SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Noumed Hayfever Relief 120 mg Film-coated tablets
ASDA Hayfever Relief 120 mg Film-coated tablets
Sainsbury's Healthcare Hayfever Relief 120mg Film-coated Tablets
Numark Hayfever Relief 120 mg Film-coated Tablets
Algexia 120mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120 mg of fexofenadine hydrochloride.

Excipient(s) with known effect: Each tablet contains 152.420 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated Tablet (tablet)
Peach coloured capsule shaped film-coated tablets of 16.00 mm x 6.20 mm x 4.90 mm, debossed as '120' on one side and 'FX' on other side.

4.1. Therapeutic Indications

The product is indicated in adults and children 12 years and older for the relief of symptoms associated with seasonal allergic rhinitis.

4.2 Posology and method of administration:

Posology

Adults
The recommended dose of fexofenadine hydrochloride for adults is 120 mg once daily taken before a meal.
Fexofenadine is a pharmacologically active metabolite of terfenadine.

Paediatric population
• Children aged 12 years and over
The recommended dose of fexofenadine hydrochloride for children aged 12 years and over is 120 mg one daily taken before a meal.

• Children under 12 years of age
The efficacy and safety of fexofenadine hydrochloride 120 mg has not been studied in children under 12.

Special populations
Studies in special risk groups (elderly, renally or hepatically impaired patients) indicate that it is not necessary to adjust the dose of fexofenadine hydrochloride in these patients.

4.3. Contraindications:

The medicinal product is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use:

There is only limited data in the elderly and renally or hepatically impaired patients. The product should only be administered in these special groups on the advice of a doctor. (See Section 4.2)

Patients with a history of or ongoing cardiovascular disease should be warned that antihistamines as a medicine class, have been associated with the adverse reactions such as tachycardia and palpitations (see section 4.8) and should use the product only on the advice of their doctor.

The product should not be used in children under 12 years of age.

In children from 6 to 11 years of age: Fexofenadine Hydrochloride 30 mg tablet (prescription only medicine) is the appropriate formulation for administration and dosing in this population.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms.

Fexofenadine is a P-glycoprotein (P-gp) and organic-anion-transporting polypeptide (OATP) substrate. Concomitant use of fexofenadine with P-gp inhibitors or inducers can affect the exposure to fexofenadine. Coadministration of fexofenadine hydrochloride with P-gp inhibitors, erythromycin or ketoconazole has been found to result in a 2-3times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse reactions compared to the medicinal products given singly.

A clinical drug-drug interaction study showed that co-administration of apalutamide (a weak inducer of P-gp) and a single oral dose of 30 mg fexofenadine resulted in a 30 % decrease in AUC of fexofenadine.

No interaction between fexofenadine and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15

minutes prior to fexofenadine hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids

4.6. Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of fexofenadine hydrochloride in pregnant women.
Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). The product should not be used during pregnancy unless on the advice of a doctor.

Lactation
There are no data on the content of human milk after administering fexofenadine hydrochloride. However, when terfenadine was administered to nursing mothers, fexofenadine was found to cross into human breast milk. Therefore, the product is not recommended for mothers breast-feeding their babies. Breast-feeding women should only use the product if advised to do so by a doctor.

Fertility
No human data on the effect of fexofenadine hydrochloride on fertility are available.
In mice, there was no effect on fertility with fexofenadine hydrochloride treatment (see section 5.3).

4.7. Effects on ability to drive and use machine

On the basis of the pharmacodynamic profile and reported adverse reactions it is unlikely that fexofenadine hydrochloride tablets will produce an effect on the ability to drive or use machines. In objective tests, the product has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify sensitive people who have an unusual reaction to medicinal products, it is advisable to check the individual response before driving or performing complicated tasks.

4.8 Undesirable effects

The following frequency rating has been used, when applicable:
Very common ≥1/10; Common ≥1/100 and <1/10; Uncommon ≥1/1,000 and <1/100; Rare ≥1/10,000 and <1/1,000; Very rare <1/10,000 and not known (frequency cannot be estimated from the available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

In adults, the following undesirable effects have been reported in clinical trials, with an incidence similar to that observed with placebo:

Nervous system disorders
Common: headache, drowsiness, dizziness

Gastrointestinal disorders
Common: nausea

General disorders and administration site conditions

Uncommon: fatigue

In adults, the following undesirable effects have been reported in post-marketing surveillance. The frequency with which they occur is not known (can not be estimated from available data):

Immune system disorders
Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis

Psychiatric disorders
Insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria)
Heart pathologies

Tachycardia, palpitations

Gastrointestinal disorders
Diarrhoea

Skin and subcutaneous tissue disorders
Rash, urticaria, pruritus

Eye disorders
Vision blurred.

