SCHEDULING STATUS:
S1

PROPRIETARY NAMES AND DOSAGE FORM:
FEXOFENADINE BIOTECH 120 tablets
FEXOFENADINE BIOTECH 180 tablets

COMPOSITION:
Each FEXOFENADINE BIOTECH 120 film-coated tablet contains 120 mg Fexofenadine hydrochloride.
Contains sugar: Lactose monohydrate 156,0 mg
Each FEXOFENADINE BIOTECH 180 film-coated tablet contains 180 mg Fexofenadine hydrochloride.
Contains sugar: Lactose monohydrate 230,0 mg
The excipients are:
Core tablet: lactose monohydrate, hydroxypropyl cellulose, magnesium stearate, maize starch.
Coating: Opadry Pink 03B54819 consisting of: hypromellose (6cP), iron oxide yellow (E172), iron oxide red (E172) macrogol 400, titanium dioxide (E171).

PHARMACOLOGICAL CLASSIFICATION:
A.5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating, selective histamine H_1-receptor antagonist.
Pharmacokinetic properties
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. 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. Fexofenadine undergoes negligible metabolism, (about 5 % of the total dose is metabolised, 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 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 between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion (faeces), while up to 10 % of the ingested dose is excreted unchanged through urine.
Effect of age:
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:
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 < 10 ml/min) were 82 % greater and half-life was 31 % longer than observed in normal volunteers.

INDICATIONS:
FEXOFENADINE BIOTECH 120: is indicated for the relief of symptoms associated with seasonal allergic rhinitis (SAR).
FEXOFENADINE BIOTECH 180: is indicated for the relief of symptoms associated with chronic idiopathic urticaria (CIU).

CONTRAINDICATIONS:
Safety in pregnancy and lactation has not been established. (See WARNINGS AND SPECIAL PRECAUTIONS below).
The safety and efficacy of FEXOFENADINE BIOTECH have not been studied in children under the age of 12 years.
Patients with known hypersensitivity to fexofenadine or to any of the ingredients, including the excipients, of FEXOFENADINE BIOTECH.

WARNINGS AND SPECIAL PRECAUTIONS:
There is only limited data for the use in elderly and renally or hepatically impaired patients. FEXOFENADINE BIOTECH should be administered with care in these special risk groups.
FEXOFENADINE BIOTECH has been detected in breast milk.
FEXOFENADINE BIOTECH 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.
The effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants. (See PHARMACOKINETIC PROPERTIES and INTERACTIONS)
Effects on the ability to drive and use machines:
FEXOFENADINE BIOTECH may affect the ability to drive or operate machinery.
FEXOFENADINE BIOTECH contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption should not take FEXOFENADINE BIOTECH.

INTERACTIONS:
FEXOFENADINE BIOTECH does not undergo hepatic biotransformation. Co-administration of FEXOFENADINE BIOTECH with erythromycin or ketoconazole has been found to result in 2 to 3 times increase in the level of FEXOFENADINE BIOTECH 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.
The increase in plasma levels of FEXOFENADINE BIOTECH 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 FEXOFENADINE BIOTECH and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to FEXOFENADINE BIOTECH, causes a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of FEXOFENADINE BIOTECH and aluminium and magnesium hydroxide containing antacids.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.
FEXOFENADINE BIOTECH should not be taken during pregnancy or lactation.

DOSAGE AND DIRECTIONS FOR USE:
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 FEXOFENADINE BIOTECH have not been studied in children under 12.
Special risk groups: (See WARNINGS AND SPECIAL PRECAUTIONS)
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.

SIDE EFFECTS:
Nervous system disorders:
Frequent: headaches, drowsiness, dizziness
Less frequent: fatigue, insomnia, nervousness and sleep disorders or paroniria
Immune system disorders:
Less frequent: hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing, and systemic anaphylaxis have been reported.
Gastrointestinal disorders:
Frequent: nausea
Less frequent: dyspepsia
Skin and subcutaneous tissue disorders:
Less frequent: rash, urticaria, pruritus
Respiratory, thoracic and mediastinal disorders:
Less frequent: sinusitis and viral infections such as cold or flu
Reproductive system and breast disorders:
Less frequent: dysmenorrhoea

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Most reports of FEXOFENADINE BIOTECH overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported. Standard measures should be considered to remove any unabsorbed drug. Haemodialysis does not effectively remove FEXOFENADINE BIOTECH from blood.

