Pharmacode position may change as per the supplier's m/c requirement

APPROVED
leshania , 2022/03/22 ,09:02:36

BINACIL P1530659

BINACIL P1530659

SKEDULERINGSTATUS

SUID AFRIKA: S4

NAMIBIË: NS2

EIENDOMSNAAM (en doseervorm):
BINACIL 125 mg (tablet)
BINACIL 250 mg (tablet)

SAMESTELLING:
BINACIL 125 mg: Elke onbedekte tablet bevat terbinafienhidrochloried ekwivalent aan 125 mg terbinafien. Suikervry.
BINACIL 250 mg: Elke onbedekte tablet bevat terbinafienhidrochloried ekwivalent aan 250 mg terbinafien. Suikervry.
Die ander bestanddele van die formulasie sluit mikrokristallyne sellulose (Avicel PH-101), natriumstyselglikolaat, kolloïdale anhidriese silika, hipromellose en magnesiumstearaat in.

FARMAKOLOGISE KLASSIFIKASIE:
A20.2.2 Antimikrobiese (chemoterapeutiese) middels. Swamdoders.

FARMAKOLOGIESE WERKING:
Farmakodinamika:
Terbinafien is 'n allielamien met 'n breë spektrum van swamwerende aktiwiteit. Teen lae konsentrasies is terbinafien swamdodend teen dermatofiete, skimmels en sekere swamme. Die aktiwiteit is swamdodend of swamstuitend, afhangende van die spesies.
Terbinafien meng op 'n vroeë stadium spesifiek in met die biosintese van swamsterol. Dit lei tot 'n tekort in ergosterol en 'n intrasellulêre akkumulasie van skwaleen, wat uiteindelik tot dood van die sel lei. Terbinafien werk deur inhibisie van skwaleenepoksidase in die selmembraan van die swam.
Die ensiem skwaleenepoksidase word nie aan die sitochroom P450 sisteem gekoppel nie. Wanneer oraal toegedien word, konsentreer die middel in die vel teen konsentrasies wat met swamdodende aktiwiteit geassosieer word.

Farmakokinetika:
'n Enkel orale dosis van 250 mg terbinafien lei binne twee ure na toediening tot 'n gemiddelde piek plasmakonsentrasie van 0,97 µg/ml. Die absorpsie-halfleeftyd is 0,8 ure en die verspreidingshalfleeftyd is 4,6 ure. Terbinafien bind sterk aan plasmaproteïene. Dit versprei vinnig deur die dermis en konsentreer in die lipofilliese stratum corneum.
Terbinafien word ook in sebum uitgeskei en bereik daarom hoë konsentrasies in die haarfollikels en haar- en sebumryke gedeeltes van die vel. Daar bestaan geen bewys dat terbinafien binne die eerste paar weke na aanvangs van terapie in die naelplaat versprei nie. Biotransformasie lei tot metaboliete met geen swamwerende aktiwiteit nie, wat hoofsaaklik in die urien uitgeskei word. Die eliminasiehalfleeftyd is 17 ure. Daar bestaan geen bewys van akkumulasie nie.
Geen ouderdomsverwante veranderinge is waargeneem nie. Die eliminasiekoers mag egter laer in pasiënte met ingekorte nier- en lewerfunksie wees, wat tot hoër terbinafienbloedvlakke lei. Die biobeskikbaarheid van terbinafien word nie deur voedsel geaffekteer nie.

INDIKASIES:
Swaminfeksies van die vel wat deur Trichophyton (bv. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis* en *Epidermophyton floccosum* veroorsaak word.
BINACIL word aangedui in die behandeling van:
- Omloop (*tinea corporis, tinea cruris* en *tinea pedis*) waar orale terapie weens die plek, graad van erns of die mate van infeksie toepaslik is.
- Onigomikose.

KONTRA-INDIKASIES:
- Hipersensitiwiteit teen terbinafienhidrochloried of enige van die eksipiënte.
- Ingekorte lewerfunksie.
- Swangerskap en laktasie.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
- **BINACIL** behoort nie in pasiënte met reeds bestaande lewersiekte gebruik te word nie en lewerfunksietoetse behoort in alle pasiënte voor die aanvangs van terapie uitgevoer te word. As kliniese of biochemiese tekens van hepatotoksisiteit ontwikkel, behoort die gebruik van **BINACIL** gestaak te word.
- **BINACIL** moet ook gestaak word indien 'n progressiewe veluitslag verskyn.
- **BINACIL** behoort met sorg en in kleiner dosisse in pasiënte met ingekorte nierfunksie gebruik te word (sien "**DOSIS EN GEBRUIKSAANWYSINGS**")
- **BINACIL** kan psoriase ontlok of vererger. **BINACIL** behoort met sorg in pasiënte met psoriase gebruik te word, aangesien selde voorkomende gevalle van verergering van psoriase aangemeld is.

