Approved Patient Information Leaflet

SCHEDULING STATUS

S3

AUSTIFEN-200 TABLETS

AUSTIFEN-400 TABLETS

AUSTIFEN-600 TABLETS

Ibuprofen

Contains sugar (lactose monohydrate)

Each AUSTIFEN–200 film coated tablet contains 8,00 mg lactose monohydrate

Each AUSTIFEN-400 film coated tablet contains 16,00 mg lactose monohydrate

Each AUSTIFEN–600 film coated tablet contains 24,00 mg lactose monohydrate

Read all of this leaflet carefully before you start taking AUSTIFEN

- 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.
- AUSTIFEN 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 AUSTIFEN is and what it is used for

2. What you need to know before you take AUSTIFEN

3. How to take AUSTIFEN

4. Possible side effects

5. How to store AUSTIFEN

6. Contents of the pack and other information

1. What AUSTIFEN is and what it is used for

AUSTIFEN is used to relieve pain and inflammation in conditions such as osteo-arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and Still's disease), ankylosing spondylitis (inflammation of one or more of the vertebrae), swollen joints, frozen shoulder, bursitis (inflammation of the bursa), tendonitis (inflammation of a tendon), tenosynovitis (inflammation of the tenosynovial fluid), low back pain, sprains and strains. AUSTIFEN can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headaches.

2. What you need to know before you take AUSTIFEN

Do not take AUSTIFEN Tablets:

If you:

- are allergic to ibuprofen or any of the ingredients of AUSTIFEN
- are suffering from (or have suffered from) stomach ulcer disease, perforations or gastrointestinal bleeding
- have a history of severe allergic reactions such as wheezing or swelling of the face or throat after taking ibuprofen, aspirin or other anti-inflammatory medicines
- suffer from heart disease including heart failure
- have had nasal polyps with breathing difficulties when taking aspirin
- are pregnant or in labour
- have severe liver or kidney problems.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking AUSTIFEN.

Warnings and precautions

Take special care with AUSTIFEN

Tell your doctor before taking or whilst taking AUSTIFEN:

- if you have or have had high blood pressure (hypertension) or other heart problems such as a

heart attack or any kind of stroke

- if you have bowel problems (including ulcerative colitis, Crohn's disease, gastro-oesophageal reflux disease)
- if you suffer from a bleeding disorder
- if you are taking medicine to thin your blood
- if you have or have had asthma or bronchospasm
- if you have anaemia
- if you have systemic lupus erythematosus (SLE), this is an immune condition which causes joint pain and changes to the skin
- if you are taking medicine which "thins" the blood such as warfarin, or any other non-steroidal anti-inflammatory medicines.
- if you have not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea, especially if you are between the ages of 12 -18 years or are an older person
- if you have an infection
- if you develop a problem with your vision
- if you develop a rash and swollen glands
- 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 AUSTIFEN. Tell your doctor if you have been having headaches while taking AUSTIFEN.

Taking AUSTIFEN while you are pregnant may cause kidney problems in your unborn baby and this can lead to low levels of the amniotic fluid that surrounds your baby. This fluid provides a protective cushion for the baby and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur when the amniotic fluid is low. Use of AUSTIFEN in the last trimester can also cause problems with the baby's heart/ blood pressure.

Children and adolescents

AUSTIFEN tablets are not recommended for children under the age of 12 years.

Other medicines and AUSTIFEN

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking other medicines on a regular basis, concomitant use of AUSTIFEN may cause undesirable interactions.

If you are taking any of the following medicines:

- anti-coagulants (like warfarin) to prevent blood clots
- anti -hypertensives (medicines for high blood pressure) or diuretics “water tablets”
- digoxin (medicine used to treat heart conditions), lithium (medicine used to treat bipolar disorder), corticosteroid tablets (medicine used to suppress the immune system), methotrexate (medicine used in the treatment of cancer or some types of arthritis), clopidrogel, and ticlopidine (medicines used to “thin” the blood), oxpentifylline (medicine used in the treatment of blood vessel disorders) or ciclosporin (medicine used to suppress the immune system)
- antidiabetic medicines (medicine used to treat high blood sugar levels)
- anti-depressants, like sertraline, paroxetine and those falling under the class of selective serotonin reuptake inhibitors (SSRIs)
- any other anti-inflammatory pain killers including aspirin or ibuprofen preparations, such as those you can buy without a prescription
- mifepristone (medicine used for abortions)
- antibiotic medicines such as ciprofloxacin or moxifloxacin or amikacin
- ginkgo biloba (herbal medicine)
- zidovudine (medicine used for HIV)
- tacrolimus (medicine used to suppress the immune system)

- fluconazole or voriconazole (antifungal medicines).

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with AUSTIFEN.

AUSTIFEN with food, drink and alcohol

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

See section 3 for more information on how to take AUSTIFEN.

Pregnancy, breastfeeding and fertility

AUSTIFEN is not for use in pregnancy and during labour.

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 AUSTIFEN.

If you are trying to become pregnant: ibuprofen belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that ibuprofen, used occasionally will affect your chances of becoming pregnant, however, tell your doctor before taking AUSTIFEN, if you have problems becoming pregnant.

Driving and using machines

AUSTIFEN may make you feel dizzy, drowsy, tired or cause disturbances in your vision. Do not drive or operate machinery until you know how AUSTIFEN affects you.

AUSTIFEN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your

doctor before taking AUSTIFEN.

3. How to take AUSTIFEN

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

Always take AUSTIFEN exactly as your doctor instructed you. You should check with your doctor or pharmacist if you are not sure.

