SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SEKALGIC® oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of SEKALGIC® contains:

Ibuprofen BP .. .. 100 mg

Paracetamol BP .... 125 mg

For the full list of excipients. (See Section)

3. PHARMACEUTICAL FORM

Bottle of 100 ml.

4. CLINICAL DATA

4.1. Therapeutic indications

SEKALGIC® is indicated for the treatment of mild to moderate pain including headache, neuralgia, migraine, toothache, sore throat, painful periods.

SEKALGIC® is indicated in case of fever for post-vaccination pyrexia but also as adjunctive treatment to relieve the symptoms of colds and flu.

4.2. Dosage and method of administration

Dosage

Infants from 3 to 12 months:

The dosage is 2.5 ml 3-4 times a day. Children from 1 year to 5 years old:

The dosage is 5 ml 3-4 times a day. Children from 5 to 12 years

The dosage is 10 ml 3-4 times a day.

Administration mode

The intake is oral.

4.3. Contraindications

SEKALGIC® should not be used in the following cases:

- hypersensitivity to ibuprofen, paracetamol or any of its excipients

- 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.

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.

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.

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

Xanthan gum, powdered orange flavor, light yellow FCF, sodium benzoate, sodium methyl hydroxy benzoate, sodium carboxymethyl cellulose, disodium EDTA, anhydrous colloidal silica, sucrose.

6.2. The duration of the conversation

2 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.