Gevalle van cholestase en hepatitis is aangemeld. Dit kom gewoonlik binne twee maande na aanvangs van behandeling voor.

As 'n pasiënt presenteer met tekens en simptome wat op lewerdisfunksie dui, soos pruritus, onverklaarde aanhoudende diaree, anoreksie, moegheid, geelsug, braking, buikpyn, donker urien en ligkleurige stoelgang, behoort hepatiese oorsprong bevestig te word en behoort die gebruik van **BINACIL** gestaak te word. Enkeldosis farmakokinetiese studies in pasiënte met reeds bestaande lewersiekte het aangetoon dat die opruiming van **BINACIL** met ongeveer 50 % kan verminder. Die terapeutiese gebruik van **BINACIL** in pasiënte met chroniese of aktiewe lewersiekte is nie in vooruitskouende proewe bestudeer nie en derhalwe kan die gebruik daarvan nie aanbeveel word nie.

Effek op die vermoë om te bestuur en met masjinerie te werk
Daar is geen data beskikbaar ten opsigte van die vermoë om 'n motor te bestuur of om met masjinerie te werk nie. Sorg word egter aanbeveel wanneer **BINACIL** gebruik word, sodat die effek op die pasiënt vasgestel kan word, veral aangesien duiseligheid en moegheid ondervind kan word.

INTERAKSIES:
Die plasma-opruiming van **BINACIL** kan deur medisyne wat die metabolisme induseer (soos rifampisien) versnel word, en kan deur medisyne wat sitochroom P450 inhibeer (soos simetidien), vertraag word. Wanneer die medetoediening van sulke medisyne nodig is, mag dit nodig wees om die dosis van **BINACIL** dienooreenkomstig aan te pas.
Daar is aangemeld dat **BINACIL** die CYP2D6-gemedieerde metabolisme inhibeer. Hierdie *in vitro* bevinding kan van kliniese belang wees in pasiënte wat medisyne ontvang wat hoofsaaklikdeur hierdie ensiem gemetaboliseer word, soos trisikliese antidepressante (TSAe), β-blokkeerders, selektiewe serotonienheropnameïnhibeerders (SSHI's) en monoamien-oksidase inhibeerders (MOAI's) Tipe B. Ander *in vitro* studies asook studies in gesonde vrywilligers wil daarop dui dat **BINACIL** 'n minimale potensiaal toon om die opruiming van medisyne wat deur ander sitochroom P450 ensieme gemetaboliseer word, te inhibeer of te induseer (bv. siklosporien, triasolam, orale voorbehoedmiddels). Sommige gevalle van menstruele afwykings (deurbraakbloeding en ongereelde siklusse) is in pasiënte aangemeld wat **BINACIL** saam met orale voorbehoedmiddels gebruik.

SWANGERSKAP EN LAKTASIE:
Die gebruik van **BINACIL** gedurende swangerskap word teenaangedui. Terbinafien word in borsmelk uitgeskei en daarom behoort moeders wat behandeling met **BINACIL** ontvang, nie hul babas te borsvoed nie (sien "**KONTRA-INDIKASIES**").

DOSIS EN GEBRUIKSAANWYSINGS:
Die duurte van behandeling wissel afhangende van die indikasie en die graad van erns van die infeksie.
250 mg een keer per dag.

Velinfeksies:
Waarskynlike duurtes van behandeling is as volg:
Tinea pedis (interdigitaal, plantaar-/mokkasintipe): 2 tot 6 weke.
Tinea corporis: 4 weke.
Tinea cruris: 2 tot 4 weke.
Onigomikose:
Die duurte van behandeling vir die meeste pasiënte is tussen 6 weke en 3 maande. Behandelingsperiodes van minder as 3 maande kan in pasiënte met vingernaelinfeksie, toonnaelinfeksie (behalwe die groottoon), of in jonger pasiënte verwag word. In die behandeling van toonnaelinfeksies is 3 maande gewoonlik voldoende, alhoewel sommige pasiënte behandeling van 6 maande of langer vereis. Swak uitgroei van die nael gedurende die eerste weke van behandeling kan pasiënte uitwys wat langer terapie sal vereis. Volledige verdwyning van die tekens en simptome van infeksie mag eers verskeie weke na mikologiese genesing voorkom.
Kinders:
Aangesien data nog beperk is, kan die gebruik nie aanbeveel word nie.
Bejaardes:
Daar bestaan geen bewys wat daarop dui dat bejaarde pasiënte verskillende dosisse benodig of newe effekte teenoor dié van jonger pasiënte ondervind nie. Die moontlikheid van ingekorte lewer- of nierfunksie behoort in hierdie ouderdomsgroep oorweeg te word.
Ingekorte nierfunksie:
Pasiënte met ingekorte nierfunksie (kreatinienopruiming < 50 ml/min of serumkreatinien > 300 mmol/l), behoort die helfte van die normale dosis te ontvang.