IDENTIFICATION:
FEXOFENADINE BIOTECH 120: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 4,2 mm.
FEXOFENADINE BIOTECH 180: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 5,4 mm.

PRESENTATION:
FEXOFENADINE BIOTECH 120: White opaque PVC/PVDC/Alu blister strips of 10 tablets are packed into cartons of 10 or 30 tablets.
FEXOFENADINE BIOTECH 180: White opaque PVC/PVDC/Alu blister strips of 10 tablets are packed into cartons of 10 or 30 tablets.

STORAGE INSTRUCTIONS:
Store in the original pack at or below 25° C. Protect from light. Keep the blisters in the carton until required for use. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
FEXOFENADINE BIOTECH 120: A40/5.7.1/0590
FEXOFENADINE BIOTECH 180: A40/5.7.1/0591

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685,South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
Date of registration: 23 May 2006
Date of notification with regard to amended Reg. 9 and 10: 07 July 2017

SKEDULERINGSTATUS:
S1

EIENDOMSNAME EN DOSEERVORME:
FEXOFENADINE BIOTECH 120 tablette
FEXOFENADINE BIOTECH 180 tablette

SAMESTELLING:
Elke FEXOFENADINE BIOTECH 120 filmbedekte tablet bevat 120 mg feksofenadienhidrochloried.
Bevat suiker: Laktose monohidraat 156,0 mg
Elke FEXOFENADINE BIOTECH 180 filmbedekte tablet bevat 180 mg feksofenadienhidrochloried.
Bevat suiker: Laktose monohidraat 230,0 mg
Die ander bestanddele is:
Kern tablet: laktose monohidraat, hidroksiepropiel sellulose, magnesium stearaat, mieliestysel.
Bedekking: Opadry Pienk 03B54819 bestaande uit: hipromellose (6cP), ysteroksied geel (E172), ysteroksied rooi (E172) makrogol 400, titaniumdioksied (E171).

FARMAKOLOGIESE KLASSIFIKASIE:
A.5.7.1 Antihistamiene

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Feksofenadienhidrochloried is 'n farmakologies aktiewe metaboliet van terfenadien en is 'n nie-sederende, selektiewe histamien H_1-reseptor antagonis.
Farmakokinetiese eienskappe
Feksofenadien word geabsorbeer in die liggaam na mondelinge toediening met T_{maks} wat ongeveer 1 tot 3 uur na toediening bereik word. Die gemiddelde C_{maks} waarde was ongeveer 427 ng/ml en 494 ng/ml na die toediening van 'n dosis van 120 mg en 180 mg een maal per dag. Die volume van distribusie is 5,4 tot 5,8 l / kg. Feksofenadien kruis nie die bloedbreinskans nie. Feksofenadien is 60 tot 70 % plasmaproteïen gebonde. Feksofenadien ondergaan slegs geringe metabolisme (ongeveer 5 % van die totale dosis word gemetaboliseer, meestal deur die intestinale mukosa, terwyl slegs 0,5 tot 1,5 % van die dosis biotransformasie ondergaan), aangesien dit die enigste belangrike verbinding is wat geïdentifiseer is in die uriene en ontlasting van beide mense en diere. Die plasmakonsentrasie profiele van feksofenadien volg op 'n bi-eksponensiële afname met 'n terminale eliminasiehalfleeftyd van 11 tot 15 uur, na veelvoudige dosering. Die farmakokinetika van enkel- en veelvoudige dosisse van feksofenadien is lineër tussen 40 mg en 240 mg wanneer daagliks geneem. Die hoofroete van eliminasie vind vermoedelik deur middel van bilière uitskeiding (ontlasting) plaas, terwyl tot 10 % van die ingeneemde dosis onveranderd deur uriene uitgeskei word.
Effek van ouderdom:
By ouer individue (> 65 jaar oud) was die piek plasma vlakke van feksofenadien 99 % groter as dié wat waargeneem word by normale vrywilligers (<65 jaar oud). Gemiddelde eliminasie halfleeftyd was soortgelyk aan dié wat by normale vrywilligers waargeneem word.
Nierdisfunksie:
By pasiënte met ligte (kreatinienopruiming 41 tot 80 ml / min) tot ernstige (kreatinienopruiming 11 tot 40 ml / min) nierdisfunksie, was piek plasma-vlakke van feksofenadien onderskeidelik 87 % en 111 % hoër, en die gemiddelde eliminasie halfleeftyd was 59 % en 72 % langer, onderskeidelik, as waargeneem in normale vrywilligers. Piek plasma vlakke by pasiënte op dialise (kreatinienopruiming <10 ml / min) was 82 % hoër en die halfleeftyd was 31 % langer as waargeneem by normale vrywilligers.

