SCHEDULING STATUS:
S3

PROPRIETARY NAME AND DOSAGE FORM:
MONTELUKAST CHEW BIOTECH 4 (Chewable tablets)
MONTELUKAST CHEW BIOTECH 5 (Chewable tablets)
MONTELUKAST BIOTECH 10 (Film-coated tablets)

COMPOSITION:
MONTELUKAST CHEW BIOTECH 4: Each chewable tablet contains 4,0 mg montelukast.
MONTELUKAST CHEW BIOTECH 5: Each chewable tablet contains 5,0 mg montelukast.
MONTELUKAST BIOTECH 10: Each film-coated tablet contains 10,0 mg montelukast.
Excipients:
MONTELUKAST CHEW BIOTECH 4 & 5: Aspartame, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, red iron oxide, strawberry flavour.
MONTELUKAST CHEW BIOTECH 4 & 5 contain mannitol (sugar alcohol).
MONTELUKAST BIOTECH 10: Croscarmellose sodium, lactose monohydrate, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, opadry colourant (polyvinyl alcohol, titanium dioxide, talc, lecithin, xanthan gum, iron oxide yellow, iron oxide red), purified water.
MONTELUKAST BIOTECH 10 contains sugar (lactose).

PHARMACOLOGICAL CLASSIFICATION:
A. 10.2.2 Other anti-asthmatics, Leukotriene receptor antagonist.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Montelukast binds with high affinity and selectivity to the cysteinyl leukotriene (Cys-LT_1) receptor. Montelukast inhibits physiological actions of cysteinyl leukotriene LTC_4, LTD_4 and LTE_4 at the Cys-LT_1 receptor without agonist activity.
The cysteinylleukotrienes (Cys-LTs) which include LTC_4, LTD_4 and LTE_4 are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (Cys-LTs) receptors in the human airway. Cys-LTs have been correlated with the pathophysiology of asthma and allergic rhinitis. In asthma, leukotriene-mediated effects include a number of airway actions, including bronchoconstriction, mucous secretion, vascular permeability and eosinophil recruitment.
Montelukast causes potent inhibition of airway cysteinyl leukotriene receptors as demonstrated by the ability to inhibit bronchoconstriction due to inhaled LTD_4, in asthmatic patients. Doses as low as 5 mg cause substantial blockage of LTD_4-induced bronchoconstriction.
Pharmacokinetic properties
Absorption
Montelukast is rapidly absorbed following oral administration.
For the 10 mg film-coated tablet, the peak plasma concentration (C_{max}) is achieved in 3 hours after oral doses in the fasted state. Bioavailability of about 64 % is unaffected by co-administration of a standard meal in the morning.
For the 5 mg chewable tablet, the peak plasma concentration is achieved in 2 hours after oral doses in the fasted state. Bioavailability of about 73 % is achieved and is not clinically been influenced by food with chronic administration.
For the 4 mg chewable tablet, C_{max} is achieved 2 hours after administration in paediatric patients 2 to 5 years of age in the fasted state. Safety and efficacy were demonstrated in clinical studies where the 4 mg chewable tablet was administered without regard to the timing of food ingestion.
Distribution
Montelukast is highly protein bound with more than 99 %. The steady-state volume of distribution of montelukast averages 8 to 11 litres.
Metabolism
Montelukast is extensively metabolized in the liver by cytochrome P450 isozymes CYP3A4 and CYP2C9.
Elimination
The plasma clearance of montelukast averages 45 ml/min in healthy adults.
Montelukast is excreted primarily in the faeces via the bile. The duration of action is 24 hours and the half-life ranges between 2,7 to 5,5 hours in healthy young adults. The pharmacokinetics of montelukast is nearly linear for oral doses up to 50 mg.
Special populations
Hepatic insufficiency:
Patients with mild to moderate hepatic insufficiency and clinical evidence of cirrhosis had evidence of decreased metabolism of montelukast resulting in approximately 41 % higher mean montelukast area under the plasma concentration curve (AUC) following a single 10 mg dose. The elimination of montelukast is slightly prolonged compared with that in healthy subjects (mean half-life 7,4 hours). No dosage adjustments are required for patients with mild to moderate hepatic insufficiency. There are no clinical data in patients with severe hepatic insufficiency (Child-Pugh score greater than 9).
Renal insufficiency:
Since montelukast and its metabolites are not excreted in the urine, the pharmacokinetics of montelukast was not evaluated in patients with renal insufficiency. No dosage adjustment is recommended in these patients.
Elderly:
The pharmacokinetic profile and the oral bioavailability of a single 10 mg dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

