

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### KOFAN INSTANT

200 mg / 200 mg / 50 mg tablets

PARACETAMOL, PROPYPHENAZONE, CAFFEINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

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4. Possible side effects
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#### 1. WHAT KOFAN INSTANT IS AND WHAT IT IS USED FOR

KOFAN INSTANT tablets are combined medicine that contains three active ingredients: paracetamol, propyphenazone and caffeine.

#### **KOFAN INSTANT tablets are used to:**

KOFAN INSTANT tablets are used to relieve pain of various origins, such as headache, toothache, menstrual pain, postoperative pain and rheumatic pain, and prevention of pain and fever in cases of colds and flu.

#### 2. BEFORE YOU TAKE KOFAN INSTANT

#### **Do not take KOFAN INSTANT**

- If you are allergic to pyrazolones or derivatives of pyrazolone (hypersensitivity to medicines containing Phenazone, propyphenazone aminophenazone mitamizol)
- If you are allergic to medicines containing phenylbutazone
- If you have a proven hypersensitivity to the active substances or any of the excipients

- If you have inherited deficiency of glucose-6-phosphate dehydrogenase (hemolytic anemia)
- If you have acute hepatic porphyria
- If you have impaired liver function (cases of chronic alcoholism or hepatitis)
- If you have Gilbert's syndrome (fluctuating benign jaundice as a result of lack of glukoronil-transferase)
- If you have a disorder of hematopoiesis (formation and development of blood cells)
- If you have asthma
- If you have chronic rhinitis
- If you have chronic urticaria
- If you are breast-feeding

KOFAN INSTANT should not be used in children younger than 12 years.

***Take special care with KOFAN INSTANT, so you must tell the doctor if you***

- If you have liver failure
- If you have high blood pressure or heart disease accompanied by fluid retention and edema
- If you suffer from blood disorders called blood dyscrasias or disorders of the bone marrow
- If you have a diseases of the digestive system, such as stomach ulcer

Because of the very rare, but potentially serious risk of shock, KOFAN INSTANT may be used only when necessary to treat pain or fever.

The medicine must not be used for longer than 7 days or in doses that are higher than recommended without the advice of a doctor.

Long-term administration analgesics containing paracetamol can also result in high cumulative doses and in rare cases lead to kidney disease associated with the use analgesics and irreversible kidney failure.

Continuous administration of analgesics for the treatment of headaches may in itself lead to chronic headaches. Particular caution is needed in patients with:

- Hepatic dysfunction in the history of disease
- High blood pressure or heart disease accompanied by fluid retention and swelling
- Blood dyscrasias or bone marrow suppression in history.

Rare cases of asthma attacks and anaphylactic shock in sensitive individuals have been associated with the administration of medicines containing propyphenazone and paracetamol.

***Taking other medicines***

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

During the administration of KOFAN INSTANT, avoid alcohol consumption because individual reactions cannot be predicted.

Concomitant administration of medicines that stimulate the activity of liver enzymes, such as, for example, hypnotics, anti-epileptics (eg, phenobarbital, phenytoin and carbamazepine) and rifampicin may enhance the hepatic toxicity of paracetamol, even at normal doses that are not harmful. This also applies to excessive alcohol consumption.

Slowing of gastric emptying, such as with propantheline, may slow the paracetamol absorption rate, and delay the onset of its action. Accelerated gastric emptying, as in the case of administration of metoclopramide, increases the absorption rate.

In combination with chloramphenicol, the elimination of this medicine can be extended with a higher risk of toxicity. The clinical significance of the interaction between paracetamol and warfarin or coumarin derivatives

is not known yet. Patients treated with oral anticoagulants may take paracetamol regularly over a prolonged period only under medical supervision.

The incidence of neutropenia (low white blood cell) is higher in cases where paracetamol and AZT (zidovudine) are administered simultaneously. KOFAN INSTANT can be used in combination with AZT only if recommended by a doctor.

Caffeine is antagonist to medicines with a sedative effect (eg. Barbiturates, antihistamines, etc). Caffeine enhances tachycardia caused by sympathomimetics, including ephedrine and thyroxine etc.

When it comes to medicines with a wide range of action (eg, benzodiazepines) interactions may occur in various forms and cannot be predicted. Oral contraceptives, cimetidine and disulfiram, slow the metabolism of caffeine, and barbiturates and smoking accelerate it. Caffeine slows the elimination of theophylline. Caffeine increases the ability to create a dependency on substances such as ephedrine. Co-administration of some gyrase inhibitors may prolong the elimination of caffeine and metabolites of Paraxanthine.