INDIKASIES:
FEXOFENADINE BIOTECH 120: word aangedui vir die verligting van die simptome wat verband hou met seisoenale allergiese rinitis (SAR).
FEXOFENADINE BIOTECH 180: word aangedui vir die verligting van die simptome wat verband hou met chroniese idiopatiese urtikarie (CIU).

KONTRAÏNDIKASIES
Veiligheid van gebruik tydens swangerskap en laktasie is nie vasgestel nie. (Sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS hieronder).
Die veiligheid en effektiwiteit van FEXOFENADINE BIOTECH is nog nie by kinders onder die ouderdom van 12 jaar bestudeer nie.
Pasiënte met bekende hipersensitiwiteit vir feksofenadien of enige van die ander bestanddele van FEXOFENADINE BIOTECH.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Daar is slegs beperkte data vir die gebruik by bejaardes en pasiënte met nierdisfunksie of pasiënte met lewer inkorting.
FEXOFENADINE BIOTECH moet met sorg in hierdie spesiale risiko groepe toegedien word.
FEXOFENADINE BIOTECH is in borsmelk opgespoor.
FEXOFENADINE BIOTECH het geen kalmerende effekte nie. Pasiënte moet egter gewaarsku word dat 'n klein aantal individue sedasie kan ervaar. Dit is dus raadsaam om individuele reaksie te bepaal voordat bestuur word of ingewikkelde take uitgevoer word.
Die effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuwe-estelsel depressante. (Sien FARMAKOKINETIESE EIENSKAPPE en INTERAKSIES).
Uitwerking op die vermoë om te bestuur en die gebruik van masjinerie
FEXOFENADINE BIOTECH kan die vermoë beïnvloed om te bestuur of om masjinerie te hanteer of gebruik.
FEXOFENADINE BIOTECH bevat laktose. Pasiënte met die seldsame oorerflike toestande van galaktose-onverdraagsaamheid, bv. Galaktosemie, Lapp laktase tekort, glukose-galaktose wanabsorpsie moet nie FEXOFENADINE BIOTECH neem nie.

INTERAKSIES:
FEXOFENADINE BIOTECH ondergaan nie hepatiese biotransformasie nie. Gesamentlike gebruik van FEXOFENADINE BIOTECH met eritromisien of ketokonasool kan 'n twee- tot drievoudige toename in die vlak van FEXOFENADINE BIOTECH in plasma tot gevolg hê. Die veranderinge was nie vergesel van enige effekte op die QT-interval nie en was nie geassosieer met enige toename in ongunstige gebeure in vergelyking met die individue vir wie dit afsonderlik gegee is nie. Die toename in plasma-vlakke van FEXOFENADINE BIOTECH waargeneem na gelyktydige gebruik van eritromisien of ketokonasool, blyk te wyte wees aan 'n toename in gastro-intestinale absorpsie en óf 'n afname in gal uitskeiding of gastro-intestinale afskeiding. Daar is geen interaksie tussen FEXOFENADINE BIOTECH en omeprasool waargeneem nie. Die toediening van 'n teensuurmiddel wat aluminium en magnesiumhidroksied jel bevat 15 minute voor die gebruik van FEXOFENADINE BIOTECH , veroorsaak egter 'n afname in biobeskikbaarheid, waarskynlik as gevolg van binding in die spysverteringskanaal. Dit is raadsaam om 2 uur te laat tussen die toediening van FEXOFENADINE BIOTECH en aluminium en magnesiumhidroksied.