INDICATIONS:
MONTELUKAST CHEW BIOTECH 4 Tablets are indicated in paediatric patients 2 – 5 years of age for the prophylaxis and chronic treatment of atopic asthma.
MONTELUKAST CHEW BIOTECH 5 Chewable tablets are indicated in paediatric patients over 6 years of age for the prophylaxis and chronic treatment of atopic asthma.
MONTELUKAST BIOTECH 10 Film-coated tablets are indicated for adults and children 15 years of age and older for the prophylaxis and chronic treatment of atopic asthma.
In those adult asthmatic patients, in whom MONTELUKAST BIOTECH is indicated for asthma, MONTELUKAST BIOTECH may also provide some symptomatic relief of seasonal allergic rhinitis.

CONTRAINDICATIONS:
Hypersensitivity to any ingredient of MONTELUKAST BIOTECH.
MONTELUKAST CHEW BIOTECH 4 is contraindicated in children under the age of 2 years as safety and efficacy of the 4 mg tablets have not been demonstrated.
MONTELUKAST CHEW BIOTECH 5 is contraindicated in children under the age of 6 years, as safety and efficacy of 5 mg tablets have not been demonstrated.
MONTELUKAST BIOTECH 10 is contraindicated in children under the age of 15 years.
Pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS:
MONTELUKAST BIOTECH is not indicated in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus.
MONTELUKAST BIOTECH should not be used for the treatment of acute asthma attacks as efficacy has not been established.
Eosinophilic conditions:
Patients on therapy with MONTELUKAST BIOTECH may present with eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Medical practitioners should be on the alert for patients presenting with eosinophilia, vasculitic rash, worsening of pulmonary symptoms, cardiac complications, and/or neuropathy.
Neuropsychiatric events:
Neuropsychiatric events have been reported in some patients taking MONTELUKAST BIOTECH. These include agitation, aggression, anxiousness, dream abnormalities, hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking and behaviour (including suicide), and tremor. Patients and healthcare professionals should be aware of the potential for neuropsychiatric events. Patients should be instructed to inform their healthcare professionals if these events occur. Healthcare professionals should carefully evaluate the risks and benefits of continuing treatment with MONTELUKAST BIOTECH if such events occur.
Hypersensitivity to aspirin:
Patients with a known hypersensitivity to aspirin should continue avoiding aspirin and NSAIDs while taking MONTELUKAST BIOTECH. Although MONTELUKAST BIOTECH is effective in improving airway function in asthmatics, it has not been shown to reduce the bronchoconstrictor response to aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) in aspirin-sensitive asthmatic patients.
Hepatic function impairment:
The metabolism of montelukast may be decreased in patients with mild to moderate hepatic function impairment and clinical evidence of cirrhosis. The half-life may be slightly prolonged; however, dosage adjustment is not necessary. Data are not available in patients with severe hepatic function impairment.
General:
MONTELUKAST BIOTECH is not indicated for use in the reversal of bronchospasms in acute asthma attacks, including status asthmaticus. Patients should be instructed to always have appropriate rescue medication available. Therapy with MONTELUKAST BIOTECH can however be continued during acute exacerbations of asthma.
Patients should be advised to take MONTELUKAST BIOTECH daily as prescribed, even if they are asymptomatic, as well as during periods of worsening asthma, and to contact their medical practitioners if their asthma is not well controlled. Medical attention should be sought if more than the prescribed maximum number of inhalations of short-acting bronchodilator treatment for a 24-hour period, are needed.
MONTELUKAST BIOTECH should not be used as mono-therapy in the treatment and management of exercise-induced bronchospasm. Patients should rather be advised to continue with their usual regimen of an inhaled beta-agonist as prophylaxis and to have a short-acting inhaled beta-agonist available for rescue treatment, if they have exacerbations of asthma after exercise.
Corticosteroid therapy should not be abruptly substituted with MONTELUKAST BIOTECH. Under medical supervision the dose of inhaled or oral corticosteroids should be tapered gradually, if appropriate. To ensure safe and appropriate use, patients should be advised to read the precautions section in the patient information leaflet.
Phenylalanine:
MONTELUKAST CHEW BIOTECH 4 and MONTELUKAST CHEW BIOTECH 5 contain aspartame, which is a source of phenylalanine. It may be harmful to patients with phenylketonuria.
Galactose intolerance:
MONTELUKAST BIOTECH 10 contains lactose. Patients with rare hereditary problems of galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, should not take MONTELUKAST BIOTECH 10.
Effects on ability to drive and use machines:
MONTELUKAST BIOTECH may cause side effects such as dizziness or drowsiness, which may affect the ability to drive. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

