SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
ACYCLOVIR BIOTECH 200 Tablets

COMPOSITION:
ACYCLOVIR BIOTECH 200: Each tablet contains 200 mg acyclovir.
Excipients: colloidal silicone dioxide, croscarmellose sodium, indigotine lake (CI 73015), lactose monohydrate, magnesium stearate, microcrystalline cellulose.
Contains sugar. Lactose monohydrate 190,0 mg.

PHARMACOLOGICAL CLASSIFICATION:
A 20.2.8 Antiviral Agents.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Acyclovir is phosphorylated after entering the herpes infected cells to the active acyclovir triphosphate compound. It is active in vitro against type 1 and 2 herpes simplex (HSV) and varicella zoster viruses.
The HSV coded thymidine kinase must be present before phosphorylation can take place. The Acyclovir triphosphate prevents DNA synthesis by inhibiting herpes specified DNA polymerase. This process takes place without affecting the normal cellular processes.

INDICATIONS:
Herpes simplex infections of the skin and mucous membranes including genital herpes (initial and recurrent) if given as soon as possible after symptoms appear.
Suppression of recurrent herpes simplex infections in patients with an incompetent immune system.
Indicated for shingles if the lesion in not older than 72 hours.
If used within 24 hours after appearance of typical chickenpox rash, ACYCLOVIR BIOTECH is indicated for treatment of the varicella zoster or chickenpox virus.
In HIV positive patients, who are severely immunocompromised, ACYCLOVIR BIOTECH is indicated to reduce the risk of developing herpes infections. ACYCLOVIR BIOTECH could be used in combination with zidovudine in patients with advanced HIV disease.

CONTRAINDICATIONS:
Any known hypersensitivity to acyclovir.
Pregnancy and lactation: Safety has not been established.

WARNINGS and SPECIAL PRECAUTIONS:
ACYCLOVIR BIOTECH should be administered with caution to patients with renal impairment and doses should be adjusted according to creatinine clearance.
The risk of renal impairment is increased by the concomitant use of other nephrotoxic agents.
Since ACYCLOVIR BIOTECH 200 contains lactose monohydrate, it is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or of glucose-galactose malabsorption.

INTERACTIONS:
Probenecid blocks the renal clearance of ACYCLOVIR BIOTECH and thus increases the mean half-life.

PREGNANCY AND LACTATION:
Safety has not been established during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

INDICATION	DOSAGE	COMMENTS
Initial and recurrent herpes simplex infections of skin and mucous membranes	200 mg 5 times daily at 4 hourly intervals for 5 days	In severe initial infection, extend treatment. In immunocompromised patients, dosage could be increased to 400 mg. The first dose should be administered as early as possible after start of infection.
Supression of recurrent genital herpes simplex infections in immunocompromised patients	200 mg acyclovir 4 times daily at 6 hourly intervals, or 400 mg 12 hourly.	Some patients may have breakthrough infections on 800 mg daily. Interrupt therapy every 6 – 12 months to observe history of disease.
Prophylaxis of herpes simplex infections in immunocompromised patients	200 mg 4 times daily at 6 hourly intervals	In severely immunocompromised patients, or impaired absorption from the gut, dosage could be doubled to 400 mg
Treatment of varicella zoster in adolescents (12-18 years)	800 mg 4 times a day for 5 days.	
Treatment of varicella zoster and herpes zoster infections in adults	800 mg 5 times daily at 4 hourly intervals for 7 days	Start treatment as early as possible. In severely immunocompromised patients, or patients with impaired gut absorption, IV dosing should be considered.
Management of severely immunocompromised patients.	800 mg 4 times daily at 6 hourly intervals.	
Dosage in children: Herpes simplex and prophylaxis of herpes simplex infections in immunocompromised patients 2 years and older	Adult dose	Orally administered acyclovir in children less than 2 years of age has not yet been fully studied.
Below 2 years: Treatment of varicella zoster (chickenpox) in children	20 mg ACYCLOVIR BIOTECH per kg body mass 4 times daily for 5 days	Dosage may not exceed 800 mg daily and start treatment as soon as chickenpox rash appear
Dosage in elderly:		Adequate hydration in patients taking high doses must be maintained. Acyclovir clearance in body declines parallel with creatinine clearance.
Treatment or prophylaxis of herpes simplex infections in patients with renal impairment	200 mg every 12 hours if creatinine clearance > 10 ml/minute	
Treatment of varicella zoster, herpes zoster and immunocompromised patients with renal impairment	800 mg twice daily at 12 hourly intervals (creatinine clearance > 10 ml/minute) 800 mg 3 times daily with 8 hourly intervals (creatinine clearance 10-25 ml/minute)	

SIDE EFFECTS:
Effects on skin: Skin rashes which disappear after withdrawal of medication.
Effects on gastro-intestinal tract: Nausea, vomiting, and diarrhoea.
Other reactions: Reversible neurological reactions, dizziness, hallucinations and somnolence especially in patients with renal impairment. Rises in bilirubin and liver related enzymes, elevations in blood urea and creatinine, minimal decreases in haematological indices, headaches and fatigue. Accelerated diffuse hair loss has also been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
ACYCLOVIR BIOTECH is removed by haemodialysis. Treatment is symptomatic and supportive, although no data is available on the effects after ingestion of high doses.

