PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

FEXOGEN 120 (120 mg film-coated tablet)

FEXOGEN 180 (180 mg film-coated tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fexogen 120: Each film-coated tablet contains fexofenadine hydrochloride 120 mg.

Fexogen 180: Each film-coated tablet contains fexofenadine hydrochloride 180 mg.

Sugar free.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets.

Fexogen 120: Peach coloured, oblong, biconvex film-coated tablet, plain on both sides.

Fexogen 180: Yellow coloured, oblong, biconvex film-coated tablet, plain on one side and scored on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fexogen 120 is indicated for the symptomatic relief of allergic conditions including seasonal allergic rhinitis (SAR).

Fexogen 180 is indicated for the relief of symptoms associated with chronic idiopathic urticaria.

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

Symptomatic relief of allergic conditions: One 120 mg tablet daily.

Symptomatic relief of chronic idiopathic urticaria: One 180 mg tablet daily.

Special populations

See section 4.4.

For patients with decreased renal function, a lower starting dose of 60 mg once daily, is recommended.

Paediatric population

Children under 12 years:

The efficacy and safety of fexofenadine has not been studied in children under the age of 12.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to fexofenadine hydrochloride or to any of the ingredients of Fexogen tablets (see section 6.1).
- Children under the age of 12.
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

As there is limited data for the use in elderly and renally or hepatically impaired patients, care must be taken when administering fexofenadine in these special risk groups (see section 4.2).

Performance of skilled tasks maybe affected (see section 4.7).

4.5 Interaction with other medicines and other forms of interaction

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.

Plasma concentrations of fexofenadine have been increased 2 - 3 fold after the concomitant administration of fexofenadine hydrochloride with P-gp inhibitors erythromycin or ketoconazole, but this was not associated with any adverse effects on the QT interval or any increase in adverse effects compared to the medicines 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 was observed between fexofenadine and omeprazole. However, antacids containing aluminium and magnesium hydroxide have reduced the absorption of fexofenadine, and it is therefore advisable to administer the two medicines 2 hours apart.

The efficacy and safety of fexofenadine has not been studied in children under the age of 12.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy has not been established in pregnancy, therefore fexofenadine hydrochloride should not be taken by pregnant women.

Lactation

Safety and efficacy has not been established in lactation, therefore fexofenadine hydrochloride should not be taken by women that are breastfeeding.

Fertility

No data on the effect of FEXOGEN on fertility are available.

4.7 Effects on ability to drive and use machines

In the case of non-sedating antihistamines like fexofenadine, although drowsiness is rare, it can occur and may affect the performance of skilled tasks.

4.8 Undesirable effects

a. Summary of the safety profile

No data is available.

b. Tabulated summary of adverse reactions

MedDRA system organ class	**Frequency**	**Adverse reactions**
Immune system disorders	Less frequent	Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis.
Psychiatric disorders	Less frequent	Insomnia, nervousness, sleep disorders or paroniria.
Nervous system disorders	Frequent	Headache, drowsiness, dizziness
Eye disorder	Frequency not known	Blurred vision
Respiratory, thoracic and mediastinal disorders	Less frequent	Chest tightness, dyspnoea
Gastrointestinal disorders	Frequent	Nausea
Skin and subcutaneous tissue disorders	Less frequent	Rash, urticaria, pruritus
Musculoskeletal and connective tissue disorders	Less frequent	Fatigue

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Information on overdosage is limited. However, dizziness, drowsiness and dry mouth have been reported. Haemodialysis does not effectively remove fexofenadine hydrochloride from the blood. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification: A 5.7.1 Antihistaminics

Pharmacotherapeutic group: other antihistamines for systemic use, ATC code: R06AX26

Fexofenadine, an active metabolite of terfenadine, is a non-sedating antihistamine with selective H-antagonist action. Fexofenadine exhibits and antihistaminic effect beginning within one hour, achieving maximum effect at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days dosing.

5.2 Pharmacokinetic properties

Absorption

Fexofenadine is rapidly absorbed after oral administration with peak plasma concentrations being reached in 2 to 3 hours.

Distribution

It is about 60 - 70 % bound to plasma proteins.

Biotransformation

About 5 % of the total dose is metabolised, mostly by the intestinal mucosa, with only 0,5 - 1,5 % of the dose undergoing hepatic biotransformation.

Elimination

Elimination half-life of about 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10 % being present in the urine. Fexofenadine does not appear to cross the blood-brain barrier.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose,

Croscarmellose sodium,

Maize starch,

Povidone,

Magnesium stearate,

Hydroxypropylmethylcellulose,

Titanium dioxide,

Polyethylene glycol 400,

Polyethylene glycol 4000,

Iron oxide yellow CI177492 and iron oxide red CI177491 (120 mg tablets only).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25 °C in the original container.

6.5 Nature and contents of container

Fexogen 120: Blister strips packed into unit cartons of 10 or 30 tablets.

Fexogen 180: Blister strips packed into unit cartons of 10 or 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Trinity Pharma (Pty) Ltd.

106 16th Road, Building 2

Midrand

1686

8 REGISTRATION NUMBER(S)

Fexogen 120: A40/5.7.1/0083

Fexogen 180: A40/5.7.1/0084

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 November 2016

10 DATE OF REVISION OF THE TEXT

05 June 2024