AUSTIFEN may be taken on an empty stomach with a glass of water. However if you experience mild indigestion or heart burn, it may help to take the tablets with meals.

The recommended daily dose of AUSTIFEN is 1200 mg spread throughout the day. Some patients may be maintained on 600 mg to 1200 mg daily. To relieve early morning stiffness, the first dose of the day can be taken immediately after awaking.

For the relief of mild to moderate pain, the following doses are recommended:

Menstrual pain – 1200 mg per day in three divided doses.

In cases of toothache or pain after an operation, an initial dose of 800 mg may be given.

The total daily dose of AUSTIFEN should not exceed 2400 mg.

Acute gout

2400 mg daily either as 800 mg 8 hourly or 600 mg 6 hourly until the acute symptoms have been relieved. If the symptoms do not resolve within three days, consult a health professional.

Children

In Juvenile Rheumatoid Arthritis, the total daily dosage of AUSTIFEN is 20 mg / kg of body mass is to be given in divided doses.

Safety in children under one year of age has not been proven.

Pain

Initial dose 5 mg/kg of body weight. 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. If pain persists for more than 7 days, consult a medical professional.

Fever

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

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

If fever persists for more than 7 days, consult a medical professional.

than 7 days, consult your doctor.

If you take more AUSTIFEN than you should

If you have taken too much AUSTIFEN you may experience pain in the stomach and nausea (feeling sick).

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

If you forget to take AUSTIFEN

If you forget to take a dose, take it as soon as you remember it. If it is almost time for the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

AUSTIFEN tablets can have side effects.

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

health care provider for advice.

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

- any signs of bleeding from the stomach or bowels (vomiting blood and/or passing black stools)
- wheezing, shortness of breath, difficulty breathing, swelling of the face, tongue or throat, worsening of asthma
- severe skin rash with redness, peeling, blistering, itching or bruising, you may also have a fever and a sore throat
- hives, fever (high temperature), swollen glands that do not go away, swelling of your lips and tongue, yellowing of your skin or the whites of your eyes, unusual bruising or bleeding, severe fatigue or weakness, unexpected pain in the muscles, frequent infections
- loss of balance, difficulty speaking or understanding others who are speaking, numbness or paralysis in the face, leg or arm, most likely on just one side of the body. These may also be signs of a stroke
- pain in the chest or discomfort including pain which radiates to the arm or jaw, with shortness of breath, nausea or light-headedness. These may be signs of a heart attack
- yellowing of the eyes or skin which can be a sign of liver disease
- neck stiffness, headache, feeling sick, being sick, fever, loss of conscious, these may be signs of aseptic meningitis
- swelling of your limbs, especially your feet or feeling short of breath or breathlessness even while resting or a persistent wheezing together with fatigue (extreme tiredness), these may be signs of your heart failing
- noticing blood in your urine or cloudy urine, back pain and/ or fluid retention, for example swollen ankles, these may be signs of problems with your kidneys

These are very serious side effects. If you have them, you may have had a serious reaction to

AUSTIFEN. You may need urgent medical attention or hospitalisation.

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

Frequent:

- unexplained stomach pain

Less frequent:

- blurred or disturbed vision
- fever, constant flu-like symptoms, sore throat, mouth ulcers, or noticing that you get infections more often
- easy bruising of the skin or noticing that it takes long for your blood to clot after an injury
- a ringing sound in the ears
- faster heartbeat.
- bladder infection

Frequency not known:

- worsening of colitis (inflammation of the colon) or Crohn's disease (chronic inflammatory disease of the intestines).

Tell your doctor if you notice any of the following:

Frequent:

- burning, indigestion, nausea or vomiting
- feeling extremely tired.
- constipation, flatulence (passing wind), stomach cramps, diarrhoea
- painful mouth ulcers
- headache, dizziness.

Less frequent:

- runny nose

- depression
- hot flushes, increase in blood pressure
- having difficulty falling off to sleep or maintaining sleep, feeling anxious
- swelling of the limbs
- tingling sensation in the skin; sensitivity of the skin to light; itchiness of skin, blood spots on skin
- feeling nervous, sleepy or drowsy.

Frequency not known:

- abnormal liver function tests (noticed on a blood test).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AUSTIFEN.

5. How to store AUSTIFEN

Keep this medicine in a dry place at or below 25 °C. Protect from light.

Keep the blister packs in the outer carton until required for use. Do not transfer the medicine to any other container.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage system (e.g toilets).

DO NOT USE AFTER THE DATE, WHICH IS STAMPED ON THE PACK.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

The active ingredient in AUSTIFEN is ibuprofen. The tablets are available in three different strengths containing either 200 mg, 400 mg or 600 mg of Ibuprofen.

The other ingredients are:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, polyvinyl povidone, maize starch, sodium lauryl sulphate, magnesium stearate, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyethylene glycol 400 and titanium dioxide.

What AUSTIFEN looks like and contents of the pack

AUSTIFEN-200

White, circular, film-coated tablets, plain on both the sides.

Blister packs of 12's, 15's, 16's, 24's, 42's, 48's or 84's.

Bulk pack of 1000's.

AUSTIFEN-400

White capsule shaped film-coated tablets, plain on both the sides.

Blister packs of 12's, 15's, 16's, 24's, 42's, 48's or 84's.

Bulk pack of 1000's.

AUSTIFEN-600

White capsule shaped film-coated tablets, plain on one side & breakline on the other side.

Blister packs of 12's, 15's, 16's, 24's, 42's, 48's or 84's.

Bulk pack of 1000's.

Holder of Certificate of Registration

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