IDENTIFICATION:
ACYCLOVIR BIOTECH 200: Round, blue, flat-faced, bevelled-edged tablets, engraved "200" on one side, other side plain.

PRESENTATION:
ACYCLOVIR BIOTECH 200 tablets are available in white plastic bottles of 25, 100, 250, 500 and 1000 tablets.
Patient ready packs (PRP's) are availabe in pack sizes of 25 tablets.
All pack sizes may not necessarily be marketed at one time.

STORAGE INSTRUCTIONS:
Store at or below 25 °C in a dry place. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
ACYCLOVIR BIOTECH 200: 31/20.2.8/0430

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: 29 May 2001
Date of latest revision of the text as approved by Council: 29 May 2001
Date of notification with regard to amended Reg. 9 and 10: 02 February 2015

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM (en doseervorm):
ACYCLOVIR BIOTECH 200 Tablette

SAMESTELLING:
ACYCLOVIR BIOTECH 200: Elke tablet bevat 200 mg asiklovir.
Hulpmiddels: Kolloïdale silikoondioksied, kroskarmellose natrium, indigotienmeer (CI7305), laktose monohidraat, magnesiumstearaat, mikrokristallyne sellulose.
Bevat Suiker. Laktose monohidraat 190,0 mg.

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.2.8 Antivirale middels.

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Asiklovir word gefosforileer om 'n aktiewe asiklovir trifosfaat verbinding te vorm nadat dit die geïnfekteerde herpes selle binnegedring het. Dit is aktief *in vitro* teen tipe 1 en 2 herpes simpleks (HSV) en varicella zoster virusse.
Die HSV gekodeerde timidien kinase moet teenwoordig wees voordat fosforilase kan plaasvind.
Asiklovir trifosfaat verhoed DNA sintese deur herpes gespesifiseerde DNA polimerase te inhibeer. Hierdie proses vind plaas sonder om die normale sellulêre prosesse te beinvloed.

INDIKASIES:
Herpes simplex infeksies van die vel en slymvliese insluitende genitale herpes (aanvanklike en herhalende) indien so gou as moontlik nadat simptome opgemerk word toegedien word.
Onderdrukking van herhalende herpes simplex infeksies in pasiënte met 'n onderdrukte immuunstelsel.
Aangedui vir gordelroos as die letsel nie ouer as 72 uur is nie.
ACYCLOVIR BIOTECH word aangedui vir die behandeling van die varicella zoster of waterpokkie-virus indien dit gebruik word binne 24 uur na die verskyning van die tipiese waterpokkies uitslag.
ACYCLOVIR BIOTECH word aangedui vir MIV-positiewe pasiënte wat ernstige immuunonderdruking ondervind om die risiko van die ontwikkeling van herpes infeksies te verminder. ACYCLOVIR BIOTECH kan gebruik word in kombinasie met zidovudine in pasiënte met gevorderde MIV-siekte.

KONTRA-INDIKASIES
Enige bekende hipersensitiwiteit teenoor asiklovir.
Swangerskap en laktasie: Veiligheid in die gebruik gedurende swangerskap en laktasie is nog nie vasgestel nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
ACYCLOVIR BIOTECH moet met versigtigheid aan pasiënte met ingekorte nierfunksie voorgeskryf word en dosisse moet aangepas word volgens kreatinien opruiming.
Die risiko van ingekorte nierfunksie word verhoog deur die gelyktydige gebruik van ander nefrotoksiese agente.
Aangesien ACYCLOVIR BIOTECH 200 laktose monohidraat bevat, word dit nie aanbeveel vir pasiente met selsame oorerflike probleme soos galaktose onverdraagsaamheid, erge laktose ontoereikendheid of glukose-galaktose wanabsorpsie nie.

INTERAKSIES
Probenesied blokkeer die nieropruiming van ACYCLOVIR BIOTECH en dus verhoog die gemiddelde half-leeftyd.

SWANGERSKAP EN LAKTASIE
Veiligheid in die gebruik gedurende swangerskap en laktasie is nog nie vasgestel nie.