INTERACTIONS:
Patients sensitive to aspirin should avoid the use of aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) while using MONTELUKAST BIOTECH (see "WARNINGS AND SPECIAL PRECAUTIONS").
MONTELUKAST BIOTECH may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma, and seasonal allergic rhinitis.
Clinical monitoring is recommended during co-administration of MONTELUKAST BIOTECH with potent cytochrome P450 enzyme inducers, such as rifampicin, phenytoin and phenobarbital. Phenobarbital induces the hepatic metabolism of MONTELUKAST BIOTECH resulting in significant decreases of approximately 40 % in the area under the curve (AUC) for MONTELUKAST BIOTECH. No dosage adjustment for MONTELUKAST BIOTECH is recommended.
MONTELUKAST BIOTECH may potentiate sodium and fluid retention caused by prednisone which could result in severe peripheral oedema.

PREGNANCY AND LACTATION:
The safety of MONTELUKAST BIOTECH in pregnant and lactating women has not been established. MONTELUKAST BIOTECH should not be used during pregnancy or breastfeeding (see "CONTRAINDICATIONS").
It is not known if MONTELUKAST BIOTECH is excreted in human breastmilk.

DOSAGE AND DIRECTIONS FOR USE:
MONTELUKAST BIOTECH should be taken once daily in the evening.
MONTELUKAST CHEW BIOTECH 4: *Paediatric patients 2 to 5 years of age with atopic asthma:*
The dosage is one 4 mg MONTELUKAST CHEW BIOTECH 4 chewable tablet daily.
MONTELUKAST CHEW BIOTECH 5: *Paediatric patients 6 to 14 years of age with atopic asthma:*
The dosage is one 5 mg MONTELUKAST CHEW BIOTECH 5 chewable tablet daily. MONTELUKAST CHEW BIOTECH 5 has not been studied in seasonal allergic rhinitis in children with asthma.
MONTELUKAST BIOTECH 10: A*dults and children 15 years of age and older with atopic asthma with or without seasonal allergic rhinitis:*
The dosage is one 10 mg MONTELUKAST BIOTECH 10 daily.
The 10 mg MONTELUKAST BIOTECH 10 should be swallowed whole.
General recommendations:
MONTELUKAST BIOTECH can be taken with or without food.
Patients should be advised to take MONTELUKAST BIOTECH every day even while their asthma is controlled, as well as during periods of worsening asthma.
No dosage adjustment is necessary for the elderly, for patients with renal insufficiency, mild to moderate hepatic impairment or for patients of either gender.
Therapy with MONTELUKAST BIOTECH in relation to other treatments for asthma:
MONTELUKAST BIOTECH can be added to a patient's existing treatment regimen.

SIDE EFFECTS:
Blood and the lymphatic system disorders:
The following side effects have been reported and the frequencies are unknown: Increased bleeding tendency, agranulocytosis.
Patients on therapy with MONTELUKAST BIOTECH may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. See "WARNINGS AND SPECIAL PRECAUTIONS – EOSINOPHILIC CONDITIONS".
Immune system disorders:
The following side effects have been reported and the frequencies are unknown: Hypersensitivity reactions including anaphylaxis, angioedema, hepatic eosinophilic infiltration.
Psychiatric disorders:
The following side effects have been reported and the frequencies are unknown: Abnormal dreams and hallucinations, agitation including aggressive behaviour, anxiousness, depression, insomnia, irritability, restlessness, suicidal thinking and behaviour (suicidality), tremor.
Nervous system disorders:
Frequent: Headache, dizziness.
The following side effects have been reported and the frequencies are unknown: Drowsiness, paraesthesia/hypoesthesia, seizure.
Cardiac disorders:
Less frequent: Palpitations, chest pain.
Respiratory, thoracic and mediastinal disorders:
Less frequent: Congestion (nasal), cough, influenza.
The following side effects have been reported and the frequencies are unknown: Epistaxis.
Gastrointestinal disorders:
Frequent: Dyspepsia, gastroenteritis (infectious), pain (dental), diarrhoea, thirst, abdominal pain.
The following side effects have been reported and the frequencies are unknown: Nausea, vomiting, dyspepsia.
Hepato-biliary disorders:
Less frequent: Cholestatic hepatitis, increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST).
Skin and subcutaneous tissue disorders:
Frequent: Rash.
The following side effects have been reported and the frequencies are unknown: Pruritus, urticaria, erythema nodosum, bruising.
Musculoskeletal, connective tissue and bone disorders:
The following side effects have been reported and the frequencies are unknown: Arthralgia, myalgia, including muscle cramps.
General disorders and administrative site conditions:
Frequent: Asthenia/fatigue, trauma.
The following side effects have been reported and the frequencies are unknown: Oedema, pyrexia and increased sweating.
Ear and labyrinth disorders
Frequent: Vertigo.