NEWE EFFEKTE:
Afwykings van die bloed- en limfsisteem:
Dikwels: Neutropenie, trombositopenie en agranulositose.

Afwykings van die immuunstelsel:
Dikwels: Angioëdeem.

Psigiatriese afwykings:
Dikwels: Psigiatriese afwykings soos depressie en angs.

Afwykings van die senuweestelsel:
Baie dikwels: Hoofpyn.
Dikwels: Parestesie, hipoëstesie, duiseligheid en vertigo.

Gastroïntestinale afwykings:
Baie dikwels: Verlies aan eetlus, naarheid, geringe buikpyn, diaree.
Dikwels: Smaakverlies en smaakafwyking is in ongeveer 0,6 % van pasiënte wat met **BINACIL** behandel is, aangemeld. Dit verdwyn gewoonlik stadig met onttrekking van die medisyne.
Die volgende newe effekte is aangemeld en die frekwensie is onbekend: Dispepsie en volheid.

Hepatobileêre afwykings:
Dikwels: Geelsug, cholestase en hepatitis. As disfunksie van die lewer ontwikkel, behoort die behandeling met **BINACIL** gestaak te word (sien **"WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS"**).

Afwykings van die vel en subkutane weefsel:
Dikwels: Stevens-Johnson se sindroom, toksiese epidermale nekrolise, uitslag, urtikarie, fotosensitiwiteit en psoriase. As progressiewe veluitslag voorkom, behoort die behandeling met **BINACIL** gestaak te word.

Muskuloskeletale, bindweefsel- en beenafwykings:
Die volgende newe effekte is aangemeld en die frekwensie is onbekend: Artralgie en mialgie. Dit kan voorkom as 'n hipersensitiwiteitsreaksie wat met allergiese velreaksies geassosieer word.

Algemene afwykings en kondisies by die plek van toediening:
Dikwels: Algemene gevoel van ongesteldheid en moegheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
'n Paar gevalle van oordosering (tot soveel as 5 g) is aangemeld en veroorsaak hoofpyn, naarheid, epigastriese pyn en duiseligheid. Die aanbevole behandeling van oordosering bestaan uit eliminasie van die middel, hoofsaaklik deur die toediening van geaktiveerde houtskool en die toediening van simptomaties ondersteunende terapie, indien nodig.

IDENTIFIKASIE:
BINACIL 125 mg: Wit tot byna-wit, ronde, onbedekte, bikonvekse tablette met skuins kante, met 'D' op die een kant en '56' op die ander kant gedruk.
BINACIL 250 mg: Wit tot byna-wit, ronde, onbedekte, bikonvekse tablette met skuins kante en 'n breeklyn, met 'D' op die een kant en '74' op die ander kant gedruk.

AANBIEDING:
BINACIL 125 mg:
Tablette word in helder 250 µm PVC stolpstrokies, bedek met 60 g/m^2 PVdc en 25 µm gedrukte aluminiumfoelie verpak. Een stolpstrokie bevat 14 tablette.
Pakgrootte: 14s – Elke karton bevat een strokie met 14 tablette elk.

BINACIL 250 mg:
Tablette word in helder 250 µm PVC stolpstrokies, bedek met 60 g/m^2 PVdc en 25 µm gedrukte aluminiumfoelie verpak. Een stolpstrokie bevat 14 tablette.
Pakgrootte: 14s – Elke karton bevat een strokie met 14 tablette elk.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 30 °C.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
SUID-AFRIKA:
BINACIL 125 mg: 42/20.2.2/0471
BINACIL 250 mg: 42/20.2.2/0472

NAMIBIË:
BINACIL 125 mg: 10/20.2.2/0261
BINACIL 250 mg: 10/20.2.2/0262

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer,
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448, Johannesburg
Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie:
1 Oktober 2015
Datum van hersiening:
17 Januarie 2022

DETACH BEFORE DISPENSING

SOUTH AFRICA: S4

NAMIBIA: NS2

BINACIL 125 mg (tablet)
BINACIL 250 mg (tablet)
Terbinafien

Lees die hele brosjure sorgvuldig voordat u begin om BINACIL te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **BINACIL** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT BINACIL BEVAT
Die aktiewe bestanddeel is terbinafien.
BINACIL 125 mg: Elke tablet bevat terbinafienhidrochloried ekwivalent aan terbinafien 125 mg. Suikervry.
BINACIL 250 mg: Elke tablet bevat terbinafienhidrochloried ekwivalent aan terbinafien 250 mg. Suikervry.
Die ander bestanddele is mikrokristallyne sellulose (Avicel PH-101), hipromellose, magnesiumstearaat, anhidriese kolloïdale silika en natriumstyselglikolaat.

