SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nefopam Hydrochloride 30mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nefopam hydrochloride 30 mg.

Excipient with known effect: 50.0 mg lactose anhydrous per tablet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated, white, round biconvex and marked A 55 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 three times daily depending on response. The recommended starting dosage is 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 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 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
- patients taking mono-amine-oxidase (MAO) inhibitors.
- 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.

Lactose

Nefopam Hydrochloride film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

Breast-feeding

Nefopam is excreted in human milk but there is insufficient information on the effect of Nefopam in newborns/infants.

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 has moderate influence on the ability to drive and use machines. Nefopam Hydrochloride may cause drowsiness. Patients should be warned not to drive or operate machinery until they know how Nefopam Hydrochloride affects them.

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, hallucination, angioedema, and allergic reactions may occur.

Less frequently, anaphylactic reactions, vomiting, blurred vision, drowsiness, sweating, insomnia, headache, tachycardia, confusional state and coma 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 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

Symptoms of nefopam toxicity in overdose are from anticholinergic origin: convulsions, hallucinations, agitation, coma (neurological system) and tachycardia with a hyperdynamic circulation (cardiovascular system). 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). Betaadrenergic blockers may help control the cardiovascular complications.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 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 has been shown not to cause respiratory depression. There is no evidence from pre-clinical research of habituation occurring with nefopam.

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 no special hazard 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:

Lactose

Silica, colloidal anhydrous

Cellulose, microcrystalline

Sodium starch glycolate (type A)

Magnesium stearate

Film-coating:

Opadry II white 85F184221

– Polyvinyl alcohol (E1203)

- Titanium dioxide (E171)
- Macrogol/PEG 3350 (E1521)
- Talc (E553b)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

PVC/PE/PVDC/Alu blister

Blister pack of 90 film-coated tablets

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2566

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/08/2016

10 DATE OF REVISION OF THE TEXT

03/07/2023