Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Azuzote 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 coloured, round, bevel edged, debossed with 'N 30' on one side and plain on other side. Diameter: 7.10 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Azuzote Film-coated Tablets 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:
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 Azuzote Film-coated Tablets and some cases of hallucinations and confusion have been reported in this age group.

PAEDIATRIC POPULATION:
The safety and efficacy of Azuzote Film-coated Tablets 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 Azuzote Film-coated Tablets. 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

Azuzote Film-coated Tablets is contraindicated in patients with a history of convulsive disorders and should not be given to patients taking monoamine oxidase (MAO) inhibitors.
Azuzote Film-coated Tablets is contraindicated in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

The side effects of Azuzote Film-coated Tablets 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 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.

Azuzote Film-coated Tablets 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 Azuzote Film-coated Tablets.

4.6 Fertility, pregnancy and lactation

Pregnancy:
There is no evidence of safety of use during pregnancy, nor is there evidence from animal work that it is free from hazard. Nefopam should not be used in pregnancy unless considered absolutely essential by the physician.

Breast-feeding:
Nefopam is excreted in human milk. Concentrations are approximately the same as those in maternal plasma. Since there is 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 effect of nefopam on fertility in humans is unknown.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Drug dependence (frequency rare).

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.

Drug dependence
Use of Azuzote 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 HPRA Pharmacovigilance. Website: www.hpra.ie.

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). Beta-adrenergic 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.

Azuzote Film-coated Tablets 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, Azuzote Film-coated Tablets has been shown not to cause respiratory depression. There is no evidence from pre-clinical research of habituation occurring with Azuzote Film-coated Tablets.

5.2 Pharmacokinetic properties

Nefopam is absorbed fromthe gastro-intestinal tract. Peak plasma concentrations occur about 1-3 hoursafter oral administration. About 73% is bound to plasma proteins. It has anelimination half-life of about 4 hours. It is extensively metabolised andexcreted mainly in urine. Less than 5% of a dose is excreted unchanged in theurine. 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, repeat dose toxicity, carcinogenicity potential and toxicity to reproduction.
Non-clinical data on genotoxicity are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core Tablet:
Microcrystalline cellulose (E460)
Calcium hydrogen phosphate dihydrate (E341)
Colloidal anhydrous silica
Pregelatinised starch
Hydrogenated vegetable oil
Magnesium stearate

Film-Coating:
Hypromellose
Titanium dioxide
Macrogol

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

Alu-PVC blisters of 30 or 90 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA22871/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last authorisation: 1st January 2025

10 DATE OF REVISION OF THE TEXT

June 2026