DOSERING EN GEBRUIKSAANWYSINGS

INDIKASIE	DOSERING	OPMERKINGS
Aanvanklike en herhalende herpes simplex infeksies van die vel en slymvliese	200 mg 5 maal daagliks vir 5 dae, elke 4 uur.	Behandeling word uitgebrei in erge aanvanklike infeksies. Die dosis kan verhoog word tot 400 mg in immuunonderdrukte pasiente. Die eerste dosis behoort toegedien te word so spoedig moontlik na aanvang van infeksie.
Die onderdrukking van terugkerende genitale herpes simplex infeksies in immuunonderdrukte pasiënte.	200 mg 4 maal daagliks elke 6 uur of 400 mg elke 12 uur.	Sommige pasiënte vertoon daagliks deurbraak infeksies op 800 mg. Onderbreek behandeling elke 6 - 12 maande om die geskiedenis van die siekte waar te neem.
Voorkoming van herpes simplex -infeksies in immuunonderdrukte pasiënte	200 mg 4 maal daagliks, elke 6 uur	Die dosis moet vermeerder word na 400 mg in pasiente met erge immuunonderdrukking of verswakte absorpsie in die derm
Behandeling van varicella zoster in adolessente (12-18 jaar)	800 mg 4 maal daagliks vir 5 dae	
Behandeling van varicella zoster en herpes zoster infeksies in volwassenes	800 mg 5 maal daagliks, elke 4 uur vir 7 dae	Behandeling moet so gou moontlik begin word. IV-dosering moet oorweeg word in pasiente met erge immuunonderdrukking of verswakte absorpsie in die derm.
Behandeling van erge immuunonderdrukte pasiënte	800 mg 4 maal daagliks, elke 6 uur.	
Dosering in kinders: Herpes simplex en die voorkoming van herpes simplex-infeksies in immuunonderdrukte pasiënte 2 jaar en ouer.	Volwasse dosering	Oraal toediening van acyclovir in kinders jonger as 2 jaar is nog nie ten volle bestudeer nie.
Kinders onder 2 jaar: Behandeling van varicella zoster (waterpokkies) in kinders	20 mg ACYCLOVIR BIOTECH per kg liggaamsmassa, 4 maal daagliks vir 5 dae	Dosis mag nie 800 mg daagliks oorskry nie. Begin behandeling sodra waterpokkies uitslag verskyn
Dosering in bejaardes:		Genoegsame hidrasie in pasiënte wat hoë dosisse neem moet gehandhaaf word. Asiklovir opruiming in die liggaam verminder met kreatinienopruiming.
Behandeling of voorkoming van herpes simplex-infeksies in pasiënte met ingekorte nierfunksie	200 mg elke 12 ure as kreatinienopruiming > 10 ml/minuut	
Behandeling van varicella zoster, herpes zoster en immuunonderdrukte pasiënte met ingekorte nierfunksie	800 mg 2 maal daagliks, elke 12 uur (kreatinienopruiming > 10 ml/minuut) 800 mg 3 maal daagliks, elke 8 uur (kreatinienopruiming 10-25 ml/minuut).	

NEWE EFFEKTE:
Uitwerking op die vel: Veluitslag wat weggaan na onttrekking van medikasie.
Uitwerking op die spysverteringstelsel: Naarheid, braking en diarree
Ander reaksies: Omkeerbare neurologiese reaksies, duiseligheid, hallusinasies en lomerigheid veral in pasiënte met ingekorte nierfunksie. Verhoging in bilirubien en lewer verwante ensieme, verhoging in bloed ureum en kreatinien, minimale dalings in die hematologiese indeks, hoofpyn en moegheid. Toenemende haarverlies is ook aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
ACYCLOVIR BIOTECH word verwyder deur hemodialise. Behandeling van oordosering is simptomaties en ondersteunend, maar geen data is beskikbaar oor die gevolge na die inname van hoë dosisse nie.

IDENTIFIKASIE:
ACYCLOVIR BIOTECH 200 mg: Ronde, blou, plat tablette met afgeskuinste ronde, "200" gegraveer aan die een kant en glad aan die ander kant.

AANBIEDING:
ACYCLOVIR BIOTECH 200 mg tablette is beskikbaar in wit plastiese bottels van 25, 100, 250, 500 en 1000 tablette.
Pasiënt verpakkings (PGP's) is beskikbaar in verpakkingsgroottes van 25 tablette.
Alle verpakkings groottes mag nie noodwendig op een slag bemark word nie.

BERGINGSAANWYSINGS:
Bewaar teen of benede 25 °C. Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS

REGISTRASIE NOMMERS:
31/20.2.8/0430

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

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:
Datum van registrasie: 29 Mei 2001
Datum van laaste hersiende voubiljet: 29 Mei 2001
Datum van kennisgewing in terme van Regulasie 9 en 10: 02 Februarie 2015

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