Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Nefogesic 30 (nefopam hydrochloride tablets 30mg)

2. Qualitative and quantitative composition

Each film coated tablet contains: nefopam hydrochloride.....30 mg
excipients.....q.s.

color: ferric oxide yellow USP, titanium dioxide bp & ferric oxide red usp

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet

A light pink colored, round shaped biconvex film coated tablet plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Nefopam 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.

Elderly: Elderly 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 the elderly appear more susceptible to; in particular, the CNS side effects of nefopam and some cases of hallucinations and confusion have been reported in this age group.

Paediatric population

The safety and efficacy of nefopam have not been evaluated in children under 12 years, 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

Hypersensitivity to the active substances or to any of the excipients.

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

4.4 Special warnings and precautions for use

The side effects of nefopam 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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 pregnancy and lactation

There is no evidence as to the drug safety in human pregnancy, nor is the 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. Psychiatric disorders (PT Drug dependence) may occur rarely.

Drug dependence

Use of Nefopam 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (pvers): https://pv.pharmacyboardkenya.org

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). Betaadrenergic blockers may help control the cardiovascular complications.

5. Pharmacological properties

5. 1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and antipyretics, ATC code: N02BG06 Nefopam 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

Absorption Nefopam is absorbed from the gastro-intestinal tract. Peak plasma concentrations occur about 1-3 hours after oral administration. Distribution About 73% is bound to plasma proteins. It has an elimination half-life of about 4 hours. Biotransformation It is extensively metabolised. Elimination Nefopam is 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

As per dossier

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a cool, dry & dark place.

6.5 Nature and contents of container

1x10 blister Alu Alu

6.6 Special precautions for disposal and other handling

Registration for KENYA NEFOGESIC 30 (NEFOPAM HYDROCHLORIDE TABLETS 30MG)

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. 7. Manufactured By RELAX BIOTECH PVT LTD.

7. Marketing authorisation holder

Krishna Chemists Ltd

3rd Floor Metrix Hardware, Lusaka Road, Industrial Area.

8. Marketing authorisation number

H2025/CTD12188/23995

9. Date of first authorisation/renewal of the authorisation

2025 July 17

10. Date of revision of the text

2025 July 17