2. WAAROOR BINACIL GEBRUIK WORD
BINACIL kan gebruik word om:
- Swaminfeksies van die vel en nael, soos atleetsvoet, omloop in die lies of omloop op die liggaam te behandel.

3. VOORDAT U BINACIL NEEM
Moenie BINACIL neem nie:
- As u al ooit in die verlede 'n allergiese reaksie teen terbinafien of enige van die ander bestanddele van **BINACIL** gehad het.
- As u ooit in die verlede aan lewerprobleme gely het.
- As u swanger is of borsvoed.

Neem spesiale sorg met BINACIL:
- Stel u dokter onmiddellik in kennis as u enige van die volgende simptome van lewerbeskadiging ontwikkel wat gewoonlik binne twee maande na die begin van behandeling met **BINACIL** voorkom: jeuk, voortdurende en aanhoudende naarheid, verlies aan eetlus, moegheid, geel verkleuring van die wit gedeelte van die oë en vel, braking, maag-/buikpyn, donker urien of ligkleurige stoelgang.
- Voordat u begin om **BINACIL** te gebruik, moet u u dokter in kennis stel:
  - As u aan psoriase ly – **BINACIL** kan agteruitgang van die simptome van psoriase veroorsaak.
  - As u aan nierprobleme ly (sien "**HOE OM BINACIL TE NEEM**).

Die neem van BINACIL met voedsel:
BINACIL kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:
- Moenie **BINACIL** gebruik nie as u swanger is – Stel u dokter in kennis as u swanger is of beplan om swanger te raak.
- Moenie **BINACIL** gebruik nie as u borsvoed aangesien **BINACIL** na die borsmelk verspreï.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies nader voordat u **BINACIL** neem.

Bestuur en die gebruik van masjinerie:
BINACIL kan duiseligheid of moegheid veroorsaak. Maak seker dat u nie geaffekteer word nie voordat u 'n motor bestuur of met masjinerie werk.

Die neem van ander medisyne saam met BINACIL:
Sommige medisyne kan met die werking van terbinafien inmeng. Voordat u begin om **BINACIL** te gebruik, moet u u dokter in kennis stel as u enige van die volgende medisyne gebruik:
- Rifampisien vir tuberkulose, aangesien dit die effektiwiteit van terbinafien kan verminder.
- Simetidien vir indigestie of maagulkusse, aangesien dit die risiko vir newe effekte kan verhoog as dit saam met terbinafien geneem word.
- Trisikliese antidepressante (bv. amitriptilien), β-blokkeerders (bv. atenolol, metoprolol of propranolol), selektiewe serotonien-heropnameïnhibeerders (SSHIs) (bv. fluoksetien) en monoamien-oksidase inhibeerders (MOAI's) Tipe B (bv. selegeliën), aangesien die risiko van hul newe-effekte deur terbinafien vererger kan word.
- Orale voorbehoedmiddels, aangesien ongereelde siklusse en deurbraakbloeding kan voorkom.
- Siklosporien.
- Triasolam.

As u enige van hierdie medisyne gebruik, mag dit moontlik wees dat u nie **BINACIL** kan gebruik nie of die dosis moet aangepas word, of u dokter moet u noukeurig vir newe effekte monitor.

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).

4. HOE OM BINACIL TE NEEM
- Die normale volwasse (insluitende bejaarde) dosis is 250 mg een keer per dag.
- Die duurte van behandeling sal van die graad van erns van die infeksie afhang. U dokter sal u inlig oor die duurte van behandeling.

Neem **BINACIL** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **BINACIL** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

Die normale duurtes van behandeling is as volg:
- Vir velinfeksies word **BINACIL** vir gewoonlik 2 tot 6 weke geneem.
- Vir naelinfeksies duur behandeling gewoonlik vir tussen 6 weke en 3 maande, alhoewel sommige pasiënte met toonnaelinfeksies vir 6 maande of langer behandeling benodig. Tekens van die infeksie mag eers verskeie weke na voltooiing van die kursus verdwyn.

- Om die infeksie behoorlik te laat opklaar, moet u **BINACIL** vir die volle kursus van die behandeling gebruik.
- Kinders – Die gebruik van **BINACIL** in kinders word nie aanbeveel nie.
- Pasiënte met nierprobleme – u dokter mag moontlik 'n laer dosis voorskryf.

As u te veel BINACIL geneem het:
- As 'n oordosis geneem is, kan simptome soos hoofpyn, naarheid, pyn in die boonste en middelste deel van die buik en duiseligheid voorkom.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftbeheersentrum.