There have been interactions with the following medicines or groups of medicine:

- ACE inhibitors, beta blockers: reduction of the antihypertensive effect
- Anticoagulants, antithrombotics, including salicylates: increased risk of bleeding
- Diuretics: reduced diuretic effect
- Methotrexate: increased concentration and consequent toxicity of methotrexate
- Lithium: increased lithium concentrations in serum

### ***Taking food and drink with KOFAN INSTANT tablets***

While using KOFAN INSTANT tablets do not drink alcohol.

### ***Pregnancy and breast-feeding***

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

KOFAN INSTANT tablets should not be taken during pregnancy, especially during the first trimester and the last 6 weeks of pregnancy (due to the inhibitory potential on the biosynthesis of prostaglandins and subsequent inhibition of contractions).

Breastfeeding

KOFAN INSTANT should not be used during breastfeeding.

### ***Driving and using machines***

KOFAN INSTANT, when taken at recommended doses, should not affect your ability to drive and use machines.

## ***3. HOW TO TAKE KOFAN INSTANT***

### ***The usual individual dose:***

Adults: 1-2 tablets

Adolescents 12 to 16 years: 1 tablet.

If necessary, this dose can be repeated up to three times a day.

Take the tablets with plenty of water or other liquids.

This medicine must not be used for longer than 7 days or in doses that are higher than recommended without consulting a doctor.

***If you take more KOFAN INSTANT than you should***

If you suspect an overdose, immediately contact your doctor, even if the symptoms are temporarily mitigated and do not take any other medication.

If you take a higher dose of KOFAN INSTANT, you can seriously damage the liver. In case of overdose it is necessary to seek medical attention immediately.

Symptoms of paracetamol overdose are loss of appetite, nausea and vomiting.

Symptoms of caffeine overdose include paleness, dilated pupils, the effect on the central nervous system such as insomnia, restlessness, stiffness, posture and tonic convulsions, nervousness, irritability, headache, excitation, rapid speech, cardiovascular effects such as increased heart rate, cardiac arrhythmias, high blood pressure, the effects on the urination and vomiting that lead to electrolyte imbalance, noise in the ear, gastrointestinal disorders such as vomiting, and rapid breathing.

Propiphenazon overdose is manifested as nausea, high blood pressure, drowsiness or seizures.

***If you forget to take KOFAN INSTANT***

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

KOFAN INSTANT is taken as necessary, depending on the symptoms.

Talk to your doctor or pharmacist if you have any additional questions.

***4. POSSIBLE SIDE EFFECTS***

Like all medicines, KOFAN INSTANT can cause side effects, although not everybody gets them.

**Blood and lymphatic system**

- Blood disorders, including reduction in the number of platelets in the blood, thrombocytopenic purpura
- Reducing the number of leukocytes in the blood
- Reducing the number of all blood cells below normal.

**Digestive disorders**

- Nausea, vomiting, discomfort, diarrhea, pain in the abdominal cavity.

**Hepatobiliary disorders**

- Hepatic dysfunction, hepatitis, dose-related liver failure
- Necrosis of the liver (including fatal outcome)
- Long-term use of non-approved doses may lead to fibrosis and cirrhosis of the liver, including death.

**Immune System**

- Allergic reaction, anaphylactic reactions and anaphylactic shock

**Nervous system**

- Dizziness
- Drowsiness

**Renal and urinary system**

- Impairment of kidney function, especially in overdose

**Respiratory system**

- Bronchospasm and asthma, including analgesic asthma syndrome

**Skin and subcutaneous tissue**

- Rash, itching, hives
- Allergic edema and angioedema
- Acute suppurative rash all over the body, skin eruptions, polymorphic erythema, Stevens-Johnson syndrome and toxic epidermal necrolysis (including fatal outcome).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE KOFAN INSTANT

Keep out of the reach and sight of children.

Do not store above 30 °C.

Shelf life: 60 months.

Do not use KOFAN INSTANT after the expiry date which is stated on the label.

## 6. FURTHER INFORMATION

### **What KOFAN INSTANT contains**

One KOFAN INSTANT tablet contains:

Paracetamol 200 mg

Propiphenazon 200 mg

Caffeine 50 mg

KOFAN INSTANT tablets contain the following excipients: microcrystalline cellulose, corn starch, talc, povidone, colloidal silicon dioxide and magnesium stearate.

### **What KOFAN INSTANT looks like and contents of the pack**

KOFAN INSTANT tablets are white, round in shape.

KOFAN INSTANT tablets are packaged in boxes of 10 (1 PVC / Al blister x 10 tablets) and 20 (2 PVC / Al blister x 10 tablets) tablets.

### **Regime of dispensing**

The medicine is issued without a doctor's prescription.

### **Manufacturer**

Bosnalijek, doo, Jukićeva 53, Sarajevo, BiH