SWANGERSKAP EN LAKTASIE:
Veiligheid van gebruik tydens swangerskap en laktasie is nog nie vasgestel nie.
FEXOFENADINE BIOTECH moet nie tydens swangerskap of laktasie geneem word nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders 12 jaar en ouer:
Chroniese idiopatiese urtikarie (CIU): Neem een 180 mg tablet een maal per dag.
Seisoenale allergiese rinitis (SAR): Neem een 120 mg tablet een maal per dag.
Kinders jonger as 12 jaar:
Die effektiwiteit en veiligheid van gebruik van FEXOFENADINE BIOTECH is nie by kinders onder 12 bestudeer nie.
Spesiale risiko groepe: (Sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS)
Op grond van verhoogde biobeskikbaarheid en halfleeftyd, word 'n dosis van 60 mg een maal daagliks aanbeveel as die aanvangsdosis by pasiënte met 'n verminderde nierfunksie.

NEWE EFFEKTE:
Senuweestelsel afwykings:
Algemeen: hoofpyn, lomerigheid, duiseligheid
Minder algemeen: moegheid, slapeloosheid, senuweeagtigheid en slaapversteurings of paroniria.
Immuunstelsel afwykings:
Minder algemeen: hipersensitiwiteitsreaksies met manifestasies soos angio-edeem, benoudheid, dispnee, blosing, en sistemiese anafilakse is aangemeld.
Gastro-intestinale afwykings:
Algemeen: naarheid
Minder algemeen: dispepsie
Vel- en subkutane weefsel afwykings:
Minder algemeen: uitslag, urtikarie, jeuk
Respiratoriese, torakale en mediastinale versteurings:
Minder algemeen: sinusitis en virale infeksies soos verkoue of griep
Reproduktiewe stelsel en bors afwykings:
Minder algemeen: dismenoreë

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Die meeste aanmeldings van FEXOFENADINE BIOTECH oordosering bevat beperkte inligting. Duiseligheid, slaperigheid en droë mond is egter aangemelde simptome. Standaard maatreëls moet oorweeg word om enige ongeabsorbeerde geneesmiddel te verwyder. FEXOFENADINE BIOTECH word nie effektief uit die bloed verwyder deur hemodialise nie.

IDENTIFIKASIE:
FEXOFENADINE BIOTECH 120: Perskekleurige, filmbedekte, kapsuul-vormige tablette, wat glad is aan weerskante, met 'n dikte van ongeveer 4,2 mm.
FEXOFENADINE BIOTECH 180: Perskekleurige, filmbedekte, kapsuul-vormige tablette, wat glad is aan weerskante, met 'n dikte van ongeveer 5,4 mm.

AANBIEDING:
FEXOFENADINE BIOTECH 120: Wit, ondeursigtige PVC / PVDC / Alu stulpstroke van 10 tablette word in kartonne van 10 of 30 tablette verpak.
FEXOFENADINE BIOTECH 180: Wit, ondeursigtige PVC / PVDC / Alu stulpstroke van 10 tablette word in kartonne van 10 of 30 tablette verpak.

BERGINGSINSTRUKSIES:
Bêre in oorspronklike verpakking teen of benede 25 °C. Beskerm teen lig.
Hou die stulpstroke in die karton tot benodig word. HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:
FEXOFENADINE BIOTECH 120: A40/5.7.1/0590
FEXOFENADINE BIOTECH 180: A40/5.7.1/0591

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Biotech Laboratories (Edms) Bpk.
Grond Vloer, Blok K Wes, Central Park
400 16de Weg, Randjespark, Midrand,1685, Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie: 23 Mei 2006
Datum van kennisgewing met betrekking tot wysiging Reg. 9 en 10: 07 Julie 2017