## SCHEDULING STATUS

Schedule 2

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**BRUFEN® FOR CHILDREN (**Liquid for Oral Administration)

**Read all of this leaflet carefully before you start giving BRUFEN® FOR CHILDREN**

**BRUFEN® FOR CHILDREN** is available without a doctor's prescription, for you to treat your child's mild illness. Nevertheless you still need to use **BRUFEN® FOR CHILDREN** 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® FOR CHILDREN** has been prescribed for your child and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as your child's.
- You must see a doctor if your child's symptoms worsen or do not improve after 3 days.

## 1. WHAT BRUFEN® FOR CHILDREN CONTAINS

**BRUFEN® FOR CHILDREN**: Each 5 ml of contains 100 mg Ibuprofen.

Other ingredients include; Methylhydroxybenzoate 0,1 % m/v, propylhydroxybenzoate 0,05 % m/v, citric acid monohydrate, light kaolin, glycerol, sorbitol liquid non crystallising, sucrose, sodium benzoate 0,25 % m/v, orange yellow, orange flavor, polysorbate, agar powder.

Contains sorbitol and sucrose

## 2. WHAT BRUFEN® FOR CHILDREN IS USED FOR

**BRUFEN® FOR CHILDREN** is used for the treatment of mild to moderate pain of inflammatory origin and fever, including;

- Soft tissue injuries such as sprain and strains,
- Headache,
- Fever,
- Pain and inflammation associated with colds and flu,
- Sore throat,
- Dental Pain,
- Earache.

## 3. BEFORE YOU GIVE YOUR CHILD BRUFEN® FOR CHILDREN

**Do not give to your child BRUFEN® FOR CHILDREN:**

If ……

- They are allergic to **ibuprofen** or any of the other ingredients in **BRUFEN® FOR CHILDREN.**
- They have experienced asthma, skin rash or any allergic-type reaction after taking aspirin, ibuprofen or any other non-steroidal anti-inflammatory drug.
- They have a history of perforation or bleeding from the stomach or bowel related to previous non-steroidal anti-inflammatory drug therapy.
- Have or had a history of peptic ulceration, ulcerative colitis or Crohn's disease.
- They have heart failure.
- They have renal failure

The following warning concerns adults, particularly women:

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

**Take special care with BRUFEN® FOR CHILDREN:**

- Speak to your doctor or pharmacist if your child is **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 your child is taking.** This includes other prescription medicines, medicines bought without a prescription, and herbal medicines. Taking any other medicine together with **BRUFEN® FOR CHILDREN** may cause undesirable interactions.
- Speak to your doctor If your child has] 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.
- Safety in children under 1 (one) year of age has not been established.

Other warnings:

The following warnings are most likely to concern adults. In any case consider them carefully before giving or taking **BRUFEN® FOR CHILDREN**

- 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® FOR CHILDREN**.
- If you are an elderly person: The elderly have an increased frequency of adverse reactions to NSAIDs including **BRUFEN® FOR CHILDREN**, 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® FOR CHILDREN**. **BRUFEN® FOR CHILDREN** should be discontinued at the first appearance of skin rash, skin lesion or any other sign of hypersensitivity.

**Using other medicines with BRUFEN® FOR CHILDREN:**

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

**Make sure you tell your doctor if you or your child take:**

- Medicines for high blood pressure including diuretics *(i.e. water pills)* - combination with **BRUFEN® FOR CHILDREN** 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® FOR CHILDREN** 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 an **BRUFEN® FOR CHILDREN** can increase the risk of you experiencing bleeding inside their digestive system.
- Aminoglycosides (a type of antibiotic) - **BRUFEN® FOR CHILDREN** 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® FOR CHILDREN** and aspirin is not generally recommended because of the potential of increased adverse effects.
- Digoxin - **BRUFEN® FOR CHILDREN** 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® FOR CHILDREN** while also taking ciclosporin
- Medicines known as corticosteroids (used in the treatment of inflammatory conditions) – concomitant use with **BRUFEN® FOR CHILDREN** increase the risk of gastrointestinal ulceration or bleeding
- Any other non-steroidal anti-inflammatory medicines - always best to use one type of **BRUFEN® FOR CHILDREN** at a time to minimise the risks of side effects.
- Herbal extracts such as Ginkgo biloba - concomitant use with **BRUFEN® FOR CHILDREN** increase the risk of bleeding
- Mifepristone – combination with **BRUFEN® FOR CHILDREN** causes a decrease in the efficacy of mifepristone
- Quinolone antibiotics - taking **BRUFEN® FOR CHILDREN** and a quinolone class of antibiotic may increase the risk of you developing a seizure.
- Tacrolimus - possible increased risk of kidney damage when **BRUFEN® FOR CHILDREN** are given with tacrolimus.
- Zidovudine - Increased risk of blood toxicity when **BRUFEN® FOR CHILDREN** are given with zidovudine.