Reporting of suspected adverse reactions
It is important to report suspected adverse reactions that occur after the medicinal product has been authorised as it enables the product's risk/benefit ratio to be continuously monitored. Healthcare professionals are asked to report any suspected adverse reactions via 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

Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine hydrochloride. Single doses up to 800 mg and doses up to 690 mg twice daily for 1 month or 240 mg once daily for 1 year have been administered to healthy subjects without the development of clinically significant adverse reactions as compared with placebo. The maximum tolerated dose of fexofenadine hydrochloride has not been established.

Standard measures should be considered to remove any unabsorbed medicinal product. Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, ATC code: R06A X26.

Mechanism of action
Fexofenadine hydrochloride is a non-sedating H1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

Clinical efficacy and safety
Human histamine wheal and flare studies following single and twice daily doses of fexofenadine hydrochloride demonstrate that the medicinal product exhibits an antihistaminic effect beginning within one hour, achieving maximum at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing. A positive dose-response relationship between doses of 10 mg to 130 mg taken orally was found to exist. In this model of antihistaminic activity, it was found that doses of at least 130 mg were required to achieve a consistent effect that was maintained over a 24 hour period. Maximum inhibition in skin wheal and flare areas were greater than 80%. Clinical studies conducted in seasonal allergic rhinitis have shown that a dose of 120 mg is sufficient for 24 hour efficacy.

No significant differences in QTc intervals were observed in seasonal allergic rhinitis patients given fexofenadine hydrochloride up to 240 mg twice daily for 2 weeks when compared to placebo. Also, no significant change in QTc intervals was observed in healthy subjects given fexofenadine hydrochloride up to 60 mg twice daily for 6 months, 400 mg twice daily for 6.5 days and 240 mg once daily for 1 year, when compared to placebo. Fexofenadine at concentrations 32 times greater than the therapeutic concentration in man had no effect on the delayed rectifier K+ channel cloned from human heart.

Fexofenadine hydrochloride (5-10 mg/kg po) inhibited antigen induced bronchospasm in sensitised guinea pigs and inhibited histamine release at supratherapeutic concentrations (10-100 μM) from peritoneal mast cells.

5.2 Pharmacokinetic properties

Absorption
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with Tmax occurring at approximately 1-3 hours post dose. The mean Cmax value was approximately 427 ng/ml following the administration of a 120 mg dose once daily.

Distribution
Fexofenadine is 60-70% plasma protein bound.

Biotransformation and elimination
Fexofenadine undergoes negligible metabolism (hepatic or non-hepatic), as it was the only major compound identified in urine and faeces of animals and man. The plasma concentration profiles of fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 15

hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear for oral doses up to 120 mg BID. A dose of 240 mg BID produced slightly greater than
proportional increase (8.8%) in steady state area under the curve, indicating that fexofenadine pharmacokinetics are practically linear at these doses between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while up to 10% of ingested dose is excreted unchanged through the urine.

5.3 Preclinical safety data

Dogs tolerated 450 mg/kg administered twice daily for 6 months and showed no toxicity other than occasional emesis. Also, in single dose dog and rodent studies, no treatment-related gross findings were observed following necropsy.

Radiolabelled fexofenadine hydrochloride in tissue distribution studies of the rat indicated that fexofenadine did not cross the blood brain barrier.

Fexofenadine hydrochloride was found to be non-mutagenic in various in vitro and in vivo mutagenicity tests.
The carcinogenic potential of fexofenadine hydrochloride was assessed using terfenadine studies with supporting pharmacokinetic studies showing fexofenadine hydrochloride exposure (via plasma AUC values). No evidence of carcinogenicity was observed in rats and mice given terfenadine (up to 150 mg/kg/day).

In a reproductive toxicity study in mice, fexofenadine hydrochloride did not impair fertility, was not teratogenic and did not impair pre- or postnatal development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Low-substituted-Hydroxypropyl Cellulose(E463)
Pregelatinised starch
Colloidal anhydrous silica (E551)
Microcrystalline cellulose (E460)
Croscarmellose sodium (E468)
Magnesium stearate (E572)
Hypromellose
Povidone
Titanium dioxide (E171)
Iron oxide Red (E172)
Iron oxide Yellow (E172)
Macrogol 400

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 condition.

6.5. Nature and contents of container-

The product is provided in blisters of Alu-PVC/PVDC or Alu /PVC/PE/ACLAR in pack size of 7, 10, 15, 20, 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Noumed Life Sciences Limited
Noumed House, Shoppenhangers Road
Maidenhead, Berskshire SL6 2RB
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 44041/0233

9 Date of first authorization / renewal of authorization:

12/10/2023

10 DATE OF REVISION OF THE TEXT

18/05/2026