PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

Ibupain® (capsules)

Ibuprofen and Paracetamol

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share IBUPAIN with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days for pain and/or 3 days for fever.

What is in this leaflet

1. What IBUPAIN is and what it is used for

2. What you need to know before you take IBUPAIN

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1. What IBUPAIN is and what it is used for

IBUPAIN is used in the treatment of mild to moderate pain with or without fever.

IBUPAIN contains paracetamol, which has analgesic (pain relieving) and antipyretic (reduces fever) effects, and ibuprofen, which has analgesic, antipyretic and anti-inflammatory activities.

2. What you need to know before you take IBUPAIN

Do not take IBUPAIN:

- If you are hypersensitive (allergic) to paracetamol or ibuprofen or to any of the other ingredients of IBUPAIN (listed in section 6).
- If you have previously had hypersensitivity reactions (e.g. asthma, running nose, swelling or a rash) after having taken aspirin or other anti-inflammatory medication.
- If you have a history of a ruptured bowel, or had an ulcer or bleeding in your stomach related to previous nonsteroidal anti-inflammatory medicines (NSAIDs) therapy, including IBUPAIN.
- If you have a history of recurring or an active stomach ulcer/bleeding (rupture).
- If you have a bleeding disorder.
- If you have heart failure.
- If you have liver failure or kidney failure.
- If you are pregnant, due to risk of kidney dysfunction in the unborn babies.
- If you are breastfeeding your baby.
- If you have uncontrolled asthma or breathing difficulties.
- If you have nasal polyps due to aspirin-induced asthma.
- If you are taking certain blood thinning medication.

Warnings and precautions

Take special care with IBUPAIN:

IBUPAIN should not be used with other nonsteroidal anti-inflammatory medicines (NSAIDs), including cyclooxygenase-2 selective inhibitors.

IBUPAIN should not be used with other products containing paracetamol, due to the risk of severe liver damage as a result of paracetamol overdose (see “If you take more IBUPAIN than you should”). Paracetamol overdose could lead to death.

In the event of overdosage or suspected overdose, even in the absence of any symptoms, the nearest doctor, hospital or poison centre must be contacted immediately.

IBUPAIN side effects may be minimised by using the lowest effective dose for the shortest possible duration necessary to control your symptoms (see “How to take IBUPAIN”).

During 20 weeks or later in pregnancy, IBUPAIN may cause kidney dysfunction in unborn babies.

Take special care with IBUPAIN:

- If you have liver or kidney disorders.
- If you are an alcoholic or consume large amounts of alcohol, as alcohol should not be used during treatment with paracetamol (one of the active substances in IBUPAIN).
- If you have an infection or think that you have an infection, as IBUPAIN may hide signs of infections such as fever and pain. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- If you have high blood pressure or heart disease.
- If you are at risk to develop heart disease (high fat content in your blood, diabetes, smoking).
- If you have a history of gastrointestinal disease (e.g. ulcerative colitis (inflammation of the intestines), Crohn’s disease (inflammation of the gastrointestinal tract), hiatus hernia (when the upper part of the stomach pushes through the diaphragm), gastro-oesophageal reflux disease (heartburn), angiodysplasia (a malformation of a vein in the stomach) as the condition may be exacerbated.
- If you have asthma or allergic conditions.

- If you have bleeding disorders.
- If you have a condition called systemic lupus erythematosus or if you have mixed connective tissue disorders.
- If you are elderly, as you are more likely to experience side effects, including ruptured bowel, ulceration and bleeding, which can result in death.
- In children and adolescents, ensuring that they are not dehydrated when taking IBUPAIN, as dehydration may increase the risk of kidney impairment.
- If you are about to have surgery, please tell your doctor if you have been taking IBUPAIN on a regular basis, as possible enhanced bleeding may occur.

Serious skin reactions have been reported in association with IBUPAIN. You should stop taking IBUPAIN 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).

Children and adolescents

IBUPAIN is not recommended for children under 12 years of age.

