Approved Patient Information Leaflet for Medicines for Human Use:

AUSTIFEN

SCHEDULING STATUS

S3

AUSTIFEN-200 TABLETS

AUSTIFEN-400 TABLETS

AUSTIFEN-600 TABLETS

Ibuprofen

Contains sugar: lactose monohydrate.

AUSTIFEN-200 TABLETS

Each film coated tablet contains 8,00 mg lactose monohydrate.

AUSTIFEN-400 TABLETS

Each film coated tablet contains 16,00 mg lactose monohydrate.

AUSTIFEN-600 TABLETS

Each 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 belongs to a group of medicines called anti-inflammatory pain killers (also called nonsteroidal anti-inflammatory drugs NSAIDs). The active ingredient, ibuprofen, has pain relieving, fever reducing and anti-inflammatory actions.

AUSTIFEN is used for:

- rheumatoid arthritis (chronic disease of the system, mainly inflammation of joints)
- idiopathic juvenile arthritis (Still's disease) of children
- ankylosing spondylitis (inflammation of one or more of the vertebrae)
- 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 frozen shoulder (capsulitis), 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 AUSTIFEN

Do not take AUSTIFEN Tablets:

- if you are allergic to ibuprofen or any of the ingredients of AUSTIFEN
- if you are suffering from (or have suffered from) stomach ulcer disease, perforations or

gastrointestinal bleeding

- if you are sensitive to aspirin or another nonsteroidal anti-inflammatory medicine
- if you 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
- if you suffer from heart disease including heart failure
- if you have had nasal polyps with breathing difficulties when taking aspirin
- if you are pregnant or in labour
- if you have severe liver or kidney problems
- if you are pregnant, do not use AUSTIFEN at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because these medicines may cause harm in your unborn baby.

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.

Repeated use of AUSTIFEN may result in you becoming accustomed to it (needing to take higher doses). Repeated use of AUSTIFEN may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
If you are taking AUSTIFEN 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).

If you experience any of the following signs whilst taking AUSTIFEN, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised.
- You need to take more than the recommended dose.
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'.
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine.
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects').

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), clopidogrel, 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.

To minimize gastrointestinal side-effects or if gastrointestinal disturbances occur,

AUSTIFEN should be given with food or milk.

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

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 AUSTIFEN.

Pregnancy

AUSTIFEN is not for use in pregnancy and during labour.

Do not use AUSTIFEN at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional 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 AUSTIFEN 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.

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.

Breastfeeding

You should not use AUSTIFEN if you are breastfeeding.

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 1 200 mg spread throughout the day. Some patients may be maintained on 600 mg to 1 200 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 – 1 200 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 2 400 mg.

Acute gout

2 400 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)

- AUSTIFEN, 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.

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. 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 AUSTIFEN.

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

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 expiry date which is stated on the carton.

Store all medicines out of the reach of children.

6. Contents of the pack and other information

The active substance 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 TABLETS:

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 1 000's.

AUSTIFEN-400 TABLETS:

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 1 000's.

AUSTIFEN-600 TABLETS:

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 1 000's.

Holder of Certificate of Registration

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AUSTIFEN-600 TABLETS: 42/3.1/0060

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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