PATIENT INFORMATION LEAFLET FOR

IBUGESIC ORAL SUSPENSION

SCHEDULING STATUS S2

IBUGESIC ORAL SUSPENSION (oral suspension)

100 mg ibuprofen per 5 mL suspension.

Preservatives:

Sodium methyl parahydroxybenzoate 0,172 % *m/v*

Sodium propyl parahydroxybenzoate 0,045 % *m/v*

Sodium benzoate 0,1 % *m/v*

Contains sugar: maltitol 1,375 g/5 mL

Contains sweetener: saccharin sodium 15 mg/5 mL

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

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

- Keep this leaflet. You may need to read it again.
- Do not share IBUGESIC ORAL SUSPENSION with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your fever worsens or does not improve after 3 days or if your pain worsens or does not improve after 7 days.

What is in this leaflet

1. What IBUGESIC ORAL SUSPENSION is and what it is used for
2. What you need to know before you take IBUGESIC ORAL SUSPENSION
3. How to take IBUGESIC ORAL SUSPENSION
4. Possible side effects.
5. How to store IBUGESIC ORAL SUSPENSION**.**
6. Contents of the pack and other information.

1. What IBUGESIC ORAL SUSPENSION is and what it is used for

IBUGESIC ORAL SUSPENSION (ibuprofen) belongs to a class of medicine known as antirheumatics (anti-inflammatory agents).

The ibuprofen in IBUGESIC ORAL SUSPENSION is a non-steroidal anti-inflammatory drug (NSAID) used to treat mild to moderate pain, fever, post-traumatic (following injury) conditions and acute attacks of gout.

2. What you need to know before you take IBUGESIC ORAL SUSPENSION

Do not take or give your child IBUGESIC ORAL SUSPENSION:

- if you (or your child) are hypersensitive (allergic) to ibuprofen or any of the other ingredients of IBUGESIC ORAL SUSPENSION (listed in **section 6**).
- if you (or your child) have been diagnosed with heart failure.
- if you (or your child) currently have or previously had repeated stomach ulcers, bleeding, or holes of the gut, including a history of bleeding or holes of the stomach or gut due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs), e.g. aspirin, diclofenac.
- if you (or your child) have had allergic reactions to aspirin or other similar pain medicines (NSAIDs) (see **section 4**).
- if you (or your child) are also taking lithium for bipolar mood disorder.

- if you (or your child) have been diagnosed with polyps (growths) inside your nose due to aspirin use, with tightness of the chest or wheezing.
- if you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- if you (or your child) are known to have a bleeding disorder.
- if you (or your child) have liver or kidney failure.
- if your child is younger than 1 year.

Warnings and precautions

Take special care with IBUGESIC ORAL SUSPENSION:

Please report to your doctor if you (or your child) have a fever that does not improve within 3 days, or pain that does not improve within 7 days (see **section 3**).

Please inform your doctor if you know that you have high blood pressure because IBUGESIC ORAL SUSPENSION may cause fluid retention and swelling that may worsen these conditions (see **section 4**). Do not take IBUGESIC ORAL SUSPENSION if you are in heart failure (see **Do NOT take IBUGESIC ORAL SUSPENSION)**

If you are elderly, you may have an increased risk of developing adverse reactions to NSAIDs, especially bleeding from the stomach or gut, which may be life-threatening (see **section 4**). The risk of developing bleeding or perforation increases with an increased dose, if you have a history of ulcers, and if you are elderly. If you vomit blood or a substance resembling coffee grounds, if you develop severe, incapacitating stomach pain, or if you pass black, foul-smelling, tarry stools, particularly in the initial stages of IBUGESIC ORAL SUSPENSION treatment, please contact your doctor as a matter of urgency. You should immediately stop taking IBUGESIC ORAL SUSPENSION.

Please inform your doctor if you (or your child) have been diagnosed with any disorder of the gut, including ulcerative colitis, Crohn's disease, diaphragmatic hernia, or acid reflux, since use of IBUGESIC ORAL SUSPENSION may aggravate these conditions (see **section 4**).

If you (or your child) develop blisters on the skin, ulcers in the mouth or on the lips, hives, itching, troubled breathing, tightness of the chest or shortness of breath, or any other symptom you think may be due to an allergic reaction, you (your child) must immediately stop taking IBUGESIC ORAL SUSPENSION and inform your doctor as a matter of urgency (see **section 4**).

