SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Nefopam Hydrochloride 30 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains Nefopam hydrochloride 30 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet
White round film-coated tablets marked with "30N" on one side and smooth on other side.

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 1 to 3 tablets three times daily depending on response. The recommended starting dosage is 2 tablets 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 three times daily as older people appear more susceptible to, in particular, the CNS side effects of Nefopam Hydrochloride some cases of hallucinations and confusion have been reported in this age group.

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 the active substance or to any of the excipients listed in section 6.1.

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 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.

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

Pregnancy

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.

Breastfeeding

Nefopam is excreted in human milk. Concentrations are approximately the same as those in maternal plasma. Since there is a risk of adverse effects in the nursing infant, breast-feeding should be discontinued during treatment with Nefopam 30 mg tablets.

Fertility

In animal studies, no adverse effects on fertility were observed (see Section 5.3). Whether or not nefopam affects the fertility in humans is unknown.

4.7 Effects on ability to drive and use machines

Nefopam hydrochloride may cause drowsiness. Patients should not drive or operate machinery during the treatment.

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, vomiting, blurred vision, drowsiness, sweating, insomnia, headache and tachycardia have been reported. Frequency not known, confusional state, coma

Reporting of suspected adverse reactions

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 Website: www.medicinesauthority.gov.mt/adrportal.

4.9 Overdose

The clinical pattern of nefopam toxicity in overdose is on the neurological (convulsions, hallucinations, coma 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 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

Non-clinical data reveal 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

Calcium hydrogen phosphate dihydrate

Microcrystalline cellulose
Hypromellose
Colloidal anhydrous silica
Magnesium stearate

Coating ingredients:
Hypromellose (E464)
Hydroxy propyl cellulose (E463)
Titanium dioxide (E171)

6.2 Incompatibilities
None

6.3 Shelf life
24 months

6.4 Special precautions for storage
This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container
Blister packs of PVC- Aluminium foil containing 7, 10, 14, 15, 20, 21, 28, 30, 40, 42, 45, 50, 56, 60, 70, 84, 90, 98 and 100 tablets.

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
RIA Generics Limited
The Black Church
St. Mary's Place, Dublin 7
D07 P4AX, Ireland

8. MARKETING AUTHORISATION NUMBER(S)
MA1405/00201

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
06/08/2018

10. DATE OF REVISION OF THE TEXT
28/05/2020