SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

TELLERGE 120 mg film-coated tablets **TELLERGE 180 mg** film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of TELLERGE 120 mg contains 120 mg of fexofenadine hydrochloride.

Sugar free

Each tablet of TELLERGE 180 mg contains 180 mg of fexofenadine hydrochloride.

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets

TELLERGE 120 mg: Peach coloured, oblong, bi-convex film-coated tablet; plain on both sides.

TELLERGE 180 mg: Yellow coloured, oblong, bi-convex film-coated tablet; plain on one side with a central breakline on the other.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

TELLERGE 120 mg is indicated for:

- the relief of symptoms associated with seasonal allergic rhinitis

(SAR). TELLERGE 180 mg is indicated for:

- the relief of symptoms associated with chronic idiopathic urticaria (CIU).

4.2. Posology and method of administration Posology

Adults and children aged 12 years and over

Chronic idiopathic urticaria (CIU): One 180 mg tablet daily.

Seasonal allergic rhinitis (SAR): One 120 mg tablet daily.

Children under 12 years of age

The efficacy and safety of TELLERGE has not been studied in children under 12 (see section 4.3 and section 4.4).

Special Populations

(See section 4.4).

Renal impairment

Based on increases of bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Paediatric population

The efficacy and safety of TELLERGE in children under twelve has not been established

Method of administration

For oral administration

4.3. Contraindications

TELLERGE is contraindicated in:

- Patients with hypersensitivity to fexofenadine hydrochloride or to any excipients in TELLERGE (see section 6.1).
- Children under the age of 12 years.
- Pregnancy and lactation (see section 4.6).

4.4. Special warnings and precautions for use

There is only limited data for the use in elderly and renally or hepatically impaired patients. TELLERGE should be administered with care in these special risk groups or special populations (see section 4.2).

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

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. Co-administration of fexofenadine hydrochloride with P-gp inhibitors erythromycin or ketoconazole has been found to result in a 2-3 times 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.

TELLERGE lacks sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants (see section 4.7*)*.

The efficacy and safety of TELLERGE has not been studied in children under the age of 12 years (see section 4.3).

4.5. Interaction with other medicines and other forms of interaction

Interaction with other medicines

TELLERGE does not undergo hepatic biotransformation and therefore will not interact with other medicines through hepatic mechanisms (see {section 5.2). Co-administration of TELLERGE with erythromycin or ketoconazole has been found to result in 2 to 3 times increase in the level of TELLERGE in plasma. The changes were not accompanied by any effects on the QT-interval and were not associated with any increase in adverse events compared to the medicines given individually.

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 TELLERGE and omeprazole has been observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to TELLERGE causes a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of TELLERGE and aluminium and magnesium hydroxide containing antacids.

4.6. Fertility, pregnancy and lactation

The safety of TELLERGE in pregnancy and lactation has not been established (see section 4.3).

Pregnancy

There are no adequate data from the use of TELLERGE in pregnant women.

TELLERGE should not be used during pregnancy, unless clearly necessary (see section 4.3).

Breastfeeding

TELLERGE is excreted into breastmilk. Mothers breastfeeding their infants should not be treated with TELLERGE (see section 4.3).

Fertility

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

4.7. Effects on ability to drive and use machines

TELLERGE has a moderate influence on the ability to drive and use machines.

Since adverse reactions such as headache, drowsiness and dizziness have been reported in patients receiving TELLERGE, patients shouldnot drive, use machinery or perform any tasks that require concentration, until they are certain that TELLERGE does not adversely affect their ability to do so (see section 4.8).

