SCHEDULING STATUS

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BRUFEN® 200 (Film-coated tablets)

Read all of this leaflet carefully before you start using BRUFEN® 200

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BRUFEN® 200** 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.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

1. WHAT BRUFEN® 200 CONTAINS

BRUFEN® 200: Each film-coated tablet contains 200 mg ibuprofen.

Other ingredients include: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, colloidal anhydrous silica, sodium laurilsulfate, magnesium stearate, hypromellose, talc, titanium dioxide, dry color dispersion, white 06A28611 and opaspray white M-1-7111B,

Contains lactose monohydrate

2. WHAT BRUFEN® 200 IS USED FOR

BRUFEN® 200 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

3. BEFORE YOU USE BRUFEN® 200

Do not use BRUFEN® 200:

If you ……

- Are allergic to **ibuprofen** or any of the other ingredients in **BRUFEN® 200.**
- Have experienced asthma, skin rash or any allergic-type reaction after taking aspirin, ibuprofen or any other non-steroidal anti-inflammatory drug.
- 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 .
- Have or had a history of peptic ulceration, ulcerative colitis or Crohn's disease.
- Have heart failure.
- Have renal failure.

Do not use BRUFEN® 200 during the third trimester of pregnancy, labour and delivery.

Take special care with BRUFEN® 200:

- Speak to your doctor or pharmacist if you are **allergic to ibuprofen** or to any other substances such as other medicines, colourants, preservatives or foods.
- Speak to your doctor or pharmacist about **all other medicines that you are taking.** This includes other prescription medicines, medicines bought without a prescription, and herbal medicines. Taking any other medicine together with **BRUFEN® 200** may cause undesirable interactions.
- Speak to your doctor if you have any **other medical problems** such as asthma, high blood pressure, heart failure, a stomach ulcer, bleeding from the stomach or bowel or any other gastric complaint.
- If your body cannot tolerate milk and dairy products (lactose intolerant). **BRUFEN® 200 c**ontains lactose monohydrate and should not be given to patients with rare hereditary problems or history of galactose intolerance, lapp lactose deficiency or glucose-galactose malabsorption
- If you have a history of high blood pressure and/or heart failure.
- If you have a history of peptic ulcers and other stomach or bowel disease.
- If you experience any unusual abdominal symptoms (especially bleeding from the stomach or bowel) during treatment with **BRUFEN® 200**.
- If you are an elderly person: The elderly have an increased frequency of adverse reactions to NSAIDs including **BRUFEN® 200**, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

Serious skin reactions, some of them fatal, have been reported in association with the use of non-steroidal anti-inflammatory medicines such as **BRUFEN® 200**. **BRUFEN® 200** should be discontinued at the first appearance of skin rash, skin lesion or any other sign of hypersensitivity.

Using other medicines with BRUFEN® 200:

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

Make sure you tell your doctor if you take:

- Medicines for high blood pressure including diuretics *(i.e. water pills)* - combination with **BRUFEN® 200** may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta-blockers and diuretics.
- Lithium salts and methotrexate - combination with lithium can disrupt the body's ability to remove lithium from the body which can lead to a dangerous build-up of lithium levels.
- Medicines that prevent blood from clotting (anti-coagulants or anti-platelet agents) – combination with **BRUFEN® 200** can enhance the effects of the medication and make you prone to excessive bleeding.
- Medicines called selective serotonin reuptake inhibitors (typically used as antidepressants) - combination with a **BRUFEN® 200** can increase the risk of you experiencing bleeding inside their digestive system.
- Aminoglycosides (a type of antibiotic) - **BRUFEN® 200** may decrease the body's ability to remove aminoglycosides from the body which can lead to a dangerous build-up of aminoglycosides levels.
- Aspirin - concomitant administration of **BRUFEN® 200** and aspirin is not recommended because of the potential of increased adverse effects.
- Digoxin - **BRUFEN® 200** may decrease the body's ability to remove digoxin from the body which can lead to a dangerous build-up of digoxin levels.
- Ciclosporin - there is a small risk of experiencing kidney and liver damage if you take **BRUFEN® 200** while also taking ciclosporin

- Medicines known as corticosteroids (used in the treatment of inflammatory conditions) – concomitant use with **BRUFEN® 200** increase the risk of gastrointestinal ulceration or bleeding
- Any other non-steroidal anti-inflammatory medicines - always best to use one type of NSAID at a time to minimise the risks of side effects.
- Herbal extracts such as Ginkgo biloba - concomitant use with **BRUFEN® 200** increase the risk of bleeding
- Mifepristone – combination with **BRUFEN® 200** causes a decrease in the efficacy of mifepristone
- Quinolone antibiotics - taking **BRUFEN® 200** and a quinolone class of antibiotic may increase the risk of you developing a seizure.
- Tacrolimus - possible increased risk of kidney damage when **BRUFEN® 200** is given with tacrolimus.
- Zidovudine - Increased risk of blood toxicity when **BRUFEN® 200** is given with zidovudine.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get new medicine. They can tell you if it is okay to take BRUFEN® 200 with other medicines.

