

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

SEKALGIC® tablet

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of SEKALGIC® contains:

Ibuprofen BP ..	400 mg
Paracetamol BP ..	500 mg
Anhydrous Caffeine BP ..	30 mg

For the full list of excipients. (See Section)

### 3. PHARMACEUTICAL FORM

Box of 12 tablets

### 4. CLINICAL DATA

#### 4.1. Therapeutic indications

SEKALGIC® tablet is indicated in adults and children from 6 years in the treatment of mild to moderate pain as well as febrile states including: headache, dental pain, flu, muscle pain, pain joints, painful periods, sprain, acute gout.

#### 4.2. Dosage and method of administration

Dosage

Children from 6 to 15 years:

The dosage is ½ tablet to one tablet every 8 hours without exceeding 3 tablets per day.

Adults and children over 15:

The dosage is 1 to 2 tablets every 8 hours without exceeding 6 tablets per day. Administration mode the tablets are swallowed with a large glass of water.

### **4.3. Contraindications**

SEKALGIC® should not be used in the following cases:

- hypersensitivity to ibuprofen, paracetamol, caffeine or any of its excipients
- in children under 6 years old
- ulceration or history of peptic ulcer
- Asthma patients in whom asthma attacks, urticaria or acute rhinitis are caused by acetyl salicylic acid or other drugs that inhibit prostaglandin synthesis.
- hepatic insufficiency, renal failure and heart failure
- last trimester of pregnancy.

4.4. Side effects :  
SEKALGIC® may cause the following side effects:

#### **Paracetamol-related**

Few cases of hypersensitivity reactions, erythema, urticaria, skin rash have been reported. Their occurrence requires the definitive discontinuation of this drug and related drugs.

#### **Related to ibuprofen**

The most commonly observed adverse reactions are gastrointestinal in nature: nausea, vomiting, gastralgia, transit disorders, dyspepsia, gastrointestinal bleeding. Hypersensitivity reactions have been reported as well as effects on the exceptional nervous system such as vertigo and headache.

#### **Caffeine related**

Sleep disturbances, agitation, convulsions, tremors, tachycardia, vomiting, diarrhea, abdominal pain.

### **4.5. Interactions with other drugs and other forms of interactions**

The risk of bleeding is increased with prolonged use of paracetamol with anticoagulants such as warfarin or other coumarins.

It is necessary precautions when taking simultaneously with the following products:

- nonsteroidal anti-inflammatory drugs (NSAIDs).

Oral anticoagulants

parenteral heparin

- ticlopidine

- thiazide diuretics

- moclobemide

- lithium

- hypoglycemic sulfonamides

- methotrexate

- zidovudine

Take into account interactions with antihypertensives (beta-blockers, converting enzyme inhibitors and diuretics), digoxin and thrombolytics.

#### **4.6. Pregnancy and breast feeding**

SEKALGIC® is not recommended during pregnancy and during breastfeeding

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic and pharmacokinetic properties**

These properties are due to the different constituents of the formulation. ibuprofen

Ibuprofen is a nonsteroidal anti-inflammatory drug belonging to the group of propionics derived from aryl carboxylic acid. It has the following properties: analgesic, antipyretic, anti-inflammatory, short-term inhibition of platelet function,

All of these properties are related to an inhibition of prostaglandin synthesis. Paracetamol:

Antipyretic with direct action on the central regulator of fever in the hypothalamus. Its analgesic action is related to the elevation of the threshold of the pain probably by the synthesis of prostaglandins of the CNS.

Caffeine:

Stimulant of the central nervous system and respiratory centers is an inhibitor of phosphodiesterase.

This enzyme is responsible for the inactivation of cyclic 3', 5' adenosine monophosphate (cAMP). The increase in intracellular cAMP levels plays the role of mediator responsible for the main pharmacological actions of caffeine. Caffeine therefore stimulates the whole of the central nervous system and in particular the respiratory centers. It can cause vasoconstriction of the cerebral vessels.

## **5.2. Pharmacokinetic data:**

Ibuprofen:

Ibuprofen is rapidly absorbed and distributed throughout the body after administration. Maximum plasma concentrations are reached approximately 1 to 2 hours after ingestion with food or within 45 minutes if taken on an empty stomach. These times may vary depending on the different dosage forms. It is metabolized to two inactive metabolites and these are rapidly excreted in the urine. Excretion is rapid and complete in the kidneys. The half-life of ibuprofen is approximately 2 hours.

Paracetamol:

Oral absorption is fast and almost complete. About 90-95% of a dose is metabolized in the liver, mainly by conjugation with glucuronic acid, sulfuric acid and cysteine.

An intermediate metabolite, which can accumulate as an overdose after saturation of the primary metabolic pathways, is hepatotoxic and possibly nephrotoxic. The half-life is 1 to 4 hours. The elimination is by the renal route, in the form of mainly conjugated metabolites, 3% of a dose can be excreted unchanged.

Caffeine:

is well absorbed after oral administration and rapidly distributed throughout the body. It crosses the blood-brain and placental barrier. Its plasma half-life is 3 to 4 hours and is metabolized in the liver with mainly urinary excretion.

## **5.3. Preclinical safety data**

Preclinical data from conventional animal studies, pharmacological safety, chronic toxicity, genotoxicity and carcinogenic and reproductive potential have not revealed any specific potential risk to humans.

## **6. PHARMACEUTICAL DATA**

### **6.1. List of excipients**

Corn starch, gelatin, cellulose, microcrystalline, sodium methylparabenzoate, sodium propylparabenzoate, magnesium stearate, purified talc, aerosil 200, carmellose sodium, tartrazine supra dye, tartrazine lake dye.

### **6.2. The duration of the conversation**

3 years.

### **6.3. Special precautions for storage**

Store in a cool place, protected from light and at a temperature not exceeding 30 ° C.

### **6.4. Special precautions for disposal and handling**

No special requirements.

## **7. HOLDER OF THE MARKETING AUTHORIZATION**

BEKRA PHARMA UK LTD

## **8. DOSIMETRY**

Not applicable.

## **9. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS**

Not applicable.

## **10 - CONDITIONS OF PRESCRIPTION AND DELIVERY**

Medicinal product not subject to medical prescription.