Approved Patient Information Leaflet: IBUCARE-200

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

IBUCARE-200 TABLETS

Read all of this leaflet carefully because it contains important information for you

IBUCARE-200 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **IBUCARE-200** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **IBUCARE-200** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

1. WHAT IBUCARE-200 CONTAINS

The active ingredient in **IBUCARE-200** is Ibuprofen.

Colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyvinyl povidone, sodium lauryl sulphate,

Film-coating:

Hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyethylene glycol, titanium dioxide.

Contains sugar (lactose).

2. WHAT IBUCARE-200 IS USED FOR

IBUCARE-200 is used for relief from pain such as back pain which is musculo-skeletal (i.e. pain related to the muscles and bones), muscle aches and pain, other painful conditions such as toothache, period pain and headaches. It can also be used for relief from migraine and for feverishness.

3. BEFORE YOU TAKE IBUCARE-200

Do not take IBUCARE-200 Tablets:

If you:

- Are allergic to any of the ingredients of **IBUCARE-200**.
- Are suffering from (or have suffered from) stomach ulcer disease, perforations or gastrointestinal bleeding.
- Have history of severe allergic reactions such as wheezing after taking ibuprofen, aspirin or other anti-inflammatory medicines.
- If you suffer from heart disease.
- If you are under 12 years of age.
- If you have had nasal polyps with breathing difficulties when taking aspirin.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking **IBUCARE-200**.

Take special care with IBUCARE-200

Talk to your doctor before taking or whilst taking **IBUCARE-200**:

- If you have or have had high blood pressure (hypertension).
- If you are pregnant (especially if you are in the third trimester of your pregnancy).
- If you have kidney, liver or bowel problems (including ulcerative colitis, Crohn's disease, gastro-oesophageal reflux disease).
- If you suffer from a bleeding disorder.

- If you have or have had asthma.
- 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 “thin” the blood such as warfarin.

Taking IBUCARE-200 with food and drink

Take **IBUCARE-200** tablets with a drink of water.

If you experience mild indigestion or heart burn, it may help to take the tablets with meals.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking **IBUCARE-200**.

Driving and using machinery

Do not drive or operate machinery until you know how **IBUCARE-200** affects you.

Important information about some of the ingredients of IBUCARE-200

IBUCARE-200 contains lactose monohydrate. Patients with rare hereditary conditions of lactose or galactose intolerance should not take **IBUCARE-200**.

Using other medicines with IBUCARE-200

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

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 cyclosporine (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 Re-uptake inhibitors.
- Any other anti-inflammatory pain killers or ibuprofen preparations, such as those you can buy without a prescription.

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with **IBUCARE-200**.

4. HOW TO TAKE IBUCARE-200

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

Adults and children over 12 years:

Initial dose 2 tablets taken with water, then if necessary, 1 or 2 tablets every four hours.

Migraine:

Take 2 tablets three times a day.

Do not exceed 6 tablets in any 24 hours. Not to be given to children under 12 years. If symptoms persist for more than 7 days, consult your doctor.

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

You should check with your doctor or pharmacist if you are unsure.

IBUCARE-200 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.

If you take more IBUCARE-200 than you should:

If you have taken too much **IBUCARE-200** 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 control centre.

If you forget to take a dose of IBUCARE-200:

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.

5. POSSIBLE SIDE EFFECTS

IBUCARE-200 can have side effects.

Not all side-effects reported for **IBUCARE-200** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **IBUCARE-200**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking **IBUCARE-200** 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, severe skin rash with redness, peeling, blistering, itching or bruising.
- Yellowing of the eyes or skin which can be a sign of liver disease.
- Neck stiffness, headache, felling 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 **IBUCARE-200**. You may need urgent medical attention or hospitalisation.

Contact a doctor as soon as possible:

Frequent:

- Severe stomach pain, with or without nausea (feeling sick), vomiting (being sick).
- Burning sensation in the stomach.
- Worsening of colitis (inflammation of the colon) or Crohn's disease (chronic inflammatory disease of the intestines).

Less frequent:

- Blurred or disturbed vision.
- 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.
- Feeling extremely tired.
- A ringing sound in the ears.
- Faster heartbeat.

Tell your doctor if you notice any of the following:

Frequent:

- Constipation, indigestion, flatulence (passing wind), stomach cramps.
- Painful mouth ulcers.

Less frequent:

- Headache.
- Depression.
- Having difficulty falling off to sleep or maintaining sleep.

- Flushing, increase in blood pressure.
- Feeling dizzy, nervous or drowsy.

Frequency not known:

- Abnormal liver function tests (noticed on a blood test).
- Itchiness of skin.

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

6. STORING AND DISPOSING OF IBUCARE-200

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.

7. PRESENTATION OF IBUCARE-200

Blister packs of 10’s, 12’s, 15’s, 16’s, 20’s, 24’s.

8. IDENTIFICATION OF IBUCARE-200

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

9. REGISTRATION NUMBER

42/3.1/0061

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Laboratories (Pty) Ltd.

52 Mineral Crescent

Crown ext 3

Johannesburg, 2092

South Africa.

Tel: 011 611 1400

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on the registration certificate of the medicine: 09 October 2009