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 30 mg nefopam hydrochloride.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
White to off-white, circular shaped, biconvex, film coated tablets, debossed with 'NT' on one face and plain on other face, approximately 7.00 mm in diameter.

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 1-2 tablets three times daily.
Elderly: 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 and 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.

Renal impairment: 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.

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 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 (drugs which block acetylcholine, and can be used to treat conditions such as bowel spasm, overactive bladder and others) 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 Hydrochloride.
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.

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 Hydrochloride 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 considered absolutely necessary by the physician.

Breast-feeding
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.

Fertility
In animal studies, no adverse effects on fertility were observed (see Section 5.3). The effects of nefopam on fertility in humans is unknown.

4.7 Effects on ability to drive and use machines

Not relevant.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

The clinical pattern of Nefopam Hydrochloride 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 ACT 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 Hydrochloride 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 no hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Microcrystalline cellulose
Calcium hydrogen phosphate dihydrate
Pregelatinised maize starch
Colloidal anhydrous silica
Magnesium stearate
Hydrogenated castor oil

Film-coating
Hypromellose
Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVdC- Aluminium blister packs containing 30 or 90 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Brown & Burk IR Limited
22 Northumberland Road
Ballsbridge
Dublin 4
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23148/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th April 2018

10 DATE OF REVISION OF THE TEXT

June 2022