

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI  
TEXA ALLERGY SYRUP**

**ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI:**

**S1**

**IGAMAKUHWABA LOMKHIQIZO KANYE NESIMO SOMTHAMOSILINGANISO**

Isiraphu i**TEXA ALLERGY SYRUP**

**Funda lonke leli pheshana ngokucophelela ngoba liqukethe ulwazi olubalulekile kuwena.**

**ITEXA ALLERGY SYRUP** iyatholakala ngaphandle kwencwadi kadokotela, uma ufuna ukwelapha ukugula okuncane, okusho, ukugula okungekhona lokho okunamandla kakhulu noma okubucayi. Kepha-ke noma kunjalo, kumele uyisebenzise ngokucophelela i**TEXA ALLERGY SYRUP** ukuze usizakale ngokuphelele kuyona.

- Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.
- Ungabelani nanoma yimuphi omunye umuntu nge**TEXA ALLERGY SYRUP**.
- Buza usokhemisi wakho uma udinga ulwazi oluthe xaxa noma iseluleko.
- Kumele ubonane nodokotela uma ziba zimbi kakhulu izimpawu ezikuphethe noma uma ungabi ngcono emuva kwezinsuku eziyisikhombisa.

**1. OKUQUKETHWE YITEXA ALLERGY SYRUP**

Isithako sokwelapha esiyinhloko esiqukethwe yilo muthi yicetirizine dihydrochloride.

Imililitha (ml) elilodwa le**TEXA ALLERGY SYRUP** liqukethe icetirizine dihydrochloride engu-1 mg.

Ezinye izithako yi-acetic acid, banana flavour (ukunambitheka okusabhanana), glycerol, methyl parahydroxybenzoate, propylene glycol, propyl hydroxybenzoate, purified water (amanzi ahlanzisiwe), saccharin sodium, sodium acetate kanye nesorbitol 70%.

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### TEXA ALLERGY SYRUP

**ITEXA ALLERGY SYRUP** iqukethe izilondolozisi (preservatives) imethyl parahydroxybenzoate kanye nepropyl hydroxybenzoate. **ITEXA ALLERGY SYRUP** iqukethe futhi nezinandisi ezisashukela (okuyiglycerol 200 mg/ml, saccharin sodium 1 mg/ml kanye noketshezi lwesorbitol 70 % olungama-450 mg/ml) (bheka isigatshana esithi **Ulwazi olubalulekile mayelana nezinye zezithako zeTEXA ALLERGY SYRUP**).

### 2. ITEXA ALLERGY SYRUP ISETSHENZISELWA LOKHU

**ITEXA ALLERGY SYRUP** iyingxenye yeqoqwana lemithi ebizwa ngamalong-acting non-sedating antihistamines, okusho imithi yokwelapha ama-aleji esebenza isikhathi eside emzimbeni futhi engenzi ukuthi umuntu ozele noma afikelwe ubuthongo.

**ITEXA ALLERGY SYRUP** isetshenziselwa ukwelapha ukugula okuphathelene nama-aleji (ukungezwani komzimba nento ethile edala inkinga emzimbeni) okusho ukugula okunjenge:

- allergic rhinitis (okusho ukugula okuhlobene nokucinana emakhaleni noma amafinyila, ukuthimula okubangelwa ngama-aleji) kanye nemfiva ethimulisayo, phecelezi ihay fever
- izifo zesikhumba ezibangelwa ukungezwani komzimba nento ethile ezinjengesifo i-urticaria (ukuqubuka kwesikhumba okuyindilinga, okungamaqhutshana abomvu aluma kakhulu, futhi kwesinye isikhathi okuhambisana nokuvuvukala okunobungozi, okubangelwa ukungezwani komzimba nokuthile).