KNOWN SYMPTOMS OF OVERDOSAGES AND PARTICULARS OF ITS TREATMENT:
No specific information is available on the treatment of overdosage with MONTELUKAST BIOTECH. Treatment may include removal of unabsorbed material from the gastro-intestinal tract, clinical monitoring and supportive therapy if required.
It is not known whether montelukast is dialysable by peritoneal or haemodialysis.

IDENTIFICATION:
MONTELUKAST CHEW BIOTECH 4: A pink, oval, biconvex tablet
MONTELUKAST CHEW BIOTECH 5: A pink, round, biconvex tablet
MONTELUKAST BIOTECH 10: A pale orange round, biconvex tablet

PRESENTATION:
MONTELUKAST BIOTECH: is available in silver polyamide/Alu/PVC and silver aluminium blister packs of 28.

STORAGE INSTRUCTIONS:
Store at room temperature at or below 25 °C, protected from moisture and light.
Keep blister in outer carton until required for use. Tablets should not be removed from blisters until required for use, to protect it from moisture.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
MONTELUKAST CHEW BIOTECH 4: A45/10.2.2/0475
MONTELUKAST CHEW BIOTECH 5: A45/10.2.2/0476
MONTELUKAST BIOTECH 10: A45/10.2.2/0477

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 THE PACKAGE INSERT:
Date of registration: 19 April 2013
Date of notification with regard to amended Reg. 9 and 10: 06 February 2015

Namibia:
NS2 MONTELUKAST BIOTECH 10
Reg. No.: 16/10.2.2/0042

SKEDULERINGSTATUS:
S3

EIENDOMSNAAM EN DOSEERVORM:
MONTELUKAST CHEW BIOTECH 4 (Koubare tablette)
MONTELUKAST CHEW BIOTECH 5 (Koubare tablette)
MONTELUKAST BIOTECH 10 (Filmbedekte tablette)

SAMESTELLING:
MONTELUKAST CHEW BIOTECH 4: Elke koubare tablet bevat 4 mg montelukast.
MONTELUKAST CHEW BIOTECH 5: Elke koubare tablet bevat 5 mg montelukast.
MONTELUKAST BIOTECH 10: Elke filmbedekte tablet bevat 10 mg montelukast.
Onaktiewe bestandele:
MONTELUKAST CHEW BIOTECH 4 en 5: Aspartaam, natriumkroskarmellose, hidroksipropiellsellulose,
magnesiumstearaat, mannitol, mikrokristallyne sellulose, rooi ysteroksied, aarbeigeur.
MONTELUKAST CHEW BIOTECH 4 & 5 bevat mannitol (suiker alkohol).
MONTELUKAST BIOTECH 10: Natriumkroskarmellose, monohidraat laktose, hidroksipropielsellulose,
magnesiumstearaat, mikrokristallyne sellulose, opadry kleurmiddel (polyvinyl alkohol, titaandioksied, talk, lesitien, xanthangom, ysteroksied geel, ysteroksied rooi), gesuiwerde water.
MONTELUKAST BIOTECH 10 bevat suiker (laktose).

FARMAKOLOGIESE KLASSIFIKASIE:
A. 10.2.2 Ander anti-asmatika, Leukotriene reseptorantagonis.

