1.4 Product Information

1.4.1 Summary of Products Characteristics (SmPC)

1. Name of the medicinal product

IBUPROFEN AND PARACETAMOL SUSPENSION

2. Qualitative and quantitative composition

Each 5 ml contains:
Ibuprofen BP 100mg
Paracetamol BP 125mg
Flavoured Syrupy Base q.s
Colour: Erythrosine

3. Pharmaceutical form

Liquid oral

Pink colour suspension

4. Clinical particulars

4. Clinical Particulars

4.1 Indication

In Pain relief

Oral Suspension contains two medicines: Paracetamol and Ibuprofen both of which are widely used as pain killers. They work in different ways to reduce pain, swelling, and inflammation. This medicine is very effective in treating mild to moderate pain associated with migraine, headache, backache, period (menstrual) pain, dental pain, and rheumatic and muscular pain. The anti-inflammatory component makes this medicine more effective in treating strains, sprains, and muscle pains.

Take it as it is prescribed to get the most benefit. Do not take too much as this can be dangerous and do not take it for longer than you need it. In general, you should take the lowest dose that works, for the shortest possible time.

In Treatment of Fever

Oral Suspension helps lower high temperature caused by fever. This medicine is effective in treating cold and flu symptoms, sore throat, and fever. Take it as it is prescribed to get the most benefit. Do not take too much or for longer than you need as this can be dangerous. In general, you should take the lowest dose that works, for the shortest possible time.

4.2 Posology and Administration

Take this medicine in the dose and duration as advised by your doctor. Check the label for directions before use. Measure it with a measuring cup and take it by mouth. Shake well before use. Suspension is to be taken with food.

4.3 Contraindication

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special Warning & precautions for use

Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction.

4.5 Interaction with other medicinal products and other forms of interaction

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic

drugs or drugs that induce liver microsomal enzymes, such as certain antiepileptics (such as phenobarbital, phenytoin, carbamazepine, topiramate), rifampicin and alcohol. The induced metabolism results in an elevated production of the hepatotoxic oxidative metabolite of paracetamol.

Hepatotoxicity will occur if this metabolite exceeds the normal glutathione binding capacity.

Paracetamol may increase the risk of bleeding in patients taking warfarin and other antivitamin K.

Patients taking paracetamol and antivitamin K should be monitored for appropriate coagulation and bleeding complications.

Co-administration of flucloxacillin with paracetamol may lead to metabolic acidosis, particularly in patients presenting risk factors of glutathione depletion, such as sepsis, malnutrition or chronic alcoholism.

This product (like any other paracetamol containing products) is contraindicated in combination with other paracetamol containing products – increased risk of serious adverse effects

The absorption rate of paracetamol may be increased by metoclopramide or domperidone.

Chelating resin can decrease the intestinal absorption of paracetamol and potentially decrease its efficacy if taken simultaneously. In general, there must be an interval of more than 2 hours between taking the resin and taking paracetamol, if possible.

4.6 Fertility, Pregnancy and lactation

Pregnancy: The use of the product should be avoided in the first six months of pregnancy and contraindicated in the last three months of pregnancy.

Lactation: It is not necessary to interrupt breastfeeding for short-term treatment with the recommended dose of this product.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs.

4.9 Overdose

Elderly persons, small children, patients with liver disorders, chronic alcohol consumption or chronic malnutrition, as well as patients concomitantly treated with enzyme-inducing drugs are at an increased risk of intoxication, including fatal outcome.

5. Pharmacological properties

5.1 Pharmacodynamic properties

It works by blocking the release of certain chemical messengers that cause fever, pain and inflammation (redness and swelling).

5.2 Pharmacokinetic properties

Ibuprofen :

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. Peak plasma concentrations occur about 1 to 2 hours after ingestion with food or in 45 minutes if taken on an empty stomach. These times may vary with different dosage forms.

The excretion is rapid and complete via the kidneys.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

It is metabolised to two inactive metabolites and these are rapidly excreted in urine. About 1 percent is excreted in urine as unchanged Ibuprofen and about 14 percent as conjugated Ibuprofen.
Ibuprofen is extensively bound to plasma proteins.

Paracetamol:
Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.
Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

6. Shelf Life

36 months

7. Special precaution for Storage

Store in a dry place, below 30°C. Protect from light.

8. Nature and contents of container

100 ml glass bottle in a carton along with insert.

9. Manufacturer

Aura Lifecare Pvt. Ltd.

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