SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nefopam Hydrochloride 30 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 30 mg nefopam hydrochloride.

3 PHARMACEUTICAL FORM

Film coated, white, round tablet and marked APN on one 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, musculoskeletal pain, acute traumatic pain and cancer pain.

4.2 Posology and method of administration

Posology

Adults:
Dosage may range from 1 to 3 tablets (30 – 90 mg) three times daily depending on response. The recommended starting dosage is 2 tablets (60 mg) followed by 1 tablet (30 mg) three times daily. This may be increased as required to the maximum recommended dose of 3 tablets (90 mg) three times a day.

Elderly:
Older patients may require reduced dosage due to slower metabolism. It is strongly recommended that the starting dose does not exceed 1 tablet (30 mg) 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.

Special populations:
Patients with end stage renal disease might experience increased serum peak concentrations during treatment with Nefopam Hydrochloride. 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 Hydrochloride.

Nefopam should be used with caution in patients with angle closure glaucoma.

Drug dependence
Use of nefopam may lead to drug dependence, which may result in drug abuse, particularly in patients with a history of substance use and/or mental health disorders. In such patients, nefopam should be prescribed with caution, and signs of dependence should be monitored.

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 Hydrochloride 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 use in pregnancy unless there is no safer treatment.

Breast-feeding:
Nefopam Hydrochloride has been identified in breastfed new-borns/infants of treated women. No effects have been shown in breastfed infants of treated mothers from the available limited data. However, caution should be exercised when prescribing for the nursing mothers taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility:
No data on the effects of Nefopam Hydrochloride on fertility

4.7 Effects on ability to drive and use machines
Nefopam Hydrochloride may affect the ability to drive and use machines.

4.8 Undesirable effects

Frequency groupings are classified according to the subsequent conventions:
Very common (≥ 1/10),
Common (≥ 1/100 to <1/10),
Uncommon (≥ 1/1,000 to <1/100),
Rare (≥ 1/10,000 to <1/1,000),
Very rare (<1/10,000) and
Not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Not known	Hypersensitivity, anaphylactic reaction, angioedema
Psychiatric disorders	Rare	PT Drug dependence*
	Not known	Agitation, hallucination, drug abuse and drug dependence, state of confusion, insomnia
Nervous system disorders	Not known	Somnolence, dizziness, paresthesia, tremor, seizure, headache, coma, syncope
Eye disorders	Not known	Blurred vision
Cardiac disorders	Not known	Tachycardia, palpitations
Vascular disorders	Not known	Hypotension
Gastrointestinal disorders	Not known	Nausea with or without vomiting, dry

		mouth, abdominal pain, diarrhoea
Skin and subcutaneous tissue disorders	Not known	Hyperhidrosis
Renal and urinary disorders	Not known	Urinary retention, urine discolouration (harmless pink colouring of urine)

*Drug dependence
Use of Nefopam Hydrochloride can lead to drug dependence. The risk of drug dependence may vary depending on a patient's individual risk factors (see section 4.4).

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:
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).

Treatment:
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 (e.g. 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 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

No additional data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic calcium phosphate dihydrate
Microcrystalline cellulose
Pregelatinised maize starch
Magnesium stearate
Hydrogenated vegetable oil
Colloidal silicon dioxide
These tablets are film coated using an aqueous solution containing: hydroxypropyl methylcellulose 2910, titanium dioxide E171.

6.2 Incompatibilities

None known

6.3 Shelf life

5 years

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

20 micron aluminium foil and 250 micron UPVC.
Blister pack of 90 tablets

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Generics (U.K.) Limited T/A Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 04569/1783

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/09/2015

10 DATE OF REVISION OF THE TEXT

08/05/2026