Other medicines and IBUPAIN

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

Tell your doctor or pharmacist if you are currently using:

- Aspirin or any other medicines that prevent the blood from clotting.
- Other nonsteroidal anti-inflammatory medicines (NSAIDs), including cyclooxygenase-2 selective inhibitors (e.g. naproxen, celecoxib, etoricoxib).
- Selective serotonin reuptake inhibitors (a class of medicines used to treat depression, e.g. fluoxetine, citalopram).
- Cardiac glycosides (a class of medicines used to treat heart conditions), e.g. digoxin.

- Immunosuppressants (medicines which reduce your immune system), e.g. ciclosporin and tacrolimus.
- Zidovudine (a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)).
- Antibiotics (such as quinolone antibiotics, e.g. ciprofloxacin, levofloxacin).
- Medication or substances which have effects on liver enzymes, e.g. barbiturates (sedatives, e.g. phenobarbital), tricyclic antidepressants, alcohol.
- Metoclopramide or domperidone (medicines used for nausea or vomiting).
- Cholestyramine (a medicine used to lower blood cholesterol).
- Probenecid (a medicine used to treat gout).
- Blood thinning tablets, e.g. warfarin, coumarins.
- Corticosteroids.
- Methotrexate.
- Lithium.
- Medication to lower your blood pressure, including water tablets (diuretics).
- Mifepristone (a medicine that is used to end pregnancies).
- Phenytoin (medicines to treat epilepsy or fits).
- Medicines to treat diabetes, including sulphonylureas.
- Propantheline (used to treat gastrointestinal ulcers).
- Chloramphenicol (an antibiotic used to treat ear and eye infections).
- Isoniazid (a medicine used to treat tuberculosis).
- Co-trimoxazole (a medicine used to treat bacterial infections).

IBUPAIN with food, drink and alcohol

IBUPAIN should be taken with or after food.

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 healthcare provider for advice before taking this medicine.

You should not take IBUPAIN during pregnancy (see “Do not take IBUPAIN”).

You should not take IBUPAIN whilst breastfeeding your baby (see “Do not take IBUPAIN”).

Driving and using machines

Be careful of driving or operating machines until you know how IBUPAIN affects you. Side effects such as dizziness, fatigue and visual disturbances are possible when taking IBUPAIN and these could affect your ability to drive or operate machines.

3. How to take IBUPAIN

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

Always take IBUPAIN exactly as described in this leaflet or as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE. If you have the impression that the effect of IBUPAIN is too strong or too weak, talk to your doctor or pharmacist.

IBUPAIN is for oral administration and short term use only.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see “Take special care with IBUPAIN”).

IBUPAIN should not be used by children under 12 years of age.

Adults and children over 12 years: 2 capsules every 4 hours when necessary. Do not take more than 6 capsules (1200 mg ibuprofen and 1500 mg paracetamol) in 24 hours.

Consult your doctor immediately:

- If you are taking IBUPAIN for pain and the pain continues for longer than 7 days.
- If you are taking IBUPAIN for fever and the fever continues for longer than 3 days.
- If your condition deteriorates.
- If new symptoms develop.

In adolescents (age range: 12 years to < 18 years):

If in adolescents IBUPAIN is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

If you take more IBUPAIN than you should

Prompt treatment is essential.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. A delay in starting treatment may mean that the antidote is given too late to be effective. Overdose can lead to liver damage and death.

Elderly subjects, young children, patients with liver disease, alcoholic patients, malnourished patients or patients taking concurrent medicines which have an effect on liver enzymes, are particularly at risk, following overdose.

Symptoms of paracetamol overdosage usually occur within 24 hours and may include nausea, vomiting, anorexia (eating disorder), pallor (skin colour becoming pale), and abdominal pain. Afterwards, your condition may improve, however, mild stomach pain may continue, which could indicate that you have liver damage.