Please discuss the use of IBUGESIC ORAL SUSPENSION with your doctor or pharmacist:

1. if you (or your child) have been diagnosed with asthma
2. if you (or your child) have been diagnosed with scarring of the liver (cirrhosis)
3. if you (or your child) experience blurred or diminished vision, or changes in colour vision (see **section 4**)
4. if you (or your child) have been diagnosed with a collagen disease, including systemic lupus erythematosus (see **section 4**). Please ask your doctor if you are not sure.
5. if you (or your child) have been diagnosed with anaemia (a decrease in the number of red blood cells).

Long-term use of IBUGESIC ORAL SUSPENSION may result in kidney disorders. If you (or your child) suffer from impaired kidney function, heart failure, impaired liver function, or are taking water pills (diuretics) or blood pressure lowering medicines (ACE inhibitors) or if you are elderly, you (or your child) may be at increased risk of developing severe kidney disorders. Avoid use of IBUGESIC ORAL SUSPENSION unless prescribed by your doctor.

Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

IBUGESIC ORAL SUSPENSION may prevent platelets from forming blood clots and may therefore prolong bleeding time.

Inflammation of the membranes surrounding the brain (meningitis) in the absence of an infection may develop while you are taking IBUGESIC ORAL SUSPENSION (see **section 4**). Although it is more likely to occur if you (or your child) have been diagnosed with a connective tissue disorder, such as systemic lupus erythematosus, or related autoimmune diseases, it has been reported in patients who do not have an underlying chronic disease. If you (or your child) develop headache, neck stiffness, vomiting, sensitivity to light, confusion, drowsiness or high fever you should report to your doctor immediately.

See **Other medicines and IBUGESIC ORAL SUSPENSION** for a list of medicines that may increase your risk of ulceration or bleeding.

Other medicines and IBUGESIC ORAL SUSPENSION

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

If you are taking any of the following medicines, please discuss their use with your doctor or pharmacist before you take IBUGESIC ORAL SUSPENSION:

- corticosteroids, such as cortisone or prednisone, for immune system disorders, chronic inflammation or asthma.
- blood thinning medicines, such as warfarin. IBUGESIC ORAL SUSPENSION may enhance the blood thinning effect and increase the possibility of ulceration or bleeding of the stomach or gut (see **Warnings and precautions**).
- medicines that reduce platelet function, such as aspirin, clopidogrel and ticlopidine.
- selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine, sertraline, or citalopram, for the treatment of depression or anxiety.
- alcohol.
- bisphosphonates, e.g. alendronate, risedronate, or pamidronate, for osteoporosis.
- pentoxifylline to treat reduced blood flow to the legs.
- insulin or other medicines for diabetes mellitus, as the blood sugar-lowering effects of these medicines may be increased.
- digoxin for heart failure or abnormal heart rhythms. IBUGESIC ORAL SUSPENSION may cause an increase in digoxin blood levels and may worsen heart failure and reduce kidney function.
- lithium for bipolar mood disorder, as IBUGESIC ORAL SUSPENSION may increase the blood levels of lithium.
- methotrexate, an immunosuppressant, as IBUGESIC ORAL SUSPENSION may increase blood levels and increase the risk of experiencing side effects due to methotrexate.
- any other medicine you have been told may damage your kidneys, e.g. ciclosporin or tacrolimus for immune system disorders, as there is an increased risk of kidney damage.
- blood pressure-lowering medicines and diuretics (water tablets) for water retention or high blood pressure, as the blood pressure-lowering effect may be decreased. Diuretics may also increase the risk of kidney damage (see **Warnings and precautions**).

- any other non-steroidal anti-inflammatory medicines (NSAIDs), such as aspirin, diclofenac, naproxen, paracetamol or celecoxib (a cyclo-oxygenase-2 inhibitor), as concomitant use could result in an increase in side effects.
- quinolone antibiotics, e.g. ciprofloxacin or levofloxacin, as IBUGESIC ORAL SUSPENSION may increase the risk of developing convulsions/seizures.
- zidovudine, an antiviral medicine used in the treatment of Human Immunodeficiency Virus (HIV) infection. There is an increased risk of side effects and of bleeding into joints and tissues in people with bleeding disorders (e.g. haemophilia).
- aminoglycoside antibiotics, e.g. amikacin, gentamicin, tobramycin.
- herbal extracts, including *Ginkgo biloba*, may increase the risk of bleeding with IBUGESIC ORAL SUSPENSION.
- voriconazole and fluconazole for fungal infections, as you may require a lower dose of IBUGESIC ORAL SUSPENSION.

