

PATIENT INFORMATION LEAFLET for
IBUGESIC PLUS (capsules)

SCHEDULING STATUS: **S2**

IBUGESIC PLUS 200 mg / 250 mg capsules

Ibuprofen and Paracetamol

Sugar free.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share IBUGESIC PLUS 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 symptoms worsen or do not improve after 7 days for pain and/or 3 days for fever.

What is in this leaflet

1. What IBUGESIC PLUS is and what it is used for

2. What you need to know before you take IBUGESIC PLUS
3. How to take IBUGESIC PLUS
4. Possible side effects
5. How to store IBUGESIC PLUS
6. Contents of the pack and other information

1. What IBUGESIC PLUS is and what it is used for

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

IBUGESIC PLUS is used in the treatment of mild to moderate pain of inflammatory origin or non-inflammatory origin with or without fever.

2. What you need to know before you take IBUGESIC PLUS

Do not take IBUGESIC PLUS:

- If you are hypersensitive (allergic) to the ibuprofen or paracetamol or to any of the inactive ingredients of IBUGESIC PLUS (listed in section 6).
- If you have a history of gastrointestinal perforation, ulceration or bleeding related to previous nonsteroidal anti-inflammatory medicines (NSAIDs) therapy, including IBUGESIC PLUS.

- If you have a history of recurring or an active stomach ulcer/haemorrhage/perforation (two or more confirmed cases of gastrointestinal ulceration or bleeding).
- 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 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 IBUGESIC PLUS:

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

IBUGESIC PLUS 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 IBUGESIC PLUS 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.

IBUGESIC PLUS side effects may be minimised by using the lowest effective dose for the shortest possible duration necessary to control your symptoms (see “3. How to take IBUGESIC PLUS”).

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

Take special care with IBUGESIC PLUS:

- 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 IBUGESIC PLUS).
- If you have an infection or think that you have an infection, as IBUGESIC PLUS 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 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 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 gastrointestinal perforation, ulceration and bleeding, which can result in death.
- In children and adolescents, ensuring that they are not dehydrated when taking IBUGESIC PLUS, 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 IBUGESIC PLUS on a regular basis, as possible enhanced bleeding may occur.

Serious skin reactions have been reported in association with IBUGESIC PLUS. You should stop taking IBUGESIC PLUS 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

IBUGESIC PLUS is not recommended for children under 12 years of age.

Other medicines and IBUGESIC PLUS

Always tell your healthcare professional 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.
- Selective serotonin reuptake inhibitors (a class of medicines used to treat depression).
- Cardiac glycosides (a class of medicines used to treat heart conditions), e.g. digoxin.
- Immunosuppressants (medicines which reduce your immune system), e.g. cyclosporine and tacrolimus.
- Zidovudine (a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)).
- Antibiotics (such as quinolone antibiotics).
- Medication or substances which have effects on liver enzymes, e.g. barbiturates (sedatives), tricyclic antidepressants, alcohol.
- Metoclopramide or domperidone.
- Cholestyramine.
- Probenecid.
- 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).

IBUGESIC PLUS with food and drink

IBUGESIC PLUS 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 professional for advice before taking this medicine.

You should not take IBUGESIC PLUS in the third trimester of pregnancy (see “Do not take IBUGESIC PLUS”).

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

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

Driving and using machines

It is not always possible to predict to what extent IBUGESIC PLUS 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 PLUS affects them.

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

3. How to take IBUGESIC PLUS

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

Always take IBUGESIC PLUS exactly as described in this leaflet or 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 IBUGESIC PLUS is too strong or too weak, talk to your doctor or pharmacist.

IBUGESIC PLUS 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 IBUGESIC PLUS”).

IBUGESIC PLUS 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 IBUGESIC PLUS for pain and the pain continues for longer than 7 days.
- If you are taking IBUGESIC PLUS 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 IBUGESIC PLUS is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

If you take more IBUGESIC PLUS than you should:**Prompt treatment is essential.**

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control 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 overdose usually occur within 24 hours and may include nausea, vomiting, anorexia, 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, exacerbated (made worse) asthma, kidney failure and liver failure may occur.

If you forget to take a dose of IBUGESIC PLUS:

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:

IBUGESIC PLUS can have side effects.

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

If any of the following happens, stop taking IBUGESIC PLUS and tell your doctor immediately or go 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 IBUGESIC PLUS. 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 or heart attack
- Abnormal heart beat
- Increased heart rate
- High or low blood pressure
- Stroke
- Aseptic meningitis (inflammation of the linings of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation)
- Blood disorders, which may affect red blood cells, white blood cells or blood platelets
- Kidney damage or failure (e.g. causing increased or decreased urination, swelling of the legs)
- Gastrointestinal bleeding, ulcers and perforation
- Gastrointestinal ulcers

- 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
- Stomach pain
- Black, tarry stools
- Vomiting blood
- Liver damage or failure
- Increased liver enzymes
- Abnormal liver function test results
- Skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (toxic epidermal necrolysis) 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
- Abnormal low blood sugar (hypoglycaemia)
- Confusion
- Excessive emotional reaction
- Hallucination
- 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 or, pharmacist. 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 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 PLUS.

5. How to store IBUGESIC PLUS

Keep well closed and store at or 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 IBUGESIC PLUS contains

The active substances are ibuprofen and paracetamol.

The other inactive ingredients are:

Capsule fill

microcrystalline cellulose

pregelatinised starch

purified talc

Capsule Shell

Gelatin capsule cap: opaque dark green

brilliant blue FCF

erythrosine

gelatin

quinolone yellow

titanium dioxide

Capsule body: opaque white

titanium dioxide

gelatin

What IBUGESIC PLUS looks like and contents of the pack

IBUGESIC PLUS :Size 0 capsule with opaque white body and opaque dark green cap containing a free-flowing white powder.

IBUGESIC PLUS is presented in:

Sealed aluminium layflat bags with 30 capsules.

PVC/Tristar/Aluminium foil Blisters with 10 and 30 capsules.

Polypropylene Opaque white securitainers with Clip-on low density or medium density or high density polyethylene pilfer proof seals with 10 and 30 capsules.

Soda lime, silica gel conforming to neutral glass Amber clear glass bottles with black, hard plastic (polypropylene) screw cap with expanded LDPC inner seal. Moisture resistant with 30 capsules.

Holder of Certificate of Registration

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This leaflet was last revised in

09 March 2023

REGISTRATION NUMBER:

37/2.8/0134

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