

**PATIENT INFORMATION LEAFLET FOR  
IBUGESIC FORTE**

**SCHEDULING STATUS: S2**

**IBUGESIC FORTE 200 mg / 250 mg / 10 mg, capsules**

Ibuprofen, paracetamol and codeine phosphate

Sugar free.

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

IBUGESIC FORTE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use IBUGESIC FORTE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IBUGESIC FORTE 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 4 days.

**What is in this leaflet**

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

## **1. What IBUGESIC FORTE is and what it is used for**

IBUGESIC FORTE capsules is a pain-relieving combination containing the following active substances: ibuprofen, paracetamol and codeine.

Ibuprofen reduces pain, fever and swelling. Paracetamol reduces pain and fever.

Codeine is metabolised to morphine, which in turn, exerts a pain-relieving effect.

IBUGESIC FORTE is indicated for the relief of mild to moderate pain of inflammatory origin (due to swelling) with or without fever.

## **2. What you need to know before you take IBUGESIC FORTE**

### **Do not take IBUGESIC FORTE:**

- if you are hypersensitive (allergic) to ibuprofen, paracetamol, codeine phosphate or to any of the other ingredients of IBUGESIC FORTE (listed in **section 6**)
- if you find it difficult to breathe, take breaths that are slower and shallower than normal
- together with a medicine classified as Monoamine Oxidase Inhibitors (MAOIs) or within 14 days of stopping such treatment (ask your doctor or pharmacist if you are unsure)
- if you have diarrhoea associated with an infection
- if you have severe liver impairment
- if you have burning stomach pain, feel bloated, nausea or if you have bleeding in your digestive system (ask your doctor or pharmacist if you are unsure)
- if you are sensitive to aspirin or other nonsteroidal anti-inflammatory medicines
- if you have uncontrolled asthma or sudden difficulty in breathing
- if you have small growths inside the nose associated with difficulty in breathing in the presence of aspirin
- if you have a bleeding disorders

- if you are pregnant, do not use NSAIDs, including IBUGESIC FORTE at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby
- if you have heart failure
- if you have had a bleeding stomach ulcer after taking a non-steroidal anti-inflammatory medicine (NSAID) (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- if you have a stomach ulcer, perforation or bleeding from the ulcer, or have had an ulcer in the past.

### **Warnings and precautions**

Take special care with IBUGESIC FORTE:

- if you have a sudden onset of stomach pain or condition as the diagnosis or clinical course may be masked by using IBUGESIC FORTE
- if your heart beats too fast, too slow or irregularly as IBUGESIC FORTE may worsen this
- if you have seizures or history thereof as IBUGESIC FORTE can bring on an attack
- if you have a history of alcoholism, drug abuse or dependence as IBUGESIC FORTE contains codeine which may predispose patients to drug dependence

### **DEPENDENCE MAY DEVELOP WITH PROLONGED USE OF HIGH DOSES**

- if you have gallbladder disease or gallstones as this may cause sudden attacks of tummy pain (ask your doctor or pharmacist if you are uncertain)
- if you had undergone recent surgery to the digestive tract
- if you have a head injury as this may increase the risk of interfering with your breathing
- IBUGESIC FORTE may also cause drowsiness and affect your eyes (pupillary changes), this may obscure the clinical course of your head injury.

- if you have liver problems as IBUGESIC FORTE is broken down by the liver
- if you have kidney problems as IBUGESIC FORTE may interfere with the body's ability to let out urine, as a result, this may lead to the accumulation of waste products which may lead to more adverse effects.
- if your thyroid gland is not able to produce enough thyroid hormone as this may increase your risk of difficulty breathing, low heart rate and loss of consciousness.
- if your body produces low levels of cortisol, symptoms may include tiredness, light-headedness and body aches (ask your doctor or pharmacist if you are uncertain)
- if you have a condition called inflammatory or obstructive bowel disorder, as this makes it difficult to pass stool or gas and IBUGESIC FORTE can worsen it
- if you have an enlarged prostate gland, narrowing of the tube that carries urine out of the body or have had recent urinary tract surgery
- if you fall in the older population group as these patients are more likely to develop liver and kidney problems, and if stomach ulcers with bleeding occurs, it is more likely to cause serious consequences, in which case the dosage should be reduced or stopped
- if you are diabetic, as it may give false blood glucose test results
- if undergoing surgery shortly, as it may possibly increase bleeding
- if you are anaemic, as it may worsen it
- if you have high blood pressure, as it may worsen it
- if you are concerned that you have an infection because IBUGESIC FORTE may mask symptoms of the occurrence or worsening of infection
- if you frequently consume alcohol as alcohol may increase your risk of liver damage.

