SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nefopam hydrochloride 60 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 60 mg nefopam hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

White to off-white, circular, biconvex, film coated tablets, debossed with ‘NT1’ on one face and plain on other face.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nefopam hydrochloride is indicated for the relief of acute and chronic pain, including post-operative pain, dental pain, musculo-skeletal pain, acute traumatic pain and cancer pain.

4.2 Posology and method of administration

Posology
ADULTS: Dosage may range from 30mg to 90mg three times daily depending on response. The recommended starting dosage is 1 tablet of 60mg three times daily.

OLDER PEOPLE: Older patients may require reduced dosage due to slower metabolism.

It is strongly recommended that the starting dose does not exceed one tablet of 30mg tablets three times daily as older people appear more susceptible to, in particular, the

CNS side effects of Nefopam hydrochloride and some cases of hallucinations and confusion have been reported in this age group.

For the dose other than 60mg, the use of alternative strength of Nefopam (i.e. Nefopam 30mg tablets) should be considered as necessary (see section 4.4)
PAEDIATRIC POPULATION: The safety and efficacy of Nefopam hydrochloride in children under 12 years has not yet been established. No dosage recommendation can be given for patients under 12 years.

Patients with end stage renal disease might experience increased serum peak concentrations during treatment with nefopam. In order to avoid that, it is recommended the daily dose should be reduced not only for the elderly, but also for patients with terminal renal insufficiency.

Method of administration
Oral use.

4.3 Contraindications

Nefopam hydrochloride is contra-indicated in patients with a history of convulsive disorders and should not be given to patients taking mono-amine-oxidase (MAO) inhibitors. Nefopam hydrochloride is contraindicated in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

The side effects of Nefopam hydrochloride 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.

Nefopam should be used with caution in patients with angle closure glaucoma. Cases of nefopam dependence and abuse have been reported with nefopam use.

Nefopam hydrochloride 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.

This product is not suitable for patients requiring the dose of 30mg as the product cannot be divided into two equal halves.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be exercised when nefopam is administered concurrently with tricyclic antidepressants.

It should be noted that nefopam may interfere with some screening tests for benzodiazepines and opioids. These tests for benzodiazepines and opioids may give false positive results for patients taking Nefopam hydrochloride.

4.6 Fertility, pregnancy and lactation

There is no evidence as to the drug safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. Avoid in pregnancy unless there is no safer treatment

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Nausea, nervousness, dry mouth and light-headedness, 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, anaphylactic reactions, coma, vomiting, blurred vision, drowsiness, sweating, insomnia, headache and tachycardia have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The clinical pattern of nefopam toxicity in overdose is on the neurological (coma, 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. Oral administration of activated charcoal may help prevent absorption.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 4.7.1 Non-opioid analgesics and compound analgesic preparations.
ATC code: N02BG06

Nefopam hydrochloride is a potent and rapidly-acting analgesic. It is totally distinct from other centrally-acting analgesics such as morphine, codeine, pentazocine and propoxyphene.

Unlike the narcotic agents, nefopam hydrochloride has been shown not to cause respiratory depression. There is no evidence from pre-clinical research of habituation occurring with nefopam hydrochloride.

5.2 Pharmacokinetic properties

Nefopam is absorbed from the gastro-intestinal tract. Peak plasma concentrations occur about 1-3 hours after oral administration. About 73% is bound to plasma proteins. It has an elimination half-life of about 4 hours. It is extensively metabolised and excreted mainly in urine. Less than 5% of a dose is excreted unchanged in the urine. About 8% of a dose is excreted via the faeces.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Calcium hydrogen phosphate dihydrate

Pregelatinised maize starch

Silica, colloidal anhydrous

Hydrogenated castor oil

Magnesium stearate

Tablet coat:

Hypromellose

Titanium dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/PVdC- Aluminium blister packs containing 30, 60 and 90 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0316

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

15/01/2024