As u vergeet het om BINACIL te neem:
Neem die oorgeslaande dosis so gou as u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, slaan die dosis oor en gaan terug na die normale dosisskedule. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE
BINACIL kan newe effekte hê.
Kry onmiddellik nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie ontwikkel:
- Velbulte, veluitslag.
- Moeite met asemhaling.
- Swelling van die gesig, lippe, tong of keel.

Raadpleeg onmiddellik u dokter as u enige van hierdie ernstige newe effekte ondervind:
- Erge blaasvorming, afskilfering en rooi veluitslag.
- Erge veluitslag wat steeds erger word.
- Ongewone kneusing of bloeding.
- Koors, koukoors, seer keel en ander tekens van infeksie.
- Simptome van lewerprobleme (bv. jeuk aanhoudende naarheid, verlies aan eetlus, moegheid, geel verkleuring van die wit gedeelte van die oë of vel, maag-/buikpyn, donker urien of liggekleurde stoelgang).

Ander moontlike newe effekte is naarheid, geringe buikpyn of volheid, diaree, smaakverlies of –veranderinge (wat gewoonlik met staking van die middel verdwyn), indigestie, hoofpyn, depressie, angs, gevoelloosheid, prikkeling of spelde en naalde, algemene gevoel van ongesteldheid, moegheid of duiseligheid, ligsensitiwiteit, psoriase (velsiekte met verhewe, growwe, skilferagtige gedeeltes), spier- en gewrigspyn, wat kan voorkom as deel van 'n allergiese reaksie saam met allergiese velreaksies (uitslag, swelling).

Stel u dokter in kennis as enige van hierdie newe effekte erg is, u kwel of nie verdwyn nie, of as u enige ander probleme het terwyl u **BINACIL** neem

Nie al die newe effekte wat vir **BINACIL** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan terwyl u hierdie medisyne neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN BINACIL
Bewaar by of benede 30 °C (kamertemperatuur).

Bewaar alle medisyne buite bereik van kinders.

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN BINACIL
BINACIL 125 mg:
Tablette word in helder 250 µm PVC stolpstrokies, bedek met 60 g/m^2 PVdc en 25 µm gedrukte aluminiumfoelie verpak. Een stolpstrokie bevat 14 tablette.
Pakgrootte: 14s – Elke karton bevat een strokie met 14 tablette elk.

BINACIL 250 mg:
Tablette word in helder 250 µm PVC stolpstrokies, bedek met 60 g/m^2 PVdc en 25 µm gedrukte aluminiumfoelie verpak. Een stolpstrokie bevat 14 tablette.
Pakgrootte: 14s – Elke karton bevat een strokie met 14 tablette elk.

8. IDENTIFIKASIE VAN BINACIL
BINACIL 125 mg:
Wit tot byna-wit, ronde, onbedekte, bikonvekse tablette met skuins kante, met 'D' op die een kant en '56' op die ander kant gedruk.
BINACIL 250 mg:
Wit tot byna-wit, ronde, onbedekte, bikonvekse tablette met skuins kante en 'n breeklyn, met 'D' op die een kant en '74' op die ander kant gedruk.

9. REGISTRASIENOMMERS/VERWYSINGSNOMMERS

SUID-AFRIKA:
BINACIL 125 mg: 42/20.2.2/0471
BINACIL 250 mg: 42/20.2.2/0472

NAMIBIË:
BINACIL 125 mg: 10/20.2.2/0261
BINACIL 250 mg: 10/20.2.2/0262

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448, Johannesburg
Suid Afrika

11. DATUM VAN PUBLIKASIE
Datum van registrasie:
1 Oktober 2015
Datum van hersiening:
17 Januarie 2022

A/s : 280 x 460 mm ■ Black Booklet Size: 40 x 60 mm

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		Binacil Leaflet	Leaflet	P1530659	19.03.2022 & 10.30 am
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		South Africa_U3	00	Commercial	
Team Leader	Kiran	Dimensions (mm)	Colours: 01		
Initiator	Bhogi	A/s: 280 x 460 mm			
Artist	Sree Designers	Pharma Code: 30659			
Additional Information: Supersede: P1518685			30659		

SCHEDULING STATUS

SOUTH AFRICA: S4

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
BINACIL 125 mg (tablet)
BINACIL 250 mg (tablet)

COMPOSITION:
BINACIL 125 mg: Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 125 mg. Sugar free.
BINACIL 250 mg: Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 250 mg. Sugar free.
The other ingredients of the formulation include cellulose microcrystalline (Avicel PH-101), sodium starch glycolate, colloidal anhydrous silica, hypromellose, and magnesium stearate.

PHARMACOLOGICAL CLASSIFICATION:
A20.2.2. Antimicrobial (chemotherapeutic) agents. Fungicides.