Pregnancy and Breastfeeding

You should not use **BRUFEN® 200** in the last 3 months of pregnancy or during labour

You should not use **BRUFEN® 200** when you breastfeed your baby

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BRUFEN® 200**

Driving and using machinery

- **BRUFEN® 200,** may make you feel drowsy/sleepy, tired and disturb your vision
- Do not drive because **BRUFEN® 200,** could interfere with your ability to drive safely
- Do not operate any tools or machines

4. HOW TO TAKE BRUFEN® 200

Always take **BRUFEN® 200** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BRUFEN® 200** is too strong or too weak, talk to your doctor or pharmacist.

Usual dose of BRUFEN® 200:

The lowest effective dose should be used and for the shortest possible duration.

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
   - Headache
   - Pain associated with migraine
   - Muscular ache and pains
1) fever
2) Period pain

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

If you take more BRUFEN® 200 than you should:

The most common symptoms of overdosage are pain in the upper middle part of the abdomen and nausea. Other symptoms include vomiting, dizziness, convulsion, loss of consciousness and depression of the central nervous system and respiratory system. If recently taken, gastric lavage will remove any unabsorbed **BRUFEN® 200**. Treatment is symptomatic and supportive.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take BRUFEN® 200:

If you miss a dose of **BRUFEN® 200**, 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.

5. POSSIBLE SIDE EFFECTS

BRUFEN® 200 can have side effects.

If any of the following happens, stop taking BRUFEN® 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Gastrointestinal system disorders:

The most common side effects of **BRUFEN® 200** include indigestion, nausea, vomiting, constipation, diarrhoea, abdominal pain, flatulence, black stools, vomiting of blood, bleeding from the stomach or bowel, headache, dizziness and rash.

Less frequent: abdominal discomfort or pain, nausea, vomiting, gastro-intestinal ulcers, sometimes with bleeding

Immune disorders:

Less frequent: Aseptic meningitis (non-infectious inflammation of the membranes covering the brain), angioedema (type of swelling that affects deeper layers in your skin, often around your eyes

and lips), anaphylaxis (a severe, potentially life-threatening allergic reaction to something you're allergic to)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BRUFEN® 200. 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:

Nervous system disorder:

Frequent: Dizziness, nervousness, tinnitus (ringing sound in the ear), drowsiness, insomnia

Psychiatric disorder:

Frequent: Depression,

Eye disorders:

Visual impairment, changes in visual colour perception, toxic amblyopia(lazy eye syndrome)

Renal and Urinary disorders:

Less frequent: Acute renal failure, cystitis (inflammation of the bladder), haematuria (blood in urine), interstitial nephritis(swelling of the kidney), nephrotic syndrome (kidney disorder that causes your body to excrete too much protein in your urine)

Hepatobiliary syndrome:

Less frequent: Hepatotoxicity (liver damage), abnormalities in liver function tests

Blood and lymphatic system disorders:

Less frequent: low blood cell count (Anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis)

Hypersensitivity disorders:

Less frequent: Fever, rashes, exacerbation of asthma and bronchospasm

Cardiovascular disorders:

Frequency unknown: Oedema (swelling), hypertension and cardiac failure.

Skin and subcutaneous tissue disorders:

Frequency unknown: Bullous reactions (sensitivity of the skin to the sun, blistering and swelling), including Stevens-Johnson syndrome and toxic epidermal necrolysis

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

Not all side effects reported for **BRUFEN® 200** are included in this leaflet. Should your general health worsen while taking **BRUFEN® 200**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF BRUFEN® 200

Keep all medicines out of the reach and sight of children.

Store at or below 25°C.

Return any unused or expired medicines to your pharmacist for safe disposal.

7. PRESENTATION OF BRUFEN® 200

PVC/Aluminium or PVC/PVDC/Aluminium blister strips of 10 or 20 tablets per pack

8. IDENTIFICATION OF BRUFEN® 200

A white, pillow-shaped, film-coated tablet.

9. REGISTRATION NUMBER/REFERENCE NUMBER

BRUFEN® 200: A/3.1/0727

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Abbott Laboratories S.A. (Pty) Ltd.

Abbott Place

219 Golf Club Terrace

Constantia Kloof

1709

11. DATE OF PUBLICATION

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