### 3. NGAPHAMBI KOKUBA UTHATHE ITEXA ALLERGY SYRUP

**Ungalokothi uthathe iTEXA ALLERGY SYRUP:**

- uma umzimba wakho ungewzwani nezithako icetirizine, hydroxyzine, piperazine noma ezinye izithako eziyingxenye yeqoqwana lemithi yokwelapha ama-aleji ezibizwa ngama-antihistamine noma uma ungewzwani nanoma yisiphi esinye isithako se**TEXA ALLERGY SYRUP** (bheka isigatshana esithi **OKUQUKETHWE YITEXA ALLERGY SYRUP**)

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- uma uxinwe kakhulu yisifo sezinsu esibucayi
- uma ukhulelwe noma uncelisa umntwana wakho (bheka isigatshana esithi **Ukukhulelwa kanye nokuncelisa**)
- uma uphethwe yisifuba somoya, phecelezi i-asthma futhi uma esikhathini esedlule uke waba nemithelela engathandeki edalwa yimithi yokwelapha ama-aleji
- Izingane ezineminyaka engaphansi kwemibili ubudala akufanele zinikezwe **ITEXA ALLERGY SYRUP**, njengoba kungaqinisekiswa ukuphepha kanye nokusebenza kahle kwayo ezinganeni.

**Qaphela kakhulu uma usebenzisa iTEXA ALLERGY SYRUP:**

- **ITEXA ALLERGY SYRUP** iwumuthi ongakwenzi ufikelwe ukozele noma ukulala, kodwa-ke ezinye iziguli zifikelwa ubuthongo emuva kokuphuza le siraphu (bheka isigatshana esithi **Ukushayela kanye nokusebenzisa imishini**)
- uma usebenzisa **ITEXA ALLERGY SYRUP** ungalokothi uphuze utshwala (bheka isigatshana esithi **Ukuphuza iTEXA ALLERGY TABLETS nokudla kanye nophuzo**)
- uma unanoma yisiphi esinye isifo esenza ungachami njengokujwayelekile (ubunzima bokusebenza kwesinye nokungachami ngendlela efanele)
- uma uyisiguli esinesifo sokuwa (uma uba nesithuthwane), noma uma uyisiguli esisengcupheni yokuhlaselwa wukudlikiza komzimba okungalawuleki
- uma uzoyohlolwa ama-aleji, kumele uyeke ukusebenzisa **ITEXA ALLERGY SYRUP** okungenani kusasele izinsuku ezintathu ngaphambi kokuba uyohlolwa, njengoba kungenzeka ukuthi iphazamise imiphumela yakho yokuhlolwa ama-aleji
- uma ungumuntu osekhulile ngokweminyaka, makhulu amathuba okuthi ube nemithelela engathandeki ebangelwa yi**ITEXA ALLERGY SYRUP**.

**Ukuphuza iTEXA ALLERGY SYRUP nokudla kanye nophuzo:**

**ITEXA ALLERGY SYRUP** ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

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Kumele ubugweme utshwala.

**Ukukhulelwa kanye nokuncelisa:**

**Ungalokothi** usebenzise i**TEXA ALLERGY SYRUP** uma ukhulelwe, uhlela ukukhulelwa noma uma usancelisa umntwana wakho (bheka isigatshana esithi **Ungalokothi uthathe iTEXA ALLERGY SYRUP**).

Uma ukhulelwe noma usancelisa umntwana wakho, bonana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze akweluleke ngaphambi kokuba uqale ukusebenzisa i**TEXA ALLERGY SYRUP**.

**Ukushayela kanye nokusebenzisa imishini:**

**ITEXA ALLERGY SYRUP** ingadala ukuthi uphathwe wubuthongo futhi kumele uqaphele kakhulu ngaphambi kokuthi ushaye imoto, usebenzise umshini onobungozi noma wenze imisebenzi eyingozi.

**Ulwazi olubalulekile mayelana nezinye zezithako ze**TEXA ALLERGY SYRUP**:**

- **ITEXA ALLERGY SYRUP** iqukethe isorbitol futhi lokhu kungadala ukuthi ukhishwe yisisu. Uma uke watshelwa ukuthi umzimba wakho uyahluleka ukubekezelela izinhlobo ezithile zikashukela, akumele uphuze **ITEXA ALLERGY SYRUP**.
- **ITEXA ALLERGY SYRUP** iqukethe izilondolozo imethyl parahydroxybenzoate kanye nepropyl hydroxybenzoate okungadala ukuthi uphathwe ngama-aleji.

**Ukusebenzisa eminye imithi ngesikhathi esifanayo ne**TEXA ALLERGY SYRUP**:**

Kumele ngaso sonke isikhathi umazise umhlinzeki wakho wosizo lwezempilo nokwelashwa uma kukhona nanoma iyiphi eminye imithi oyisebenzisayo. (Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)

- Akulungile neze ukuphuza i**TEXA ALLERGY SYRUP** kanyekanye nanoma iyiphi

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eminye imithi engakwenza ufikelwe wubuthongo (izidungamizwa, imithi elalisayo noma iziqedazinhlungu ezinamandla).

