Approved Patient Information Leaflet for Medicines for Human Use: IBROFEX 400

SCHEDULING STATUS: S3

IBROFEX 400 Film-coated tablets

Ibuprofen

Sugar free.

Read all of this leaflet carefully before you start taking IBROFEX 400

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your medical practitioner, pharmacist, nurse or other health care provider.
- IBROFEX 400 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 IBROFEX 400 is and what it is used for
2. What you need to know before you take IBROFEX 400
3. How to take IBROFEX 400
4. Possible side effects
5. How to store IBROFEX 400
6. Contents of the pack and other information

1. What IBROFEX 400 is and what it is used for

IBROFEX 400 tablets contains the active substance ibuprofen and belongs to a group of medicines called antirheumatics.

IBROFEX 400 is used for the treatment of mild to moderate pain of inflammatory origin and fever,

including:

- Soft tissue injuries such as sprains and strains
- headache
- back pain of musculo-skeletal origin
- fever
- muscular aches and pain
- menstrual pain
- toothache
- pain associated with migraine
- earache.

2. What you need to know before you take IBROFEX 400

Do not take IBROFEX 400

- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of IBROFEX 400 (listed in section 6)
- if you have experienced asthma, skin rash or any allergic-type reaction after taking aspirin, ibuprofen or any other non-steroidal anti-inflammatory medicine.
- if you have a history of perforation or bleeding from the stomach or bowel related to previous use of a medicine belonging to a class of medicines called non-steroidal anti-inflammatory NSAID's.
- if you have or had a history of peptic ulceration, ulcerative colitis or Crohn's disease.
- if you have heart failure
- if you have severe kidney problems.

If you are uncertain whether any of these apply to you, please discuss this with your medical practitioner or pharmacist before taking IBROFEX 400.

Warnings and precautions

Take special care with IBROFEX 400

Tell your medical practitioner before taking or whilst taking IBROFEX 400:

- if you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- if you are asthmatic or suffer from kidney, liver or bowel problems, or from hayfever
- if you are suffering from 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 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 medical practitioner before taking this medicine, if you have problems becoming pregnant)
- if you are in the first 6 months of pregnancy
- if you are 12-18 years old as there is a risk of renal impairment. Therefore ask a medical practitioner before use if you are a 12-18 year old who has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea.
- if you have an infection - please see heading "Infections" below.

The elderly have an increased frequency of adverse reactions to NSAIDs including IBROFEX 400, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

Skin reactions

Serious skin reactions have been reported in association with Anadin Joint Pain treatment. You should stop taking Anadin Joint Pain and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Infections

IBROFEX 400 may hide signs of infections such as fever and pain. It is therefore possible that IBROFEX 400 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.

Children and adolescents

IBROFEX 400 tablets are not recommended for children under the age of one year.

Other medicines and IBROFEX 400

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Taking Other Medicines

Do not use the medicine if you are:

- taking other NSAID painkillers, or aspirin with a daily dose above 75 mg

IBROFEX 400 may affect or be affected by some other medicines.

Talk to your medical practitioner or pharmacist if you are taking:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid,

warfarin, ticlopidine).

- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).
- medicines such as corticosteroids, antiplatelet medicines, cardiac glycosides, selective serotonin reuptake inhibitors, lithium, methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine, or quinolone antibiotics.
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Alcohol: IBROFEX 400 may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with IBROFEX 400 might make these side effects worse.

Some other medicines may affect or be affected by the treatment of IBROFEX 400. You should therefore always seek the advice of your medical practitioner or pharmacist before you use IBROFEX 400 with other medicines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your medical practitioner, pharmacist or other health care provider for advice before taking IBROFEX 400.

You should not use IBROFEX 400 in the last 3 months of pregnancy or during labour. You should not use IBROFEX 400 when you breastfeed your baby.

Driving and using machines

IBROFEX 400 may make you feel drowsy/sleepy, tired and disturb your vision.

