



AURA LIFECARE PVT. LTD.

Product: Ibuprofen and Paracetamol suspension

MODULE: 1

1.4.3 PATIENT INFORMATION LEAFLET (PIL)

1 Name of Product

Ibuprofen and paracetamol suspension

2 Description of Product

Pink colour suspension

3 What is in the medicine?

It contains paracetamol & Ibuprofen

4 Strength of the medicine

Ibuprofen BP 100mg

Paracetamol BP 125mg

5 What is this medicine used for?

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.

6 How much and how often should you use this medicine?

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.

7 When should you not take this medicine?

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

8 Undesirable effects

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

9 What other medicine or food should be avoided whilst taking this medicine?

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.

Module 1: ADMINISTRATIVE INFORMATION



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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.

10 What should you do if you miss a dose?

Do not take double dose. Consult your doctor.

11 How should you keep this medicine?

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

KEEP OUT OF REACH OF CHILDREN

12 Signs & Symptoms of over dosage

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.

13 What to do when you have taken more than the recommended dosage?

Contact your doctor or pharmacist immediately. They may empty your stomach or can take other measures to alleviate the symptoms.

14 Name/logo of manufacturer/importer/Marketing Authorisation Holder

Name and Address of Marketing Authorisation Holder

Sun Enterprises LTD

BP 1952

Kigali, Rwanda

15 Care that should be taken when taking this medicine?

Hypersensitivity to any of the components of Ambroxol

16. Date of Revision of PIL
