Professional Information for TELFAST® 120 tablets

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINAL PRODUCT

TELFAST® 120 tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains fexofenadine base 112 mg (as fexofenadine hydrochloride 120 mg).

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Peach, oblong, biconvex, film-coated tablets. One face is embossed “012”, the other face with an “e”

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TELFAST 120 is indicated in adults and children aged 12 years and over, for the relief of symptoms associated with seasonal allergic rhinitis (SAR).

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

One 120 mg tablet daily*:*

Special populations:

A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see section 4.4 and 5.2)

Paediatric population

Children under 12 years of age:

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.4).

Method of administration

Oral administration.

The film-coated tablet should not be chewed.

4.3 Contraindications

TELFAST 120 is contra-indicated in patients with known hypersensitivity to fexofenadine hydrochloride or any of its ingredients listed in section 6.1.

There is no experience with TELFAST 120 in pregnant women (see section 4.6).

TELFAST 120 should not be taken during pregnancy or by mother's breastfeeding their babies (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.

TELFAST 120 should be administered with care in these special risk groups (see section 4.2 and 5.2).

Paediatric population

The efficacy and safety of TELFAST 120 has not been studied in children under 12 (see section 4.2).

4.5 Interaction with other medicines and other forms of interaction

TELFAST 120 does not undergo hepatic biotransformation.Co-administration of TELFAST 120 with 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 events compared to the drugs given singly.

Animal studies have shown that the increase in plasma levels of TELFAST 120 observed after co-administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

No interaction between TELFAST 120 and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to TELFAST 120, caused a reduction in bioavailability, most likely due to binding in the gastro-intestinal tract. It is advisable to leave 2 hours between administration of TELFAST 120 and aluminium and magnesium hydroxide containing antacids.

Paediatric population

The efficacy and safety of TELFAST 120 has not been studied in children under the age of 12 years (see section 4.2 and 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no experience with TELFAST 120 in pregnant women. TELFAST 120 should not be taken during pregnancy (see section 4.3).

Breast-feeding

TELFAST 120 should not be taken by mothers breastfeeding their babies (see section 4.3).

Fertility

No data are available

4.7 Effects on ability to drive and use machines

TELFAST 120 lacks significant 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.

4.8 Undesirable effects

The following frequency rating has been used, where relevant:

Very common: (>1/10); Common: (>1/100, <1/10); Uncommon:

(> 1/1000, <1/100);

Rare: (> 1/10 000, <1/1000); Very rare: (<1/10 000), including

'isolated reports'.

In controlled clinical trials, the most frequent adverse events reported, include:

Nervous system disorders:

> 3 %: headache; 1 – 3 %: drowsiness, dizziness.

Gastrointestinal disorders:

1 – 3 % nausea

Events that have been reported during controlled trials and during post-marketing surveillance with incidences less than 1 %, include:

Nervous system disorders:

fatigue, insomnia, nervousness and sleep disorders or paroniria.

Immune system disorders:

In rare cases, rash, urticaria, pruritus and hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis have been reported.

Paediatric population

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.2 and 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of TELFAST 120 is important. It allows continued monitoring of the benefit/risk balance of TELFAST 120. 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, or to the Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Overdose

Symptoms of overdose

Most reports of TELFAST 120 overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported.

Management of overdose

Standard measures should be considered to remove any unabsorbed drug. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

Paediatric population

No data are available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fexofenadine belongs to the medicine class A 5.7.1 Antihistamines.

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating, selective histamine H1-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.

Paediatric population

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.2 and 4.4).

5.2 Pharmacokinetic properties

Absorption

Fexofenadine is 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

Fexofenadine undergoes negligible metabolism, as it was the only major compound identified in urine and faeces of animals and 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 biliary excretion, while up to 10 % of ingested dose is excreted unchanged through the urine.

Special populations:

The elderly: (see section 4.4).

In older subjects (≥ 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.

Renally impaired: (see section 4.4).

In patients with mild (creatinine clearance 41 - 80 mL/min) to severe (creatinine clearance 11 - 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 ≤ 10 mL/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 and 4.4).