PHARMACOLOGICAL ACTION:
Pharmacodynamics:
Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain fungi. The activity is fungicidal or fungistatic depending on the species.
Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane.
The enzyme squalene epoxidase is not linked to the cytochrome P450 system. When given orally, the medicine concentrates in skin at levels associated with fungicidal activity.

Pharmacokinetics:
A single oral dose of 250 mg terbinafine results in mean peak plasma concentrations of 0,97 µg/ml within 2 hours after administration. The absorption half-life is 0,8 hours and the distribution half-life is 4,6 hours. Terbinafine binds strongly to plasma proteins. It rapidly diffuses through the dermis and concentrates in the lipophilic stratum corneum.
Terbinafine is also secreted in sebum, thus achieving high concentrations in hair follicles, hair and sebum rich skins. There is also evidence that terbinafine is distributed into the nail plate within the first few weeks of commencing therapy. Biotransformation results in metabolites with no antifungal activity, which are excreted predominantly in the urine. The elimination half-life is 17 hours. There is no evidence of accumulation.
No age-dependent changes in pharmacokinetics have been observed but the elimination rate may be reduced in patients with renal or hepatic impairment, resulting in higher blood levels of terbinafine.
The bioavailability of terbinafine is unaffected by food.

INDICATIONS:
Fungal infections of the skin caused by Trichophyton (e.g. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis* and *Epidermophyton floccosum*.
BINACIL is indicated in the treatment of:
- ringworm *(tinea corporis, tinea cruris* and *tinea pedis)* where oral therapy is considered appropriate due to the site, severity or extent of the infection.
- onychomycosis.

CONTRA-INDICATIONS:
- Hypersensitivity to terbinafine hydrochloride or any of the excipients.
- Impaired liver function.
- Pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS:
- **BINACIL** should not be used in patients with existing liver disease and liver function tests should be performed in all patients before starting therapy. If clinical or biochemical indications of hepatotoxicity appear, **BINACIL** should be discontinued.
- **BINACIL** should also be discontinued if a progressive skin rash appears.
- **BINACIL** should be used with caution and in reduced doses in patients with renal impairment (see **"DOSAGE AND DIRECTIONS FOR USE"**).
- **BINACIL** may provoke or exacerbate psoriasis. **BINACIL** should be used with caution in patients with psoriasis, as very rare cases of exacerbation of psoriasis have been reported.

Cases of cholestasis and hepatitis have been reported, these usually occur within two months of starting treatment.

If a patient presents with signs or symptoms suggestive of liver dysfunction such as pruritus, unexplained persistent nausea, anorexia, tiredness, jaundice, vomiting, fatigue, abdominal pain, dark urine, or pale stools, hepatic origin should be verified and **BINACIL** should be discontinued. Single dose pharmacokinetic studies in patients with pre-existing liver disease have shown that the clearance of **BINACIL** may be reduced by about 50 %. The therapeutic use of **BINACIL** in patients with chronic or active liver disease has not been studied in prospective clinical trials, and therefore cannot be recommended.

Effects on ability to drive and use machines
There is no data regarding the ability to drive vehicles and use machinery. However, patients should be advised to exercise caution when using **BINACIL** until the effect is established, especially since dizziness and fatigue may be experienced.

INTERACTIONS:
The plasma clearance of **BINACIL** may be accelerated by medicines which induce metabolism (such as rifampicin) and may be inhibited by medicines which inhibit cytochrome P450 (such as cimetidine). Where co-administration of such medicines is necessary, the dosage of **BINACIL** may need to be adjusted accordingly.
It has been reported that **BINACIL** inhibits the CYP2D6-mediated metabolism. This *in vitro* finding may be of clinical relevance for patients receiving medicines predominantly metabolised by this enzyme, such as tricyclic antidepressants (TCA's), β-blockers, selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOI's) Type B. Other studies undertaken *in vitro* and in healthy volunteers suggest that **BINACIL** shows negligible potential to inhibit or induce the clearance of medicines that are metabolised via other cytochrome P450 enzymes (e.g. ciclosporin, triazolam, oral contraceptives). However, some cases of menstrual disturbance (breakthrough bleeding and irregular cycles) have been reported in patients taking **BINACIL** concomitantly with oral contraceptives.

PREGNANCY AND LACTATION:
BINACIL is contra-indicated in pregnancy. Terbinafine is excreted in breast milk and therefore mothers who receive treatment with **BINACIL** should not breastfeed their infants (see **"CONTRA-INDICATIONS"**).

