

Solpadeine

TABLETS

Strong fast pain relief (ANALGESIC/ANTIPYRETIC)

DESCRIPTION

Each tablet contains 500 mg paracetamol Ph. Eur., 30 mg caffeine Ph. Eur. and 8 mg codeine phosphate Ph. Eur.

INTRODUCTION

Paracetamol is a clinically proven analgesic and antipyretic. It produces its effects by its action on central and peripheral prostaglandin synthesis inhibition.

INDICATIONS

Solpadeine Tablets are recommended for relief of mild to moderate pain and fever from: headache, migraine, neuralgia, toothache, sore throat, menstrual pain, rheumatic and muscular pain, feverishness and cold symptoms and influenza.

DOSAGE AND ADMINISTRATION

For oral administration only.

Solpadeine Tablets are suitable for adults and children over 12 years of age.

ADULTS

Two tablets up to three or four times a day



Not recommended for children under 12 years
If necessary the dose may be repeated every four hours but do not take more than four doses in 24 hours.

CONTRAINDICATIONS

Solpadeine Tablets are contra-indicated in patients with known hypersensitivity to paracetamol or codeine and in those patients with G6PD deficiency (haemolytic anaemia).

PRECAUTIONS

This preparation contains paracetamol. Do not take other paracetamol containing medications at the same time.

Keep this and all medication out of the reach of children. Solpadeine Tablets should be used with caution in cases of severe liver or kidney damage.

Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor.

If pain or fever persists or gets worse, if new symptoms occur, or if redness and swelling is present, consult a doctor because these could be signs of a serious condition. If sore throat is severe and persists for more than 2 days, is accompanied by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

PREGNANCY AND LACTATION

Although there is epidemiological evidence of the safety of paracetamol in pregnancy and lactation, medical advice should be sought before using this product.

Do not use this product or any codeine-containing products while breastfeeding unless under supervision of your doctor.
Use of these products may harm your baby.

SIDE-EFFECTS

When taken in recommended doses, Solpadeine Tablets are usually free from side-effects. However skin reactions such as urticaria have been reported rarely.

DRUG INTERACTIONS

Solpadeine Tablets may interact with anticoagulant agents on prothrombin time. The liver effects of Solpadeine Tablets may be increased by the use of alcohol and the concomitant use of certain drugs which enhance the metabolism of Solpadeine in the liver (ie. barbiturates, tricyclic antidepressants).

OVERDOSAGE

In massive overdosage exceeding 10 g. Solpadeine Tablets may cause liver damage. Early symptoms may cause pallor, nausea, vomiting, (diaphoresis) and general malaise. Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours post-ingestion. Overdose should be promptly treated by gastric lavage followed by intravenous N-acetylcysteine or methionine without waiting for the results of plasma paracetamol levels. Additional antidote therapy is normally considered in light of further plasma paracetamol levels and the time elapsed since ingestion. Nausea and vomiting are prominent symptoms of codeine toxicity and there is evidence of circulatory and respiratory depression. Suggested treatment is gastric lavage and catharsis. If CNS depression is severe, artificial respiration, oxygen and parenteral naloxone may be needed.

In all cases of suspected overdose, prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C. Store in a well sealed container.



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THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENT OUT OF THE REACH OF CHILDREN