**Know the medicines your child takes. 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 for your child to take BRUFEN® FOR CHILDREN with other medicines**.

## 4. HOW TO GIVE YOUR CHILD BRUFEN® FOR CHILDREN

Always give your child **BRUFEN® FOR CHILDREN** 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® FOR CHILDREN** is too strong or too weak for your child, talk to your doctor or pharmacist.

**Usual dose of BRUFEN® FOR CHILDREN:**

Safety in children under 1 (one) year of age has not been established.

Use the lowest effective dose for the shortest duration necessary to control symptoms.

Pain: an initial dose of 5 mg/kg bodyweight. A second dose of 5 mg/kg may be given after 2 hours if pain persists. Thereafter 5 mg/kg every 4 to 6 hours. DO NOT EXCEED 20 mg/kg of bodyweight per day. If pain persists for more than 7 days, consult your doctor.

Fever: 5 mg/kg of bodyweight every 4 to 6 hours. DO NOT EXCEED 20 mg/kg of bodyweight per day. If fever persists for more than 3 days, consult your doctor.

| **Age** | **Bodyweight** | **Daily dosage** |
|---|---|---|
| 1 – 2 years | 7 – 12 kg | 2.5 ml up to 3 – 4 times daily |
| 3 – 7 years | 14 – 23 kg | 2.5 – 5 ml up to 3 – 4 times daily |
| 8 – 12 years | 25 – 40 kg | 10 ml up to 3 – 4 times daily |

**Do not give to children weighing less than 7 kg or 1 years of age.**

**If you give your child more BRUFEN® FOR CHILDREN 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® FOR CHILDREN** 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 give your child BRUFEN® FOR CHILDREN:**

If you miss to give your child a dose of **BRUFEN® FOR CHILDREN**, give it as soon as you remember unless it is almost time for their next dose. If it is, do not give your child the missed dose at all. DO NOT GIVE A DOUBLE DOSE TO MAKE UP FOR FORGOTTEN INDIVIDUAL DOSES.

## 5. POSSIBLE SIDE EFFECTS

**BRUFEN® FOR CHILDREN** can have side effects.

**If any of the following happens to your child, stop giving BRUFEN® FOR CHILDREN 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® FOR CHILDREN** 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 your child has them, your child may have had a serious allergic reaction to BRUFEN® FOR CHILDREN. Your child 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), insomnia

*Psychological 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. Your child may need urgent medical attention.**

Not all side effects reported for **BRUFEN® FOR CHILDREN** pare included in this leaflet. Should your child's general health worsen while taking **BRUFEN® FOR CHILDREN** please consult your doctor, pharmacist or other health care professional for advice.

## 6. STORING AND DISPOSING OF BRUFEN® FOR CHILDREN

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

Store at or below 25°C. Protect from light. Shake well before use.

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

## 7. IDENTIFICATION OF BRUFEN® FOR CHILDREN

An orange coloured, orange flavoured syrupy suspension.

## 8. PRESENTATION OF BRUFEN® FOR CHILDREN

100 mℓ or 200 mℓ suspension in amber glass or polyethylene (plastic) bottles fitted with a white closure.

## 9. REGISTRATION NUMBER/REFERENCE NUMBER

**BRUFEN® FOR CHILDREN** (100mg/5ml) Q/3.1/323

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Abbott Laboratories S.A. (Pty) Limited

Abbott Place

219 Golf Club Terrace

CONSTANTIA KLOOF

1709

## 11. DATE OF PUBLICATION

02 October 2015