DOSAGE AND DIRECTIONS FOR USE:
The duration of treatment varies according to the indication and the severity of the infection.
250 mg once daily.
Skin infections:
Likely durations of treatment are as follows:
Tinea pedis (interdigital, plantar/moccasin type): 2 to 6 weeks
Tinea corporis: 4 weeks
Tinea cruris: 2 to 4 weeks
Onychomycosis:
The duration of treatment for most patients is between 6 weeks and 3 months. Treatment periods of less than 3 months can be anticipated in patients with fingernail infection, toenail infection other than of the big toe, or patients of younger age. In the treatment of toenail infections, 3 months is usually sufficient although a few patients may require treatment of 6 months or longer. Poor nail outgrowth during the first weeks of treatment may enable identification of those patients in whom longer therapy is required.
Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure.
Children:
As data is still limited, its use is not recommended.
Elderly:
There is no evidence to suggest that elderly patients require different dosages or experience side effects different to those of younger patients. The possibility of impairment of liver or kidney function should be considered in this age group.
Impaired renal function:
Patients with impaired renal function (creatinine clearance less than 50 ml/minute or serum creatinine of more than 300 mmol/l) should receive half the normal dose.

SIDE EFFECTS:
Blood and the lymphatic system disorders:
Less frequent: Neutropenia, thrombocytopenia and agranulocytosis.

Immune system disorders:
Less frequent: Angioedema.

Psychiatric disorders:
Less frequent: Psychiatric disturbances such as depression and anxiety.

Nervous system disorders:
Frequent: Headache.
Less frequent: Paraesthesia, hypoaesthesia, dizziness and vertigo.

Gastrointestinal disorders:
Frequent: Loss of appetite, nausea, mild abdominal pain, diarrhoea.
Less frequent: Taste loss and taste disturbance have been reported in approximately 0,6 % of patients treated with **BINACIL.** This usually resolves slowly on medicine discontinuation.
The following side effects have been reported but the frequencies are unknown: Dyspepsia and fullness.

Hepato-biliary disorders:
Less frequent: Jaundice, cholestasis and hepatitis. If hepatic dysfunction develops, treatment with **BINACIL** should be discontinued (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

Skin and subcutaneous tissue disorders:
Less frequent: Stevens-Johnson syndrome, toxic epidermal necrolysis, rash, urticaria, photosensitivity and psoriasis. If progressive skin rash occurs, treatment with **BINACIL** should be discontinued.

Musculoskeletal, connective tissue and bone disorders:
The following side effects have been reported but the frequencies are unknown: Arthralgia and myalgia. These may occur as part of a hypersensitivity reaction in association with allergic skin reactions.

General disorders and administrative site conditions:
Less frequent: Malaise and fatigue.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
A few cases of overdose (up to 5 g) have been reported, giving rise to headache, nausea, epigastric pain and dizziness. The recommended treatment of overdosage consists of eliminating the drug, primarily by the administration of activated charcoal, and giving symptomatic supportive therapy if needed.

IDENTIFICATION:
BINACIL 125 mg: White to off-white, round uncoated, biconvex bevelled edge tablets having 'D' debossed on one side and '56' on the other side.
BINACIL 250 mg: White to off-white, round uncoated, biconvex bevelled edge tablets with break line and 'D' debossed on one side and '74' on the other side.

PRESENTATION:
BINACIL 125 mg:
Tablets are packed in clear 250 µm PVC coated with 60 g/m^2 PVdc and 25 µm printed aluminium foil. One blister contains 14 tablets.
Pack size: 14's - Each carton contains 1 blister of 14 tablets each.

BINACIL 250 mg:
Tablets are packed in clear 250 µm PVC coated with 60 g/m^2 PVdc and 25 µm printed aluminium foil. One blister contains 14 tablets.
Pack size: 14's - Each carton contains 1 blister of 14 tablets each.

STORAGE CONDITIONS:
Store at or below 30 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
BINACIL 125 mg: 42/20.2.2/0471
BINACIL 250 mg: 42/20.2.2/0472

NAMIBIA:
BINACIL 125 mg: 10/20.2.2/0261
BINACIL 250 mg: 10/20.2.2/0262

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, 1448,
Johannesburg,
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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1 October 2015
Date of revision:
17 January 2022

P1530659

DETACH BEFORE DISPENSING

SOUTH AFRICA: S4

NAMIBIA: NS2

BINACIL125 mg (tablet)
BINACIL 250 mg (tablet)
Terbinafine

Read all of this leaflet carefully before you start taking BINACIL.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BINACIL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT BINACIL CONTAINS
The active substance is terbinafine.
BINACIL 125 mg: Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 125 mg. Sugar free.
BINACIL 250 mg: Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 250 mg. Sugar free.
The other ingredients are cellulose microcrystalline (Avicel PH-101), hypromellose, magnesium stearate, silica colloidal anhydrous and sodium starch glycolate.

2. WHAT BINACIL IS USED FOR
BINACIL may be used to treat:
- Fungal infections of the skin and nail such as athlete's foot, ringworm of the groin (jock itch) or ringworm of the body.

