SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nefopam Hydrochloride DAWA 30 mg Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains Nefopam Hydrochloride 30 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

White colour, round shaped tablets plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nefopam 30 mg tablets are 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

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.

Special populations

Elderly: Dosage adjustment may be required 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 30 mg tablets and some cases of hallucinations and confusion have been reported in this age group.

Paediatric population

The safety and efficacy of nefopam has 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 substance or to any of the excipients listed in section 6.1.

Nefopam is contraindicated 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 30 mg 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. Nefopam 30 mg 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.

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.

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 30 mg tablets.

4.6 Fertility, pregnancy and lactation

There is no evidence as to the drug safety in human pregnancy, nor is there evidence from animal studies that is free from hazard. Avoid in pregnancy unless there is no safer treatment.

4.7 Effects on ability to drive and use machines

Nefopam 30 mg tablets may cause drowsiness. If affected do not drive or operate machinery.

4.8 Undesirable effects

The following undesirable effects have been reported with the following frequency:
Not known (cannot be estimated from the available data)

System organ class	Frequency	Undesirable effects
Immune system disorders	Not known	Allergic reaction, anaphylactic reactions
Psychiatric disorders	Not known	Nervousness, convulsions, confusional state, hallucination, insomnia
	Rare	Drug dependence
Nervous system disorders	Not known	Light-headedness, syncope, dizziness, paraesthesia, tremor, drowsiness, headache, coma
Eye disorders	Not known	Blurred vision
Cardiac disorders	Not known	Palpitations, tachycardia
Vascular disorders	Not known	Hypotension
Gastrointestinal disorders	Not known	Nausea, vomiting, dry mouth, gastrointestinal disturbances (including abdominal pain and diarrhoea)
Skin and subcutaneous tissue disorders	Not known	Angioedema, sweating
Renal and urinary disorders	Not known	Urinary retention

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 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 Website:

w ww.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 toxicity in overdose is on the neurological (convulsions, hallucinations, coma and agitation) and cardiovascular systems (tachycardia with a hyperdynamic circulation).

Management

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: 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 hydrochloride 30 mg Film-coated tablets.

5.2 Pharmacokinetic properties

Absorption

Nefopam hydrochloride 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

Nefopam hydrochloride is extensively

metabolised

Elimination

Nefopam hydrochloride 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

Core tablet:
Calcium hydrogen phosphate dihydrate
Microcrystalline cellulose
Partially Pregelatinized Maize Starch
Silica, Colloidal anhydrous
Magnesium Stearate

Film-coating:
Hypromellose
Titanium dioxide
Polyethylene glycol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Blister made of PVC/PVDC and aluminium foil 0.025mm.

Pack size: 30, 90 & 100 tablets

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

DAWA Limited

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Harrow Middlesex

HA1 1XD

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 30684/0340

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/12/2020

10 DATE OF REVISION OF THE TEXT

07/04/2026