4.8. Undesirable effects

System organ class	***Frequent***	***Less frequent***	***Frequency unknown*** (cannot be estimated from the available data)
Respiratory thoracic and mediastinal disorders			Sinusitis and viral infections such as cold and flu
Immune system disorders		Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing, and systemic anaphylaxis	
Psychiatric disorders			Insomnia, nervousness, sleep disorders**,** nightmares/excessive dreaming (paroniria)
Nervous system disorders	Headache, drowsiness, dizziness		
Cardiac disorders			Tachycardia, palpitations
Gastrointestinal disorders	Nausea		Diarrhoea, dyspepsia
Skin and subcutaneous tissue disorders		Rash, urticaria, pruritus	
Reproductive system and breast disorders			Dysmenorrhoea
Musculoskeletal, connective tissue and bone disorders		Fatigue	
Eye disorders			Vision blurred

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/publications/Index/8

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

4.9 Overdose

Symptoms

Most reports of TELLERGE overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported.

Treatment

Standard measures should be considered to remove any unabsorbed medicine.

Haemodialysis does not effectively remove TELLERGE from blood.

5. PHARMACOLOGICAL PROPERTIES

5.1.Pharmacodynamic properties

Classification: A 5.7.1

Antihistaminics

Mechanism of action

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating, selective histamine H_1-receptor antagonist.

Fexofenadine exhibits an 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 of dosing.

5.2 Pharmacokinetic properties

Absorption

Fexofenadine is absorbed into the body following oral administration, with T_{max} occurring at approximately 1 to 3 hours post dose. The mean C_{max} value was approximately 427 ng/ml and 494 ng/ml following the administration of a 120 mg and 180 mg dose once daily, respectively.

Distribution

The volume of distribution is 5,4 to 5,8 ℓ/kg. Fexofenadine does not cross the blood brain barrier.

Fexofenadine is 60 % to 70 % plasma protein bound.

Biotransformation

Fexofenadine undergoes negligible metabolism (about 5 % of the total dose is metabolized, mostly by the intestinal mucosa, with only 0,5 % to 1,5 % of the dose undergoing hepatic biotransformation), as it was the only major compound identified in urine and faeces of man.

Elimination

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 between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via billiary excretion (faeces), while up to 10 % of the ingested dose is excreted unchanged through the urine.

Elderly patients

In older patients (≥ 65 years old), peak plasma levels of fexofenadine were 99 % greater than those observed in normal volunteers (< 65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Renal impairment

In patients with mild (creatinine clearance 41 to 80 mL/min) to severe (creatinine clearance 11 to 40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87 % and 111 % greater, respectively, and mean elimination half-lives were 59 % and 72 % longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance ≤ 10mL/min) were 82 % greater and half-life was 31 % longer than observed in normal volunteers. Based on increases of bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see section 4.2).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Each tablet of TELLERGE 120 mg:

Croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, macrogol, magnesium stearate, microcrystalline cellulose, povidone, starch maize, titanium dioxide

Each tablet of TELLERGE 180 mg:

Croscarmellose sodium, hypromellose, iron oxide yellow, macrogol, magnesium stearate, microcrystalline cellulose, povidone, starch maize, titanium dioxide

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25 °C.

Keep the blister strips in the unit carton until required for use.

6.5. Nature and contents of container

TELLERGE 120 mg:

10 or 30 film-coated tablets are packed in a clear, colourless polyvinylchloride and polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed in an outer cardboard carton.

TELLERGE 180 mg:

10 or 30 film-coated tablets are packed in a clear, colourless polyvinylchloride/ polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed in an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

6.6. Special precautions for disposal

No special requirements.

7. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram

Limited 1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

8. REGISTRATION NUMBER

TELLERGE 120 mg:

41/5.7.1/0352 TELLERGE 180

mg: 41/5.7.1/0353

9. DATE OF FIRST AUTHORISATION

Date of registration: 09 December 2008

10. DATE OF REVISION OF TEXT

20 November 2023

Botswana: S2
TELLERGE 120 mg: BOT1402530
TELLERGE 180 mg: BOT1402529

Namibia: NS1
TELLERGE 120 mg: 12/5.7.1/0019
TELLERGE 180 mg: 12/5.7.1/0018