FARMAKOLOGIESE WERKING:
Farmakodinamika eienskappe
Montelukast bind met hoë affiniteit en selektiwiteit aan die sisteïeniel leukotriene ($SisLt_1$) reseptor. Montelukast inhibeer, sonder agonitiese aktiwiteit, die fisiologiese werking van LTC_4, LTD_4 and LTE_4 by die $SisLT_1$ reseptor.
Die sisteïeniël leukotriene (Sis-LTs), wat LTC_4, LTD_4 and LTE_4 insluit, is kragtige inflammatoriese eikosanoïede wat uit verskeie selle, insluitende masselle en eosinofiele, vrygestel word. Hierdie belangrike proasmatiese tussenganger bind aan sisteïeniel leukotriene reseptore (SisLT) wat in menslike lugweë aangetref word. Sisteïeniel leukotriene reseptore (SisLT) word verbind met die patofisiologie van asma en allergiese rinitis. In asma sluit leukotriene-tussenganger effekte 'n aantal lugwegreaksies, insluitende brongokonstriksie, slymafskeiding, vaskulêre deurlaatbaarheid en eosinofielaanvulling in.
Montelukast veroorsaak kragtige inhibering van die lugweg sisteïeniel leukotriene reseptore, soos bewys deur die vermoë daarvan om brongokonstriksie, as gevolg van ingeasemde LTD_4 in asmatiese pasiënte, te inhibeer. Dosering so laag as 5 mg veroorsaak aansienlike inhibisie van die LTD_4 veroorsaakde brongokonstriksie.
Farmakokinetika eienskappe
Absorpsie
Montelukast word vining geabsorbeer na oral toediening. Vir die 10 mg filmbedekte tablet, is die piek plasmakonsentrasie (C_{maks}) bereik binne 3 ure na mondelingse toediening onder vastende toestande. Die biobeskikbaarheid van ogeveer 64 % word nie beïnvloed deur die gelyktydige toediening van 'n standard ete in die oggend nie.
Met die 5 mg koubare tablet, is die piek plasmakonsentrasie binne 2 ure na die toediening van mondelinge dosis onder vastende toestande bereik. Biobeskikbaarheid van ongeveer 73 % is bereik en word nie klinies beïnvloed deur voedsel met kroniese toediening nie.
Met die 4 mg koubare tablet is C_{maks} binne 2 ure na die toediening aan pediatriese pasiënte 2 tot 5 jaar oud, onder vastende toestande bereik. Veiligheid en doeltreffendheid is bewys met kliniese proewe, waartydens die 4 mg koubare tablet toegedien is sonder inagneming van tyd van voedselinname.
Verspreiding
Montelukast word meer as 99 % aan plasmaproteïene gebind. Die gelykvlak volume van verspreiding van montelukast is 8 tot 11 liters.
Metabolisme
Montelukast word omvattend gemetaboliseer in die lewer deur sitochroom P450 3A4 en 2C9.
Eliminasie
Die plasma-opruiming van montelukast is 45 ml/min in gesonde volwassenes.
Montelukast word hoofsaaklik in die feses en gal uitgeskei. Die duur van werking van montelukast is 24 uur en die halfleeftyd van montelukast wissel tussen 2,7 tot 5,5 uur in gesonde jong volwassenes. Die farmakokinetika van montelukast is amper liniër vir mondelinge dosisse tot by 50 mg.
Spesiale populasies
Lewerontoereikendheid:
Pasiënte met ligte tot matige lewerontoereikendheid en kliniese bewys van sirrose, het bewese verminderde metabolisme van montelukast wat na 'n enkele 10 mg dosis aanleiding gegee het tot ongeveer 41 % hoër gemiddelde montelukast area onder die plasma-konsentrasiekurwe (AOK). Die eliminasietyd van montelukast is effens langer as onder gesonde proefpersone (gemiddelde halfleeftyd 7,4 uur). Geen dosisaanpassing word vir pasiënte met ligte tot matige lewerontreikendheid benodig nie. Daar is geen kliniese data oor pasiënte met erge lewerontoereikendheid (Child-Pugh-telling hoër as 9) nie.
Nierinkorting:
Aangesien montelukast en die metaboliete daarvan nie in die uriene uitgeskei word nie, is die farmakokinetika van montelukast nie onder pasiënte met nierinkorting ondersoek nie. Geen dosisaanpassing word by hierdie pasiënte aanbeveel nie.
Bejaardes:
Die farmakokinetiese profiel en mondelingse bio-beskikbaarheid van 'n enkele 10 mg dosis montelukast is soortegelyk in bejaardes en jong volwassenes. Die plasma halfleeftyd is effens langer in die geval van bejaardes. Geen dosisaanpassings word benodig.

