

SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)

1. Name of the medicinal product

Afrab Ibuprofen suspension.

2. Qualitative and quantitative composition

Each 5ml drop contains 100mg of Ibuprofen.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Suspension

Orange coloured suspension with a sweet taste

4. Clinical particulars

Therapeutic indications

Ibuprofen suspension is indicated for the relief of:

- Fever in children including post immunisation fever.
- Mild to moderate pain and inflammation.
- Minor aches and pains due to colds, flu, sore throat, earache and toothaches.

Posology and method of administration

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Child up to 6 months -1 year: 2.5ml 3 times daily.

1year to 6 years : 5ml 3 times daily.

7years to 12years : 10ml 3 times daily.

Contraindications

Hypersensitivity to Ibuprofen and any component of the preparation or severe hepatic impairment.

Special warnings and precautions for use

Warnings: Avoid use in severe hepatic impairment. Non steroidal anti-inflammatory drugs (NSAID) may increase risk of serious cardiovascular thrombotic events, myocardial infarction (MI), and stroke which can be fatal.

NSAIDs increase risk of serious GI adverse events, including bleeding, ulceration and gastric or intestinal perforation, which can be fatal.

Precautions: Use caution in asthma (bronchial), cardiac congestive heart failure (CHF), hepatic or renal impairment, hypertension, bleeding disorder, duodenal/gastric/peptic ulcerative colitis, upper GI disease, late pregnancy (may cause premature closure of ductus arteriosus).

Long-term administration of NSAIDs may result in renal papillary necrosis and other renal injury, patients at great risk include elderly individuals: those with impaired renal function, hypovolemia, heart failure, liver dysfunction, or salt depletion: and those taking diuretics, angiotensin-converting enzyme (ACE) inhibitors, or angiotensin receptor blockers.

Interaction with other medicinal products and other forms of interaction

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines like aspirin, benazepril, Captopril, Enalapril, Erdafitinib, Fosinopril, Lisinopril, Methotrexate, Methyl aminolevulinate, Naproxen

Pregnancy and Lactation

≥ 30 weeks gestation: May cause premature closure of ductus arteriosus; avoid during 1st and 3rd trimesters. Drug excreted into human breast milk in extremely low levels.

Effects on ability to drive and use machines

If you experience drowsiness, dizziness, a headache as side-effects when using ibuprofen medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects.

Undesirable effects

Such allergic reactions as dizziness, Epigastric pain, Heartburn, constipation, Nausea, Rash, and Tinnitus. In rare cases the following reactions are possible: Edema, Fluid retention, Headache, Vomiting.

Overdose

Symptoms

Management of overdoses

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Ibuprofen, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

- Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdose.

5. Pharmacological properties

Pharmacodynamic properties

Mechanism of action: Ibuprofen inhibits synthesis of prostaglandins in body tissues by inhibiting at least 2 cyclooxygenase (COX) isoenzymes COX-1 and COX-2.

PHARMACODYNAMIC:

Pharmacokinetic properties

The pharmacokinetics of Ibuprofen, an analgesic, anti-pyretic, inflammatory, agent,

Absorption

Ibuprofen is rapidly absorbed (85%), a bioavailability of 80-100%, has an onset of action of 30-60 minutes, duration of action of 4-6 hours. Its Protein bound: 90-99%: concentrations >20mcg/ml.

Metabolism

Ibuprofen is rapidly metabolised in liver (primarily by CYP2C9: CYP2C19 substrate) via oxidation to inactive metabolites.

Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline cellulose

Sorbitol solution

Polysorbate 80

(Tween 80)

Glycerine.

Xathan gum

Sodium benzoate

Disodium edetate

Strawberry flavor liquid

Citric acid

monohydrate

Allura red

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3years.

6.4 Special precautions for storage

Store below 30 ° C.

6.5 Nature and contents of container

Afrab Ibuprofen Suspension is packaged in 100ml PET bottle.

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. Applicant /Manufacturer

Afrab Chem Limited

22 Abimbola Street, Isolo Industrial Estate, Isolo-Lagos, Nigeria