Do not drive or operate any tools or machines until you are aware of the measure to which IBROFEX 400 affects you.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take IBROFEX 400

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

Always take IBROFEX 400 exactly as your medical practitioner or pharmacist has instructed you. Check with your medical practitioner or pharmacist if you are not sure.

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

Adults:

The recommended dose is 1200 mg daily in divided doses (1 to 2 tablets every four hours) for the relief of:

1) Mild to moderate pain of

- Soft tissue injuries such as sprains and strains
- Toothache
- Back pain of musculo-skeletal origin
- Earache
- Pain associated with migraine
- Muscular ache and pains
- Fever
- Period pain

Children

Not to be given to children under 12 years of age.

Duration of administration

Your medical practitioner will tell you how long your treatment with IBROFEX 400 will last. Do not stop treatment early. If you have the impression that the effect of IBROFEX 400 is too strong or too weak, tell your medical practitioner or pharmacist.

Method of administration

You can take IBROFEX 400 with meals. If you have a sensitive stomach, you should best take IBROFEX 400 with meals or milk.

If you take more IBROFEX 400 than you should

If you take more tablets than you should or if children have taken the medicine by accident always contact a medical practitioner or nearest hospital to get an opinion of the risk and advice on action to be taken. Bring any remaining tablets with you to show your medical practitioner. The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take IBROFEX 400

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

IBROFEX 400 can have side effects.

Not all side effects reported for IBROFEX 400 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBROFEX 400, please consult your health care provider for advice.

If any of the following happens, stop taking IBROFEX 400 and tell your medical practitioner 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
- severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools
- stiff neck, headache, nausea, vomiting, fever or feeling disorientated.
- 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
- Worsening of asthma and wheezing or difficulty breathing

These are very serious side effects. If you have them, you may have had a serious reaction to IBROFEX 400. You may need urgent medical attention or hospitalisation.

Tell your medical practitioner if you notice any of the following:

Less frequent side effects:

- hives
- skin rashes
- itching
- abdominal pain
- indigestion

- heartburn
- nausea
- headache
- diarrhoea
- flatulence or wind
- constipation
- vomiting
- pale skin or yellow, cause fever, sore throat, mild mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose
- high blood pressure, heart failure or chest pain
- nervousness, visual impairment, ringing in the ears and vertigo
- yellowing of the skin or the whites of the eyes
- swelling of the ankles
- blistering
- swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- feeling depressed or confused
- feeling anxious
- difficulty sleeping
- feeling a tingling sensation or ‘pins and needles’
- hearing problem

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

Reporting of side effects

If you get side effects, talk to your medical practitioner or pharmacist or nurse. You can also report

side effects to SAHPRA via the "**6.04 Adverse Medicine 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 IBROFEX 400.

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 IBROFEX 400

Store all medicines out of reach of children

- Store in a cool dry place at or below 25 °C.
- Protect from light.
- Keep the blister in the carton until required for use.

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 IBROFEX 400 contains

- The active substance is ibuprofen. Each film-coated tablet contains ibuprofen 400 mg.
- The other ingredients are

  Tables core

  Colloidal silicon dioxide

  Maize starch

  Magnesium stearate

  Purified talc

  Sodium lauryl sulfate

Sodium starch glycolate (type A)

Film-coating

Instacoat-pink (A05R03211) consisting of:

Hypromellose

Lake erythrosine

Propyl glycol

Sodium acetate

Titanium dioxide.

What IBROFEX 400 looks like and contents of the pack

IBROFEX 400 tablets are pink coloured, circular, slightly biconvex film-coated tablets.

IBROFEX 400 is supplied in

- Blister packs (composed of colourless PVC and aluminium foil) of 10 tablets or 84 tablets per carton.
- Opaque white High Density Polyethylene (HDPE) containers containing 1 000 tablets.
- White Low Density Polyethylene (LDPE) plastic Patient Ready Packs (PRPs) containing different pack sizes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG, 2193

Tel: +27 11 611 1400 or +27 860 287 835

This leaflet was last revised in

Registration/Application number

56/3.1/1085

Access to the corresponding Professional Information

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

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

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835s