INDIKASIES:
MONTELUKAST CHEW BIOTECH 4 word aangedui vir pediatriese pasiënte 2 tot 5 jarige ouderdom, vir die profilaktiese en kroniese behandeling van atopiese asma.
MONTELUKAST CHEW BIOTECH 5 word aangedui vir pediatriese patiënte ouer as 6 jaar vir die profilaktiese en kroniese behandeling van atopiese asma.
MONTELUKAST BIOTECH 10 filmbedekte tablette word aangedui vir volwassenes en kinders 15 jaar en ouer vir profilaktiese en kroniese behandeling van atopiese asma.
In volwasse asmatiese pasiënte waar MONTELUKAST BIOTECH aangedui is vir asma, kan MONTELUKAST BIOTECH simptomatiese verligting van seisonale allergiese rinitis bring.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir enige bestandeel van MONTELUKAST BIOTECH.
MONTELUKAST CHEW BIOTECH 4 is teenaangedui vir kinders onder die ouderdom van 2 jaar aangesien die veiligheid en doetreffendheid van die 4 mg koubare tablette nie bekend is.
MONTELUKAST CHEW BIOTECH 5 is teenaangedui vir kinders onder die ouderdom van 6 jaar, aangesien die veiligheid en doeltreffendheid van die 5 mg koubare tablette nie bekend is.
MONTELUKAST BIOTECH 10 is teenaangedui vir kinders onder die ouderdom van 15 jaar.
Swangerskap en borsvoeding.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
MONTELUKAST BIOTECH word nie aangedui in die ommekeer van bronghospasma in akute asma aanval, insluitend status asthmatikus nie.
Die doeltreffendheid van MONTELUKAST BIOTECH in die behandeling van akute asma is nog nie bepaal nie.
Eosinofilliese toestande:
Onder seldsame omstandighede kan daar pasiënte op behandeling met MONTELUKAST BIOTECH sistemiese eosinofilie, soms met kliniese tekens van vaskulitis wat ooreenkom met die Churg-Strauss-sindroom, 'n toestand wat dikwels met sistemiese kortikosteroïde behandel word, na vore kom. Hierdie voorvalle word gewoonlik, maar nie altyd nie, met 'n vermindering in mondelikse kortikosteroïedbehandeling in verband gebring. Mediese praktisyns moet attent gemaak word op pasiënte met eosinofilie, vaskulitisuitslag, verergerende pulmonêre simptome, hartkomplikasies, en/of neuropatie.
Neuropsigiatriese gebeure:
Neuropsigiatriese gebeure is aangemeld by sommige paiënte wat MONTELUKAST BIOTECH gebruik het. Dit sluit in agitasie, aggressie, angstigheid, abnormale drome, hallusinasies, depressie, slaaploosheid, prikkelbaarheid, rusteloosheid, selfmoordgedagtes en gedrag (selfmoordneigings) en bewing. Pasiënte en proffesionele gesondheidsorgwerkers moet bewus wees van die moontlikheid van neuropsigiatriese gebeure. Pasiënt moet ingelig word om proffesionele gesondheidsorgwerkers in kennis te stel indien neuropsigiatriese gebeure plaasvind. Proffesionele gesondheidsorgwerkers moet noukeurig die risiko's en voordele van die voortgesette behandeling met MONTELUKAST BIOTECH evalueer indien neuropsigiatriese gebeure voorkom.
Hipersensitiwiteit vir aspirien:
Pasiënte met bekende aspiriensensitiwiteit moet die gebruik van aspirien of nie-steroïede anti-inflammatoriese middels vermy terwyl hulle MONTELUKAST BIOTECH neem. Alhoewel MONTELUKAST BIOTECH doeltreffend is om lugwegfunksie by asmalyers te verbeter, is dit nie getoon dat dit die brongokonstruksierespons tot aspirien en ander nie-steroïde anti-inflammatoriese geneesmiddels by aspiriensensitiewe asmatiese pasiënte keer nie.
Lewerfunksie inkorting:
Pasiënte met ligte en matige lewerfunksie inkorting en kliniese bewyse van sirrose, toon verminderde metabolisme van montelukast. Die halfleeftyd is effens langer, maar geen dosisaanpassings word benodig nie. Geen kliniese data oor pasiënte met erge lewerfunskie inkorting is nie beskikbaar nie.
Algemeen:
MONTELUKAST BIOTECH word nie aangedui in die omkering van brongospasma in akute asma aanvalle, insluitende status asmatikus, aangedui nie. Pasiënte moet aanbeveel word om toepaslike noodmedikasie beskikbaar te hê. Behandeling met MONTELUKAST BIOTECH kan egter tydens akute opflikkering van asma volgehou word. Sien "Waarskuwings".
Pasiënte word aangeraai om MONTELUKAST BIOTECH daagliks soos voorgeskryf te neem, selfs as hulle asimptomaties is, asook tydens periodes van verergende asma, en om hulle geneeshere te kontak indien hulle asma nie goed onder beheer is nie. Mediese sorg moet bekom word indien meer as the maksimum voorgeskrewe inhalasies van die kortwerkende brongodilators behandeling 'n 24 uur periode benodig word.
MONTELUKAST BIOTECH moet nie as monoterapie vir die behandeling en beheer van oefening-geïnduseerde brongospasma gebruik word nie. Pasiënte moet ingelig word om voort te gaan met hulle gewone skedule van profilaktiese inhalasie van beta-agoniste en om inhalasie beta-agoniste beskikbaar te hê vir noodbehandling indien hulle verergering het van asma na oefening.
Kortikosteroiedbehandeling moet nie skielik vervang word met MONTELUKAST BIOTECH nie. Die dosis van inhalasie of mondelingse kortikosteroïede moet geleidelik onder mediese toesig verminder word indien nodig. Vir veilige en toepaslike gebruik word pasiënte versoek om die gedeelte in verband met voorsorgmaatreëls in die pasiënt inligtingspamflet aandagtig deur te lees.
Feniel alanien:
MONTELUKAST CHEW BIOTECH 4 en MONTELUKAST CHEW BIOTECH 5 bevat aspartaam wat 'n bron van fenielalanien is. Dit mag skadelik wees vir pasiënte met fenielketonurie.
Galaktose intoleransie:
MONTELUKAST BIOTECH 10 bevat laktose. Pasiënte met seldsame oorerflik probleem van galaktose
intoleransie, b.v. galaktosemie, Lapp laktase tekort, glukose-galaktose wanabsorption of fruktose intoleransie, moet nie MONTELUKAST BIOTECH 10 gebruik nie.
Invloed op bestuur van voertuie en gebruik van masjinerie:
MONTELUKAST BIOTECH veroorsaak newe-effekte soos lighoofdigheid of lomerigheid, wat die vermoë om te bestuur mag beïnvloed. Pasiënte word aanbeveel om nie te bestuur of masjinerie te gebruik totdat die invloed van MONTELUKAST BIOTECH per individu vasgestel is nie.