Paediatric population

No data are available

5.3 Preclinical safety data

No data are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Croscarmellose Sodium

Pre-gelatinised Maize Starch

Microcrystalline Cellulose

Magnesium Stearate

Film coat:

Hypromellose E-15

Hypromellose E-5

Povidone

Titanium Dioxide (E171)

Colloidal anhydrous silica

Pink Iron Oxide Blend

Yellow Iron Oxide Blend

Macrogol 400

6.2 Incompatibilities

No data are available

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN

6.5 Nature and contents of container

Blister strips of 5, 10 or 15 tablets are packed into cartons of 10 or 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No data are available.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Road, Midrand, 1652

Tel. no.: 011 256 3700

8. REGISTRATION NUMBER

32/5.7.1/0446

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 September 2008

10. DATE OF REVISION OF THE TEXT

05 October 2022

NAMIBIA Reg. No. 04/5.7.1/0386	NS1

Professionele Inligting vir TELFAST® 120 tablette

SKEDULERINGSTATUS

S1

1. NAAM VAN DIE MEDISYNE

TELFAST® 120 tablette

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Elke filmbedekte tablet bevat feksofenadienbasis 112 mg (as feksofenadienhidrochloried 120 mg).

Suikervry.

Vir die volledige lys toevoegings, sien afdeling 6.1.

3. FARMASEUTIESE VORM

Perskekleurige, langwerpige, bikonvekse, filmbedekte tablette. Aan die een kant is die syfer “012” gedruk, aan die ander kant, ‘n “e”.

4. KLINIESE BESONDERHEDE

4.1 Terapeutiese indikasies

TELFAST 120 is aangedui vir die verligting van simptome wat verband hou met seisoenale allergiese rinitis (SAR) in volwassenes en kinders ouer as12 jaar.

4.2 Dosering en metode van aanwending

Dosering

Volwassenes en kinders 12 jaar en ouer:

Een 120 mg tablet een keer per dag.

Spesiale populasies

‘n Aanvangsdosis van 60 mg een keer per dag word aanbeveel by pasiënte met ingekorte nierfunksie (sien afdeling 4.4 en 5.2).

Pediatriese populasie

Kinders jonger as 12 jaar:

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.4).

Metode van aanwending

Mondelingse toediening.

Die filmbedekte tablet moet nie gekou word nie.

4.3 Kontra-indikasies

TELFAST 120 is teenaangedui by pasiënte met ‘n geskiedenis van hipersensitiwiteit vir feksofenadienhidrochloried of enige bestanddeel daarvan, soos gelys in afdeling 6.1.

Daar is geen ondervinding in die gebruik TELFAST 120 in swanger vroue nie (sien afdeling 4.6).

TELFAST 120 moet nie tydens swangerskap of deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.6).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik

Daar is slegs beperkte data beskikbaar oor die gebruik by bejaarde pasiënte of pasiënte met ingekorte nier- of lewerfunksie. TELFAST 120 moet met omsigtigheid toegedien word in hierdie spesiale risikogroep (sien afdeling 4.2 en 5.2).

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2).

4.5 Interaksie met ander medikasie en ander vorms van interaksie

TELFAST 120 ondergaan nie hepatiese biotransformasie nie. Die gelyktydige toediening van TELFAST 120 met eritromisien of ketokonasool het die vlak van feksofenadien in plasma, 2-3 keer laat styg. Die veranderings het nie gepaard gegaan met enige uitwerking op die QT-interval nie en is nie geassosieer met enige toename in newe-effekte in vergelyking met dié wanneer die middels afsonderlik toegedien is nie.

Toetse op diere het getoon dat die toename in die plasmavlakke van TELFAST 120 wat na die gelyktydige toediening met eritromisien of ketokonasool waargeneem is, waarskynlik toegeskryf kan word aan verhoogde gastroïntestinale absorpsie, asook aan ’n afname in ó f galuitskeiding ó f gastroïntestinale sekresie, onderskeidelik.