IBUGESIC ORAL SUSPENSION with food, drink and alcohol

Take IBUGESIC ORAL SUSPENSION with or after food.

Pregnancy, breastfeeding and fertility

Do not take IBUGESIC ORAL SUSPENSION while you are pregnant or breastfeeding your baby (see **Do NOT take IBUGESIC ORAL SUSPENSION**). Taking IBUGESIC ORAL SUSPENSION while you are pregnant may harm your baby.

If you are attempting to become pregnant the dose of IBUGESIC ORAL SUSPENSION should be kept as low and duration of treatment as short as possible as IBUGESIC ORAL SUSPENSION may interfere with your ability to become pregnant.

Please discuss this with your doctor if you are not sure.

Do not take IBUGESIC ORAL SUSPENSION around 20 weeks or later in pregnancy as it may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn lungs and muscles develop. Complications can occur with low levels of this fluid.

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 health care provider for advice before taking IBUGESIC ORAL SUSPENSION.

Driving and using machines

IBUGESIC ORAL SUSPENSION may influence your ability to drive or operate machinery. You may experience dizziness, drowsiness, fatigue and visual disturbances after taking IBUGESIC ORAL SUSPENSION. You should not drive a car or operate machinery until you know how IBUGESIC ORAL SUSPENSION affects you.

It is not always possible to predict to what extent IBUGESIC ORAL SUSPENSION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IBUGESIC ORAL SUSPENSION affects them.

IBUGESIC ORAL SUSPENSION contains maltitol

IBUGESIC ORAL SUSPENSION may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take IBUGESIC ORAL SUSPENSION.

3. How to take IBUGESIC ORAL SUSPENSION

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

Always take IBUGESIC ORAL SUSPENSION exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

USE THE LOWEST EFFECTIVE DOSE FOR THE SHORTEST POSSIBLE DURATION OF TREATMENT.

Take IBUGESIC ORAL SUSPENSION with or after food.

***Adults*:**

The recommended dosage of IBUGESIC ORAL SUSPENSION is 600 mg (6 medicine measures) 6 to 8 hourly.

Do not exceed the total dose of 1,200 mg (12 medicine measures) IBUGESIC ORAL SUSPENSION per day.

Children:

Do not give to children under 1 year of age, as safety has not been proven (see **Do NOT take or give your child IBUGESIC ORAL SUSPENSION**)

The total daily dosage of IBUGESIC ORAL SUSPENSION is 20 mg/kg (1 mL/kg) of body mass given in divided doses.

Pain:

Initial dose of 0,25 mL IBUGESIC ORAL SUSPENSION per 1 kg of your child's bodyweight. If pain is not controlled, a second dose of 0,25 mL IBUGESIC ORAL SUSPENSION per 1 kg of

your child's bodyweight may be given after 2 hours. Thereafter, of 0,25 mL IBUGESIC ORAL SUSPENSION per 1 kg of your child's bodyweight every 4 to 6 hours.

DO NOT GIVE more than 1 mL of IBUGESIC ORAL SUSPENSION per 1 kg of your child's bodyweight per day (24 hours). Should the pain persist for more than 7 days, you should contact your doctor.

Fever:

Give 0,25 mL of IBUGESIC ORAL SUSPENSION per 1 kg of your child's bodyweight every 4 to 6 hours.

DO NOT GIVE more than 1 mL of IBUGESIC ORAL SUSPENSION per 1 kg of your child's bodyweight per day (24 hours).

Should the fever persist for more than 3 days, contact your doctor.

Dosage for suspension:

Age	***Bodyweight***	***Daily dosage***
1 to 2 years	7 to 12 kg	2,5 mL up to 3 to 4 times daily
3 to 7 years	14 to 23 kg	2,5 to 5 mL up to 3 to 4 times daily
8 to 12 years	25 to 40 kg	10 mL up to 3 to 4 times daily

Do not give to children weighing less than 7 kg or younger than 1 year of age.

Elderly:

If you are 65 years of age, or older you may be at increased risk of serious of adverse reactions. If IBUGESIC ORAL SUSPENSION is considered necessary, the lowest effective dose should be used and for the shortest possible duration.

You should be monitored regularly during therapy by your doctor for bleeding of the stomach or

gut.