INTERAKSIES:
Patiënte met aspiriensensitiwiteit moet die gebruik van aspirien of nie-steroïede anti-inflammatoriese middels vermy terwyl hulle MONTELUKAST BIOTECH neem (sien "WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS").
MONTELUKAST BIOTECH kan in kombinasie met ander behandeling wat gereeld by die profilaktiese en kroniese behandeling van asma en seisoenale allergiese rinitis gebruik word, toegedien word.
Die kombinasie van kragtige sitochroom P450 ensieminduseerders soos rifampisien, fenitoïen en fenobarbitoon wat saam MONTELUKAST BIOTECH gebruik word, moet klinies gemoniteer word. Fenobarbitoon induseer hepatise metabolisme van MONTELUKAST BIOTECH, wat aanleiding gee tot 'n ooglopende verlaging van ongeveer 40 % in die oppervlak onder die plasma-konsentrasiekurwe (AOK) van MONTELUKAST BIOTECH. Geen dosisaanpassing vir MONTELUKAST BIOTECH word aanbeveel nie.
MONTELUKAST BIOTECH kan moontlik natrium en vloeistofretensie vererger tydens die gebruik van prednisoon wat kan lei tot ernstige perifere edeem.

SWANGERSKAP EN BORSVOEDING:
Die veiligheid van MONTELUKAST BIOTECH in swanger en lakterende vroue is nie vasgestel nie.
MONTELUKAST BIOTECH moet nie tydens swangerskap of deur moeders wat borsvoed gebruik word nie (sien "KONTRA-INDIKASIES").
Dit is nie bekend of MONTELUKAST BIOTECH in menslike borsmelk uitgeskei word nie.

DOSIS EN GEBRUIKSAANWYSIGINGS:
MONTELUKAST BIOTECH moet een keer per dag in die aand geneem word.
MONTELUKAST CHEW BIOTECH 4: *Pediatriese patiënte 2 tot 5 jarige ouderdom met atopiese asma:*
Die dosis is een 4 mg koubare tablet daagliks.
MONTELUKAST CHEW BIOTECH 5: *Pediatriese pasiënte 6 tot 14 jarige ouderdom met atopiese asma:*
Die dosis is een 5 mg koubare tablet daagliks.
MONTELUKAST CHEW BIOTECH 5 se gebruik vir die behandeling van seisoenale rinitis in kinders met asma is nog nie vasgestel nie.
MONTELUKAST BIOTECH 10: *Volwassenes en kinders 15 jaar en ouer met atopiese asma met of sonder seisoenale rinitis:*
Die dosis is 10 mg filmbedekte tablet daagliks.
Die 10 mg MONTELUKAST BIOTECH 10 moet nie gebreek of gekou word nie.
Algemene Aanbevelings:
MONTELUKAST BIOTECH kan met of sonder voedsel geneem word.
Pasiënte word aanbeveel om voort te gaan om MONTELUKAST BIOTECH te neem terwyl hulle asma onder beheer is en ook gedurende tydperke van erger asma.
Geen dosisaanpassing is nodig vir pediatriese pasiënte, pasiënte met nierinkorting, of met ligte tot matige lewerinkorting nie, of vir pasiënte van 'n spesifieke geslag nie.
Terapie met MONTELUKAST BIOTECH in verhouding tot ander behandelings vir asma:
MONTELUKAST BIOTECH kan by 'n pasiënt se bestaande behandelingsskedule gevoeg word.