Ibuprofen overdose may present with nausea, vomiting, stomach pain, or more rarely diarrhoea. Tinnitus (ringing in the ears), headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system and may include vertigo (dizziness), headache, breathing difficulty, drowsiness, occasionally excitation (feeling excited) and disorientation, coma and convulsions. In serious poisoning, hypotension (low blood pressure), hyperkalaemia (high potassium levels in the blood), metabolic acidosis (high acid levels in the body), reduced blood clotting, worsening of asthma, kidney failure and liver failure may occur.

If you forget to take IBUPAIN

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for the forgotten individual doses. Continue to take the next capsule at the usual time.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

4. Possible side effects

IBUPAIN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching

- Fainting
- Yellowing of the skin and eyes, also called jaundice

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

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

- Oedema (swelling of your body and limbs)
- Heart failure (causing breathlessness, swelling) or heart attack
- Abnormal heart beat
- Increased heart rate
- High or low blood pressure
- Stroke
- Signs of inflammation of the brain lining such as: stiff neck, headache, feeling or being sick, fever or feeling disorientated
- Blood disorders, which may affect red blood cells, white blood cells or blood platelets (seen in a blood test)
- Kidney damage or failure (e.g. causing increased or decreased urination, swelling of the legs)
- Gastrointestinal bleeding, ulcers and perforation (signs of intestinal bleeding: severe stomach pain, vomiting blood or liquid with what looks like coffee granules, blood in the stools/motions, black tarry stools)
- Exacerbation of colitis (inflammation of the intestines) and Crohn's disease (inflammation of the gastrointestinal tract)
- Inflammation of the stomach lining (gastritis), oesophagus (the tube from the throat entering the stomach) or pancreas
- Liver problems (causing yellowing of the skin and white of eyes)

- Skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules, peeling of the skin and bleeding in the lips, eyes, mouth, nose and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome)
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis)
- Depression or psychotic (mental) reactions

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

Tell your doctor if you notice any of the following:

- Nervousness
- Breast enlargement (in males)
- Abnormally low blood sugar (hypoglycaemia)
- Confusion
- Excessive emotional reactions
- Hallucinations
- Abnormal dreams
- Dizziness
- Inability to sleep
- Headache
- Agitation, irritability or feeling tired
- Numbness or abnormal skin sensations (e.g. burning, tingling or pricking) in the hands and feet
- Slowing of physical and emotional reactions

- Involuntary muscle movements/spasms
- Tremors and convulsions
- Temporary vision loss, pain during eye movements
- Fast or irregular heartbeats, also called palpitations
- Asthma, wheezing, shortness of breath
- Thickening of respiratory secretions (mucous)
- Difficulty breathing
- Nausea (feeling sick) and vomiting
- Indigestion
- Diarrhoea or constipation
- Flatulence (wind)
- Mouth ulcers
- Visual disturbances
- Blurred vision
- Ringing in the ears (tinnitus)
- Vertigo
- Blood in urine
- Difficulty urinating
- Fatigue, generally feeling unwell

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug 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 IBUPAIN.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store IBUPAIN

Keep in a dry place below 25 °C. Protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the blisters and containers. Decomposed products may be toxic.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IBUPAIN contains

The active substances are ibuprofen and paracetamol.

The other inactive ingredients are: microcrystalline cellulose, pregelatinised starch, purified talc and gelatine capsules (brilliant blue FCF, erythrosin, gelatine, quinolone yellow, titanium dioxide).

What IBUPAIN looks like and contents of the pack

IBUPAIN are size 0 capsules with an opaque white body and opaque dark green cap containing a free flowing white powder.

IBUPAIN is packed in:

Sealed aluminium layflat patient ready bags with LDPE ribbed zipper with 30, 60 or 100 capsules.

PVC/Tristar/Aluminium foil blisters packed into printed cardboard boxes together with the package leaflet with 10, 30, 60, 100 or 500 capsules.

Opaque white polypropylene securitainers with clip-on, low density or medium density or high density polyethylene pilfer proof seals with 10, 30, 60, 100 or 500 capsules.

Amber glass containers with black, hard plastic (polypropylene) screw caps with expanded LDPC inner seals with 30, 60 or 100 capsules.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

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Access to the corresponding Professional Information

Not applicable.

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