If your kidney or liver function is impaired, the dosage should be assessed on an individual basis. Please ask your doctor or pharmacist for advice.

If you have the impression that the effect of IBUGESIC ORAL SUSPENSION is too strong or too weak for you, please discuss this with your doctor or pharmacist.

If you take more IBUPROFEN ORAL SUSPENSION than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may experience any of the following side effects (see **Section 4**):

Nausea, vomiting, stomach pain, lethargy, drowsiness, headache, ringing in the ears, dizziness, convulsions/seizures and loss of consciousness, involuntary eye movement, decreased body temperature, bleeding of the stomach or gut, coma, difficult breathing, loose stools, disorientation, excitation, fainting, low blood pressure, increased or decreased heart rate, kidney failure and liver damage.

If you forget to take IBUGESIC ORAL SUSPENSION

If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

IBUGESIC ORAL SUSPENSION can have side effects.

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

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

- allergic reactions, including fever, hives or itching, wheezing, laboured breathing, swelling of the lips, tongue, face or whole body, and skin rash (see **Warnings and precautions**).
- swelling of the hands, feet or legs, inability to lie flat due to shortness of breath, or coughing with the production of pink sputum (see **Warnings and precautions**).

These are all very serious side effects. If you have them, you may have had a serious reaction to IBUGESIC ORAL SUSPENSION. 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:

- Sore throat, unusual bleeding, pinpoint red spots on the skin, easy bruising, bleeding from the gums or blood in the urine, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, as these symptoms may be due to abnormal blood cell and platelet counts.
- Any skin rash with blisters.
- Vomiting of blood or a substance resembling coffee grounds, severe, incapacitating stomach pain, or passing of black, foul-smelling, tarry stools (see **Warnings and precautions**).
- ulcers inside the mouth or on the lips (see **Warnings and precautions**).
- yellow discolouration of the skin or whites of the eyes with pain over the liver area.

- cloudy, dark or discoloured urine, reduced frequency or increased frequency of urination, difficulty passing urine, or pain over the bladder or kidneys.
- vision loss, distorted vision, blurred vision, changes in visual colour perception or visual impairment.
- headache, neck stiffness, nausea and vomiting, sensitivity to light, confusion, drowsiness or fever (see **Warnings and precautions**).
- confusion.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea, vomiting, or stomach cramps and pain.
- stomach discomfort, loose stools, gas, constipation, or indigestion.

Less frequent side effects:

- pins and needles.
- rapid heart rate.
- impaired hearing or feeling that you or your environment is moving or spinning.
- skin rash in sun-exposed areas.
- stuffy nose, runny nose, and post-nasal drip.
- nervousness, depression, sleeplessness, and anxiety.
- dizziness, headache, drowsiness or sleepiness.
- ringing in the ears.
- flushing/redness of the skin.
- feeling ill or unwell, fatigue.

Side effects with unknown frequency:

- increased blood pressure (see **Warnings and precautions**).
- temporary burning in the mouth or throat.
- renal tubular acidosis (damage to your kidneys which affects them removing acids properly from your blood into the urine).
- very low levels of potassium in your blood (see section 2). Signs and symptoms include muscle weakness and light-headedness.

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 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of IBUGESIC ORAL SUSPENSION.

5. How to store IBUGESIC ORAL SUSPENSION

- Store at or below 25 °C.
- Protect from light. Shake well before use.
- Keep well closed. Do not refrigerate.
- Store all medicines out of reach of children.
- Store in the original container.
- Keep the container in the outer carton.
- Do not use after the expiry date stated on the container.

- 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 IBUGESIC ORAL SUSPENSION contains

The active substance is ibuprofen.

Each 5 mL contains 100 mg of ibuprofen.

The other ingredients are:

- carboxymethylcellulose sodium.
- citric acid monohydrate.
- liquid maltitol.
- microcrystalline cellulose.
- polysorbate 80.
- saccharin sodium.
- sodium benzoate.
- sodium citrate dihydrate.
- sodium methyl parahydroxybenzoate.
- sodium propyl parahydroxybenzoate.
- strawberry flavour.
- xanthan gum.

What IBUGESIC ORAL SUSPENSION looks like and contents of the pack

Off-white coloured suspension with a characteristic strawberry flavour.

100 mL amber coloured transparent PET bottle with a pilfer-proof, child resistant cap. The amber PET bottle that is closed with CR caps is then placed in carton with leaflets and 5 mL syringe.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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