NEWE-EFFEKTE:
Bloed- en limfstelsel versteurings:
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Neiging tot verhoogde bloeding, agranulositosis.
Pasiënte op behandeling met MONTELUKAST BIOTECH kan sistemiese eosinofilie ontwikkel, soms met kliniese tekens van vaskulitis in ooreenstemmimg met die Churg-Strauss-sindroom, 'n toestand wat dikwels behandel kan word met sistemiese kortikosteroïedbehandeling. Sien "WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS – EOSINOFILIESE TOESTANDE".
Immuunsisteem versteurings:
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Hipersensitiwiteitsreaksies insluitende anafilakse, angioedeem en infiltrasie van eosinofiele in die lewer.
Psigiatriese versteurings:
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Abnormale drome en hallusinasies, agitasie insluitende aggresiewe gedrag, angstigheid, depressie,
slaaploosheid, prikkelbaarheid, rusteloosheid, selfmoordgedagtes en gedrag (selfmoordneigings), bewing.
Senuweestelsel versteurings:
Gereeld: Hoofpyn, lighoofdigheid.
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Lomerigheid, parastesie/hipoestesie, stuipe.
Versteurings van die hart:
Minder gereeld: Hartkloppings, borspyn.
Respiratoriese, bors- en mediastinale versteurings:
Minder gereeld: Nasale kongestie, hoes, griep.
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend: Neusbloeding.
Gastro-intestinale versteurings:
Gereeld: Dispepsie, gastro-enteritis (aansteeklike), tandpyn, diarree, dors, abdominale pyn.
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Naarheid, braking.
Versteurings van die lewer en gal:
Minder gereeld: Cholestatiese hepatitis, verhoodge alanine aminotransferase (ALT) en aspartaat aminotransferase (AST).
Versteurings van die vel- en onderhuidseweefsel:
Gereeld: Uitslag.
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Pruritus, urtikarie, erythema nodosum, kneusing.
Versteurings van die muskuloskeletale stelsel, bindweefsel en skeletbene
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Artralgie, mialgie, insluitende spierkrampe.
Algemene en plek van toediening versteurings:
Gereeld: Astenie/moegheid, trauma.
Die volgende newe-effekte is aangemeld en die frekwensies daarvan is onbekend:
Edeem, pyreksie en verhoogde sweet
Oor en labyrint versteurings:
Gereeld: Vertigo

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Daar is nie spesifieke inligting oor die behandeling van oordosering met MONTELUKAST BIOTECH beskikbaar nie.
Behandeling sluit in die verwydering van ongeabsorbeerde bestandeel uit die gastro-intestinale kanaal, kliniese monitoring en ondersteunende terapie indien nodig.
Dit is nie bekend of montelukast verwyder kan word deur middel van peritoniale- of hemodialise nie.

IDENTIFIKASIE:
MONTELUKAST CHEW BIOTECH 4: 'n Pienk, ovaal, bikonvekse tablet
MONTELUKAST CHEW BIOTECH 5: 'n Pienk, ronde, bikonvekse tablet
MONTELUKAST BIOTECH 10: Bleek oranje ronde, bikonvekse tablet

AANBIEDING:
MONTELUKAST BIOTECH: is beskikbaar in silwer polyamide/Alu/PVC en silwer aluminium stulpverpakking van 28.

BERGINGSINSTRUKSIES:
Bewaar by kamertemperatuur by of benede 25 °C, beskerm teen vog en lig.
Hou stulpverpakking in buitenste karton tot nodig vir gebruik. Tablette moet nie verwyder word uit die stulpverpakking nie tot benodig word vir gebruik, om sodoende tablet te beskerm teen vog.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
MONTELUKAST CHEW BIOTECH 4: A45/10.2.2/0475
MONTELUKAST CHEW BIOTECH 5: A45/10.2.2/0476
MONTELUKAST BIOTECH 10: A45/10.2.2/0477

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: 19 April 2013
Datum van kennisgewing met betrekking tot wysiging Reg. 9 en 10: 06 February 2015

Namibië:
NS2 MONTELUKAST BIOTECH 10
Reg. Nr.: 16/10.2.2/0042

PA450475/6/7-3