Geen interaksie is tussen TELFAST 120 en omeprasool waargeneem nie. Die toediening van ‘n teensuurmiddel wat aluminium- en magnesiumhidroksied jels bevat, 15 minute voor die toediening van TELFAST 120, het egter ‘n afname in die biobeskikbaarheid tot gevolg gehad, waarskynlik toe te skryf aan binding in die gastroïntestinale kanaal. Dit is raadsaam om minstens 2 ure te laat verloop, tussen die toediening van TELFAST 120 en aluminium- en magnesiumhidroksied-bevattende teensuurmiddels.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

4.6 Fertiliteit, swangerskap en borsvoeding

Swangerskap

Daar is geen ondervinding in die gebruik van TELFAST 120 in swanger vroue nie. TELFAST 120 moet nie tydens swangerskap gebruik word nie (sien afdeling 4.3).

Borsvoeding

TELFAST 120 moet nie deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.3).

Fertiliteit

Geen data is beskikbaar nie.

4.7 Effek op die vermoë om te bestuur en masjienerie te gebruik

TELFAST 120 het nie betekenisvolle sederende effekte nie. Pasiënte word nogtans gemaan dat ‘n klein hoeveelheid individue wél ‘n sederende effek mag ervaar. Dit is daarom raadsaam om individuele reaksie op die middel te toets, voordat ’n motor bestuur, of ingewikkelde take aangepak word. Hierdie effek mag vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweesisteem depressante.

4.8 Newe-effekte

Waar van toepassing, is die volgende frekwensie-beoordeling gebruik:

Baie algemeen: (>1/10); Algemeen: (>1/100, <1/10); Ongewoon:

(> 1/1000, <1/100); Seldsaam: (> 1/10 000, <1/1000); Baie seldsaam: (<1/10 000), insluitend ‘geisoleerde gevalle’.

In gekontroleerde kliniese studies, het die mees algemene aangemelde newe-effekte die volgende ingesluit:

Senuweesisteem afwykings:

> 3 %: hoofpyn; 1 – 3 %: lomerigheid, duiseligheid.

Gastro-intestinale afwykings:

1 – 3 %: naarheid.

Gevalle met ’n insidensie van minder as 1 %, wat gedurende gekontroleerde kliniese studies en gedurende na-bemarking-waarneming aangemeld is, sluit in:

Senuweesisteem afwykings:

Moegheid, slapeloosheid, senuagtigheid en slaapstoornisse of paroniria.

Immuunsisteem afwykings:

In seldsame gevalle is uitslag, urtikarie, pruritis en hipersensitiwiteitsreaksies met manifestasies soos angio-edeem, beklemming van die borskas, dispnee, gloede en sistemiese anafilakse aangemeld.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

Rapportering van vermoede ongunstige reaksies

Rapportering van vermoede ongustige reaksies, na die goedkeuring van TELFAST 120 is belangrik. Dit laat toe vir die voortdurende monitering van die voordeel/risiko balans van TELFAST 120. Gesondheidsdiens verskaffers word gevra om enige vermoede ongunstige reaksies aan SAHPRA te rapporteer, via die "**6.04 Adverse Drug Reactions Reporting Form**", wat gevind kan word onder SAHPRA se publikasies;

- https://www.sahpra.org.za/Publications/Index/8, óf aan die
- Waaksaamheidseenheid van Sanofi by za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Oordosering

Simptome van oordosering

Die meeste verslae oor TELFAST 120 oordosering bevat beperkte inligting. Nietemin is duiseligheid, lomerigheid en droë mond aangemeld.

Behandeling van oordosering

Standaard prosedures behoort oorweeg te word vir die verwydering van enige ongeabsorbeerde geneesmiddel. Hemodialise verwyder nie feksofenadienhidrochloried doeltreffend uit die bloed nie.

Pediatriese populasie

Geen data is beskikbaar nie.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

Feksofenadien behoort tot die medisyne-klas A 5.7.1 Antihistamiene.

Feksofenadienhidrochloried is ‘n farmakologies-aktiewe metaboliet van terfenadien en is ‘n nie-sederende,selektiewe histamien H_1-reseptor antagonis.

Feksofenadien toon ‘n antihistaminergiese effek binne een uur en bereik ‘n maksimum effek na 6 uur, wat 24 uur lank duur. Daar was geen bewys van toleransie teen hierde uitwerkings na 28 dae se toediening nie.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

5.2 Farmakokinetiese eienskappe

Absorpsie

Feksofenadien word na mondelingse toediening deur die liggaam geabsorbeer en T_{maks} word ongeveer 1-3 uur na toediening bereik. Die gemiddelde K_{maks}-waarde was ongeveer 427 ng/ml na toediening van ‘n 120 mg dosis een keer per dag.