3. BEFORE YOU TAKE BINACIL
Do not take BINACIL:
- If you have ever had an allergic reaction to terbinafine or any of the other ingredients found in **BINACIL**.
- If you have liver problems.
- If you are pregnant or breastfeeding.

Take special care with BINACIL:
- Check with your doctor at once if you develop any of the following symptoms of liver damage which usually occur within two months of starting treatment with **BINACIL**: itching, a feeling of sickness that won't go away (persistent nausea), loss of appetite, tiredness, yellowing of the whites of the eyes or skin, being sick (vomiting), fatigue, stomach/abdominal pain, dark urine or pale coloured stools.
- Before using **BINACIL**, tell your doctor:
  - if you have psoriasis – **BINACIL** may cause a worsening of psoriasis symptoms.
  - if you have kidney problems (see **"HOW TO TAKE BINACIL"**).

Taking BINACIL with food:
BINACIL may be taken with or without food.

Pregnancy and Breastfeeding:
- Do not take **BINACIL** if you are pregnant - Tell your doctor if you are pregnant or plan to become pregnant.
- Do not take **BINACIL** if you are breastfeeding, since **BINACIL** passes into breast milk.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking **BINACIL**.

Driving and using machinery:
BINACIL may make you feel dizzy or fatigued. Make sure you are not affected before you drive or operate machinery.

Taking other medicines with BINACIL:
Some medicines may interact with terbinafine. Before taking **BINACIL**, tell your doctor if you are using any of the following medicines:
- Rifampicin for tuberculosis because it may decrease the effectiveness of terbinafine.
- Cimetidine for indigestion or stomach ulcers, because it may increase the risk of side effects when taken with terbinafine.
- Tricyclic antidepressants (e.g. amitriptyline), β-blockers (e.g. atenolol, metoprolol or propranolol), selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine) and monoamine oxidase inhibitors (MAOI's) Type B (e.g. selegeline), because the risk of their side effects may be increased by terbinafine.
- Oral contraceptives – as irregular periods and breakthrough bleeding may occur.
- Ciclosporin
- Triazolam

If you are using any of these medicines, you may not be able to take **BINACIL**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE BINACIL
- The usual adult (including elderly) oral dose is 250 mg once a day.
- The length of your course of treatment will depend on the nature and severity of infection. Your doctor will tell you how long to take your medicine for.

Always take **BINACIL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BINACIL** is too strong or too weak, talk to your doctor or pharmacist.

Usual course lengths are as follows:
- For skin infections **BINACIL** is usually taken for between 2 to 6 weeks.
- For nail infections, treatment usually lasts between 6 weeks and 3 months, although some patients with toenail infections may need to be treated for 6 months or longer.
  Signs of the infection may not disappear until several weeks after completing the course of treatment.
- To clear up your infection completely, take **BINACIL** for the full course of treatment.
- Children – The use of **BINACIL** in children is not recommended.
- Patients with kidney problems – Your doctor may prescribe a lower dose.

If you take more BINACIL than you should:
- If an overdose has been taken, there may be symptoms such as headache, feeling sick (nausea), pain in upper, middle region of stomach and dizziness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take BINACIL:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS
BINACIL can have side effects.
Get emergency medical help at once if you have any of these signs of an allergic reaction:
- hives, skin rash
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:
- Severe blistering, peeling and red skin rash
- Severe skin rash that keeps getting worse
- Unusual bruising or bleeding
- Fever, chills, sore throat, and other signs of infection
- Symptoms of liver problems (e.g. itching, a feeling of sickness that won't go away (persistent nausea), loss of appetite, tiredness, yellowing of the whites of the eyes or skin, being sick (vomiting), fatigue, stomach/abdominal pain, dark urine or pale coloured stools).

Other possible side effects are: nausea (queasiness); mild abdominal pain or fullness; diarrhoea; loss of taste or changes in taste (which usually resolves on discontinuation of the medicine); indigestion; headache; depression; anxiety; numbness, tingling or pins and needles; feeling unwell, tired or dizzy; oversensitivity to light; psoriasis (skin disease with raised, rough, scaly areas); pains in the muscles and joints, which may occur as part of an allergic reaction along with allergic skin reactions (rash, swelling).
Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **BINACIL**.

Not all side effects reported for **BINACIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF BINACIL
Store at or below 30 °C (room temperature).

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BINACIL
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9. REGISTRATION NUMBERS/REFERENCE NUMBERS
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BINACIL 125 mg: 42/20.2.2/0471
BINACIL 250 mg: 42/20.2.2/0472

NAMIBIA:
BINACIL 125 mg: 10/20.2.2/0261
BINACIL 250 mg: 10/20.2.2/0262

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, 1448,
Johannesburg,
South Africa

11. DATE OF PUBLICATION
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Date of revision:
17 January 2022