If any of these applies to you, tell your doctor or nurse before you take IBUGESIC FORTE.

If taking for pain, including arthritic pain, and the pain persists for longer than 5 days, or if taking for fever and the fever persists for longer than 3 days, or if the condition deteriorates or new symptoms develop, the doctor needs to be contacted as additional treatment may be necessary.

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

Skin reactions have been reported. If you develop any skin reactions, stop taking IBUGESIC FORTE immediately and contact your doctor or go to the nearest hospital.

### **Children and adolescents**

IBUGESIC FORTE is not recommended for children under twelve years of age.

### **Other medicines and IBUGESIC FORTE**

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

Please note that use of MAOIs with IBUGESIC FORTE is CONTRAINDICATED and may cause possibly severe and sometimes fatal reactions.

Tell your doctor if you are taking any of the following:

- alcohol or central nervous system depressants enhance the depressant effects
- anticholinergic medicines as they increase the risk of severe constipation
- antidiarrheals as they increase the risk of severe constipation and central nervous system depression

- medicines that decrease blood pressure may be potentiated
- medicines that affect the liver increases the risk of liver toxicity
- enzyme inducing medicines as they increase the risk of liver toxicity, and the potential decrease in the therapeutic effects of paracetamol
- metoclopramide as it may cause the absorption of paracetamol to be accelerated
- probenecid as it may alter and affect the excretion of paracetamol and plasma concentrations
- cholestyramine as it may decrease the absorption of paracetamol if given within one hour of cholestyramine
- anticoagulants as they enhance the anticoagulant effect and the possibility of gastrointestinal ulceration or bleeding
- alcohol, corticosteroids, clopidogrel, ticlopidine, bisphosphonates, oxpentifylline as they increase the risk of gastrointestinal bleeding and ulceration
- antidiabetic agents as they may cause increased hypoglycaemic effects (lowering blood sugar effect)
- digoxin – increased serum concentration of digoxin
- lithium – increase in the steady-state concentration of lithium
- methotrexate – increased and prolonged methotrexate plasma concentration and an increased risk of methotrexate toxicity
- medicines that can cause kidney toxicity e.g., ciclosporin – increased risk of kidney toxicity
- medicines to lower high blood pressure (antihypertensive effect) or diuretics – reduction or reversal of the antihypertensive effect may occur
- bone marrow depressants as they may potentiate the effects of the medicine; this will result in a decreased number of white blood cells and/or blood platelets

- anti-platelet medicines (e.g., clopidogrel, ticagrelor, prasugrel dipyridamole or aspirin to name a few) and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression, e.g., escitalopram, fluoxetine, paroxetine to name a few) as it might increase your risk of gastrointestinal bleeding.

### **IBUGESIC FORTE with food, drink and alcohol**

Avoid alcohol when taking IBUGESIC FORTE.

### **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 health care provider for advice before taking IBUGESIC FORTE.

Use of NSAIDs (as in IBUGESIC FORTE) during the third trimester of pregnancy may result in breathing problems of your newborn child (see **section 2** and '**Warnings and precautions**').

### **Driving and using machines**

It is not always possible to predict to what extent IBUGESIC FORTE may interfere with the daily activities of a patient. IBUGESIC FORTE may make you feel dizzy or sleepy. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which IBUGESIC FORTE affects you.

## **3. How to take IBUGESIC FORTE**

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

Always take IBUGESIC FORTE 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.

The usual dose is 1 to 2 capsules 6 hourly. Do not take more than 6 capsules in 24 hours.

If no effective pain relief is achieved, the patients should be advised to seek the views of a physician. IBUGESIC FORTE is for short term use and is not recommended for use beyond 4 days.

Your doctor will tell you how long your treatment with IBUGESIC FORTE will last. Do not stop treatment early. If you have the impression that the effect of IBUGESIC FORTE is too strong or too weak, tell your doctor or pharmacist.