Verspreiding

Feksofenadien is 60 - 70 % plasmaproteïen gebonde.

Biotransformasie

Feksofenadien ondergaan geringe metabolisme, aangesien dit die enigste noemenswaardige produk is wat in dierlike en menslike uriene en feses voorgekom het.

Eliminasie

Die plasmakonsentrasie profiele van feksofenadien volg ‘n bi-eksponesiële afname met ‘n terminale eliminasie halfleeftyd wat wissel tussen 11 tot 15 uur na herhaalde inname. Die enkel- en meervoudige dosis farmakokinetika van feksofenadien is lineêr tussen daaglikse dossise van 40 mg en 240 mg.Die vernaamste eliminasie roete is waarskynlik galuitskeiding, terwyl tot 10 % van die dosis wat ingeneem is, onveraderd deur die uriene uitgeskei word.

Spesiale populasies

Bejaardes: (sien afdeling 4.4).

In ouer persone (≥ 65 jaar oud), was piek plasmavlakke van feksofenadien 99 % groter as dié waargeneem in normale vrywilligers (< 65 jaar oud). Gemiddelde eliminasie halfleeftye was soortgelyk as dié waargeneem in normale vrywilligers.

Renale inkorting: (sien afdeling 4.4).

In pasiënte met matige (kreatinienopruiming 41 - 80 mL/min) tot erge (kreatinienopruiming 11 - 40 mL/min) renale inkorting, was piek plasmavlakke van feksofenadien onderskeidelik 87 % en 111 % hoër, en gemiddelde eliminasie halfleeftye onderskeidelik 59 % en 72 % langer, as dié waargeneem in normale vrywilligers. Piek plasmavlakke in pasiënte op dialise (kreatinienopruiming ≤ 10 mL/min) was 82 % hoër en halfleeftyd was 31 % langer as dié waargeneem in normale vrywilligers. Gegrond op dié toename in biobeskikbaarheid en halfleeftyd, word ‘n aanvangsdosis van 60 mg een keer per dag aanbeveel vir pasiënte met ingekorte nierfunksie (sien afdeling 4.2 en 4.4).

Pediatriese populasie

Geen data is beskikbaar nie.

5.3 Pre-kliniese veiligheidsdata

Geen data is beskikbaar nie.

6. FARMASEUTIESE BESONDERHEDE

6.1 Lys van toevoegings

Tabletkern:

Natriumkroskarmellose

Pre-gegelatiniseerde mieliestysel

Mikrokristallyne sellulose

Magnesiumstereaat

Filmbedekking:

Hipromellose E-15

Hipromellose E-5

Povidoon

Titaandioksied (E171)

Kolloïdale anhidriese silika

Pienk silweroksied mengsel

Geel ysteroksied mengsel

Makrogool 400

6.2 Onverenigbaarhede

Geen data is beskikbaar nie.

6.3 Raklewe

36 maande

6.4 Spesiale voorsorgmaatreëls vir berging

Berg in ‘n digsluitende houer teen of benede 25 °C.

HOU BUITE DIE BEREIK VAN KINDERS.

6.5 Aard en inhoud van houer

Stulpverpakte stroke van 5, 10 of 15 tablette is verpak in kartonne van 10 of 30 tablette.

Nie alle pakgroottes word noodwendig bemark nie.

6.6 Spesiale voorsorgmaatreëls vir wegdoening en ander hantering

Geen data is beskikbaar nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Opella Healthcare South Africa (Edms) Bpk
4de Vloer, Gebou I, Hertford Office Park,
Bekkerweg 90, Midrand, 1652

Tel. nr.: 011 256 3700

8. REGISTRASIE NOMMER(S)

32/5.7.1/0446

9. DATUM VAN EERSTE GOEDKEURING / HERNUWING VAN GOEDKEURING

02 September 2008

10. DATUM VAN HERSIENING VAN TEKS

05 Oktober 2022

NAMIBIA Reg. No. 04/5.7.1/0386	NS1