12 years old.
- If you are pregnant, do not use IBUSOR at 20 weeks or later in pregnancy because these medicines may cause harm in your unborn baby.
- if you are in the third trimester of pregnancy and during labour.
- If you are breastfeeding.

Warnings and precautions

IBUSOR may hide signs of infections such as fever and pain. It is therefore possible that IBUSOR may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have
an infection and your symptoms of the infection persist or worsen, consult a medical practitioner without delay.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). If you have frequent or daily headaches despite (or because of) the regular use of pain killers, you should not treat your headache with increased doses of IBUSOR. Tell your doctor if you have been having headaches while taking IBUSOR.

Tell your doctor or pharmacist:

- if you are elderly, or suffer from asthma or bronchospasm, bleeding disorders, perforation in the digestive tract, heart disease and in liver or kidney failure.
- if you have a history of peptic ulcers and other stomach or bowel disease (including ulcerative colitis, Crohn’s disease)
- if you experience any unusual abdominal symptoms (especially bleeding from the stomach or

bowel) during treatment with IBUSOR.

- if you have a history of high blood pressure and/or heart failure. Ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses.

Special care should be taken with IBUSOR

- if you have not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea, especially in children, if you are between the ages of 12 -18 years or are an older person
- if you have an abnormal accumulation of fluid due to heart disease, cirrhosis (liver disease), volume depletion due to water tablets or kidney problems.
- if you have systemic lupus erythematosus (SLE) - a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs.
- If you develop a skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- Severe skin reactions like Stevens-Johnson syndrome and toxic epidermal necrolysis - these are indicated by fever and body aches, painful/reddish rash on the skin, mouth, throat and/or genitals followed by blistering.
- if you are receiving anti-blood clotting medicine (such as warfarin).
- if you have a disease of the connective tissue, you may be at risk of developing aseptic meningitis (inflammation of the membranes of the brain).
- if you experience blurred or diminished vision, or changes in colour vision.

If you are taking IBUSOR for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Other medicines and IBUSOR

Always tell your health care provider if you are taking any other medicine. (This includes all

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complementary or traditional medicines.)

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with IBUSOR:

- anti-coagulants (like warfarin) to prevent blood clots
- corticosteroid tablets (medicine used to suppress the immune system)
- clopidrogel, and ticlopidine (medicines used to “thin” the blood)
- pentoxyfylline (medicine used in the treatment of blood vessel disorders)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes or high blood sugar levels)
- lithium (medicine used to treat bipolar disorder)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (medicine used to suppress the immune system))
- antihypertensives (medicines for high blood pressure) or diuretics “water tablets”
- digoxin (medicine used to treat heart conditions
- cholestyramine (a drug used to lower cholesterol)
- mifepristone (medicine used for abortions)
- any other anti-inflammatory pain killers including aspirin or ibuprofen preparations, such as those you can buy without a prescription
- antibiotics called quinolones such as ciprofloxacin
- zidovudine (medicine used for HIV)
- aminoglycosides (a type of antibiotic)
- ginkgo biloba (herbal medicine)
- fluconazole or voriconazole (antifungal medicines).

IBUSOR with alcohol

IBUSOR may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with IBUSOR might make these side effects worse.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking IBUSOR.

Pregnancy

Do not use IBUSOR at 20 weeks or later in pregnancy-because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

Additionally, do not use IBUSOR at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.

If taken late in pregnancy, may increase the length of pregnancy, prolong labour, or cause other problems during the delivery.

Breastfeeding

You should not use IBUSOR if you are breastfeeding.

Fertility

IBUSOR may make it more difficult to become pregnant. You should inform your health care professional if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

It is not always possible to predict to what extent IBUSOR may interfere with the daily activities of a

patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IBUSOR affects them.

IBUSOR may cause dizziness, drowsiness, fatigue and visual disturbances. If you experience this do not drive or operate any machinery.

3. How to take IBUSOR

Do not share medicines prescribed for you with any other person.

Always take/use IBUSOR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose of IBUSOR unless otherwise recommended by your doctor is 600 mg every 6 to 8 hours. Do not take more than 2 400 mg of IBUSOR per day.

Children:

This formulation is not suitable for children under the age of 12 years.

Duration of administration

Your doctor will tell you how long your treatment with IBUSOR will last. Always use the lowest effective dose for the shortest possible duration of treatment. If you have the impression that the effect of IBUSOR is too strong or too weak, tell your doctor or pharmacist.

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.

If you take more IBUSOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may experience nausea, stomach pain, vomiting, drowsiness, headache, ringing in the ears, confusion and shaky eye movement. Other symptoms include chest pain, palpitations, loss of consciousness, convulsions, dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

Treatment is symptomatic and supportive.

If you forget to take IBUSOR

If you miss a dose of IBUSOR, take it as soon as you remember unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

IBUSOR can have side effects.

Not all side effects reported for IBUSOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUSOR, please consult your health care provider for advice.

If any of the following happens, stop taking IBUSOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to IBUSOR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light
- signs of intestinal bleeding such as passing blood in your faeces (stools/motions), black tarry stools or vomiting any blood or dark particles that look like coffee grounds
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- skin becomes sensitive to light
- IBUSOR, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness
- yellowing of the eyes or skin which can be a sign of liver disease and liver failure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, diarrhoea/constipation, excessive wind, feeling sick and/or vomiting
- headache
- dizziness
- tiredness.

Less frequent side effects:

- sneezing, blocked, itchy or runny nose (rhinitis)
- low blood cell count (anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis)
- difficulty sleeping
- anxiety
- depression and confusion
- feeling a tingling sensation or ‘pins and needles’
- disturbed vision (visual impairment)
- inflammation or damage of optic nerve
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)
- increased risk of heart attack or heart failure
- increase in blood pressure
- asthma
- difficulty breathing
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- inflammation of your pancreas

- oedema (swelling).

Side effects with frequency unknown:

- blurred vision
- changes in visual colour perception
- toxic amblyopia (lazy eye syndrome)
- worsening of colitis (inflammation of the colon) or Crohn's disease (chronic inflammatory disease of the intestines).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of IBUSOR**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za.

5. How to store IBUSOR

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IBUSOR contains

- The active substance is ibuprofen.
- The other ingredients are pregelatinised starch, maize/corn starch, colloidal silicon dioxide and magnesium stearate.
- The film coating consists of titanium dioxide, hypromellose, polyethylene glycol, polysorbate, and lake erythrosine.

IBUSOR 200 tablets:

Each film coated tablet contains ibuprofen 200 mg.

Sugar-free.

IBUSOR 400 tablets:

Each film coated tablet contains ibuprofen 400 mg.

Sugar-free.

What IBUSOR looks like and contents of the pack

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

IBUSOR is supplied in:

- 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.

Holder of Certificate of Registration

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

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

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://shanur.co.za/product-info/

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