**DO NOT EXCEED THE RECOMMENDED DOSE.**

#### **If you take more IBUGESIC FORTE than you should**

The following is a list of the signs and symptoms that might help you identify an overdose:

- abdominal pain
- coma or depressed level of consciousness
- decreased urine output
- drowsiness
- gastrointestinal bleeding
- lethargy (lack of energy)
- low blood pressure
- nausea
- seizures
- shortness of breath
- slower breathing rate

- swelling of legs, ankles, or feet
- the pupils shrink (becomes smaller)
- vomiting.

In the event of 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.**

### **If you forget to take IBUGESIC FORTE**

Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

IBUGESIC FORTE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems,
- drug-induced hypersensitivity syndrome (DIHS) (a severe reaction usually characterised by fever, rash, and multiorgan failure).

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:*

- abdominal cramps and pain,
- bloating,
- confusion,
- constipation,
- diarrhoea,
- drowsiness,
- dyspepsia (indigestion),
- nausea,
- vomiting.

*Less frequent side effects:*

- abnormalities of liver function tests,
- agranulocytosis (low white blood cells), thrombocytopenia (low platelets),
- blurred vision and other eye reactions,
- bradycardia (slow heart rate), palpitations (the heart is racing, pounding, fluttering or can skip a beat), orthostatic hypotension (sudden drop in blood pressure when standing up),
- changes in myosis (excessive constriction of the pupil),
- dizziness, nervousness, depression, drowsiness, insomnia (inability to fall asleep), headache,
- dry mouth,
- pancytopenia (red blood cells, white blood cells, and platelets),
- heart failure may be precipitated in compromised patients, angina pectoris (chest pain experience on physical exertion), cardiac arrhythmias (heart beats too slow, too fast or irregular),
- hepatitis (swelling on the liver),
- impairment of renal function, acute reversible renal failure, oedema (build up of fluid results in tissue swelling),
- micturition difficulties (difficulty urinating), ureteric or biliary spasm (presence of a urinary stone that can cause an excruciating pain that can strike without warning),
- low levels of neutrophils (type of white blood cell),
- peptic ulceration (sores that develop in the lining of the stomach, lower esophagus, or small intestine), gastrointestinal bleeding, decreased appetite,
- renal failure,
- respiratory depression (difficulty breathing),

- restlessness, vertigo (dizziness), changes in mood, hypothermia (dangerously low body temperature), growing pressure inside your skull leading to headaches,
- sensitivity reactions resulting in reversible skin rash (which may be accompanied by fever and lesions or sores in the mouth) or blood disorders,
- skin rash and itchiness,
- sweating, facial flushing, urticaria (swollen pale red itchy bumps on the skin),
- tinnitus (ringing noises in the ear), hypersensitivity reactions.

*Side effects with unknown frequency:*

- fixed drug eruptions (FDE) (fever, malaise, nausea, diarrhoea, abdominal cramps, anorexia, and dysuria),
- low potassium levels (hypokalaemia),
- renal impairment (renal tubular acidosis),
- inflammation of the stomach.

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 “**Adverse drug reaction and quality problem reporting form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/> or to Cipla Medpro (Pty) Ltd. by e-mail: [drugsafetysa@cipla.com](mailto: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 FORTE.

## **5. How to store IBUGESIC FORTE**

Store all medicines out of reach of children.

Securitainer and amber glass bottle: Keep well closed and store at or below 25 °C.

Blister strips and patient ready packs: Keep in outer carton until required for use. Store at or below 25 °C.

Protect from light.

Store in the original container.

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 FORTE contains**

The active substance is ibuprofen 200 mg, paracetamol 250 mg and codeine phosphate 10 mg.

The other ingredients are:

#### *Capsule fill*

Microcrystalline cellulose

Pregelatinised starch

Purified talc

#### *Capsule shell*

#### *Capsule body (red)*

Erythrosine

Gelatin

Red iron oxide

Titanium dioxide

Yellow iron oxide

*Capsule cap (dark green)*

Indigo carmine

Gelatin

Quinoline yellow

Titanium dioxide

### **What IBUGESIC FORTE looks like and contents of the pack**

Size 0 capsule with red body and dark green cap containing a free flowing white powder.

White opaque securitainers with 10 or 30 capsules.

Clear PVC or Tristar blisters sealed with aluminium foil with 30 capsules packed into a cardboard carton.

Sealed aluminium bags with 30 capsules.

Amber glass bottles with 30 capsules.

### **Holder of certificate of registration**

**CIPLA MEDPRO (PTY) LTD.**

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