Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acupan 30mg film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 30 mg nefopam hydrochloride.
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-Coated Tablets

Product imported from the UK
White, circular, biconvex tablet, 7mm in diameter and marked APN on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acupan is indicated for the relief of pain including: post-operative pain; dental pain; musculoskeletal pain; acute traumatic pain and cancer pain. Each course of treatment should be limited to 7 days except in the case of cancer therapy.

4.2 Posology and method of administration

Adults: Dosage may range from one to three tablets three times daily depending on response. The recommended starting dose is two tablets three times daily.

Elderly: Patients may require reduced dosage due to slower metabolism. It is strongly recommended that the starting dose does not exceed one tablet three times daily as the elderly appear more susceptible to in particular, the CNS side effects of Acupan and some cases of hallucinations and confusion have been reported in this age group.

Children: Since Acupan has not been evaluated in children no dosage recommendation can be given for patients under 12 years.

4.3 Contraindications

Acupan is contra-indicated in patients with hepatic and renal failure and those hypersensitive to the active ingredient.

Since it possesses CNS stimulant effects its use is contra-indicated in patients with convulsive disorders. It should not be given to patients taking monoamine-oxidase (MAO) inhibitors or within 14 days of their ingestion.

4.4 Special warnings and precautions for use

The side effects of Acupan may be additive to those of other agents with anticholinergic or sympathomimetic activity. It should not be used in the treatment of myocardial infarction since there is no clinical experience in this indication. Hepatic and renal insufficiency may interfere with the metabolism and excretion of nefopam.

Acupan should be used cautiously in patients with hypertension, thyrotoxicosis and heart disease, and when nefopam is administered concurrently with tricyclic antidepressants. Acupan should be used with caution in patients with, or at risk of, urinary retention. Rarely a temporary, harmless pink discolouration of the urine has occurred.

4.5 Interaction with other medicinal products and other forms of interaction

Acupan should be used cautiously in conjunction with aspirin since blood levels of nefopam may be significantly raised in some patients. While excessively high doses of paracetamol and nurofen used concurrently have given rise to hepatotoxicity in dogs, clinical doses have not done so. Caution should nevertheless be exercised when both agents are considered for simultaneous use.

4.6 Fertility, pregnancy and lactation

There is no evidence of safety of use during pregnancy nor is there evidence from animal work that it is free from hazard. The product should not be used unless considered absolutely essential by the physician.

Nefopam is excreted in human milk. Concentrations are approximately the same as those in maternal plasma. Risk of adverse effects in the nursing infant is very small.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Nausea, dry mouth, fatigue, flushing, urinary retention, hypotension, syncope, palpitations, gastrointestinal disturbances (including abdominal pain and diarrhoea), dizziness, paraesthesia, convulsions, tremor, confusion, hallucination, angioedema, and allergic reactions may occur. Less frequently, vomiting, blurred vision, drowsiness, sweating, insomnia, headache and tachycardia have been reported.

4.9 Overdose

The clinical pattern of nefopam toxicity in overdose is on the neurological (convulsions, hallucinations and agitation) and cardiovascular systems (tachycardia with a hyperdynamic circulation). Routine supportive measures should be taken and prompt removal of ingested drug by gastric lavage or induced vomiting with Syrup of Ipecacuanha should be carried out. Induction of vomiting using salt water is contra-indicated. Oral administration of activated charcoal may help prevent absorption.

Convulsions and hallucinations should be controlled (eg with intra-venously or rectally administered diazepam). Beta-adrenergic blockers may help control the cardiovascular complications.

If a mixed overdose including nefopam and paracetamol is taken, there is a theoretical possibility of interference by nefopam in the metabolism of paracetamol. Measures to counter paracetamol toxicity should therefore be implemented at lower plasma concentrations of paracetamol than usual.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nefopam is a non-narcotic analgesic with central stimulant and sympathomimetic properties.

5.2 Pharmacokinetic properties

Metabolism of nefopam takes place in the liver and excretion is through the urine. The plasma half-life is approximately four hours.

5.3 Preclinical safety data

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

Non-clinical data on genotoxicity are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
dicalcium phosphate dihydrate,
microcrystalline cellulose,
pregelantinised maize starch,
magnesium stearate,
hydrogenated vegetable oil,
colloidal silicone dioxide

Film coating:
hydroxypropylmethylcellulose
titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister strip and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Acupan are supplied in UPVC/aluminium/UPVC blister strips of 30 tablets. Each pack contains 90 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1562/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th February 2010

10 DATE OF REVISION OF THE TEXT