**4. ISETSHEZISWA KANJANI ITEXA ALLERGY SYRUP:**

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela. Kumele njalo **iTEXA ALLERGY SYRUP** uyiphuze ncimishi ngendlela oyalelwe ngayo kuleli pheshana lolwazi. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Abantu abadala noma izingane ezineminyaka eyi-12 ubudala noma ngaphezulu:

10 mg (10 ml) kanye njalo ngosuku.

Izingane ezineminyaka eyisithupha kuya kweyi-12 ubudala:

10 mg (10 ml) njalo ngosuku, okungaba wumthamosilinganiso owodwa kumbe umthamosilinganiso ohlukaniswe kabili ube ngama-5 ml ekuseni kanye nama-5 ml kusihlwa.

Izingane ezineminyaka emibili kuya kweyisithupha ubudala:

5 mg (5 ml) njalo ngosuku, okungaba wumthamosilinganiso owodwa kumbe umthamosilinganiso ohlukaniswe kabili ube ngama-2,5 ml ekuseni kanye nama-2,5 ml kusihlwa.

Uma unenkinga yesifo sezinso noma sesibindi, kumele uphuze ama-5 mg (5 ml) kanye njalo ngosuku.

**Uma uphuze iTEXA ALLERGY SYRUP engaphezulu kwaleyo okumele uyiphuze:**

Uma kwenzekile waphuza umthamosilinganiso wesiraphu oweqile, xhumana nodokotela wakho noma usokhemisi. Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu.

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Izimpawu zokuphuza umthamosilinganiso oweqile kulowo okumele uwuphuze kungenzeka zibandakanye ukudideka, isifo sohudo, isiyenzi, ikhanda elibuhlungu, ukuzizwa ungaphilile neze emzimbeni wonke, izinhlamvu zamehlo ezinwebekile, ukungahlaliseki (ukungabi nasinqe), ukozela, ukuba sesimweni sokundwaza nje okwenza kube nzima ukwenza lokho okuthiwa kwenze, ukuzizwa unobuthongo noma ukhathele, inhliziyi encane (ukucasuka kalula), ukuqubuka esikhunjeni, ukuphuma komchamo omncane kunalokho okujwayelekile kuwena lapho uchama, ukuqhaq hazela noma ukuthuthumela okungalawuleki, kanye nenhliziyi eshaya ngamandla.

**Uma kwenzeka ukhohlwa ukuphuza iTEXA ALLERGY SYRUP:**

Phuza lowo mthamosilinganiso ongawuphuzanga ngokushesha emuva kokukhumbula. Uma sekusondele isikhathi sokuphuza umthamosilinganiso wesiraphu olandelayo, ungabe usawuphuza lowo mthamosilinganiso ongawuphuzanga futhi uqhubeke uphuze umthamosilinganiso we**TEXA ALLERGY SYRUP** njengokujwayelekile ngesikhathi esilandelayo esibekiwe. Ungalokothi uphuze imithamosilinganiso yesiraphu ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

**Imithelela ongahlangabezana nayo uma uyeka ukwelashwa ngeTEXA ALLERGY SYRUP:**

Uma uyeka ukwelashwa nge**TEXA ALLERGY SYRUP**, kungenzeka isikhumba sakho sibe nokuluma okukhulu noma simile amaqhubu amakhulu. Uma kwenzeka lokhu, qala futhi usebenzise **iTEXA ALLERGY SYRUP**, futhi izophela imithelela engathandeki.

**5. IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA:**

**ITEXA ALLERGY SYRUP** kungenzeka ibe nemithelela engathandeki emzimbeni. Akuyona yonke imithelela engathandeki ebikiwe ye**TEXA ALLERGY SYRUP** equkethwe kuleli pheshana lolwazi. Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa

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umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa i**TEXA ALLERGY SYRUP**, xhumana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa i**TEXA ALLERGY SYRUP** futhi utshele udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe:

- ukuvuvukala kwezandla, izinyawo, amaqakala, ubunzima bokuphefumula, okungenzeka kuhambisane noma kungahambisani nokuvuvukala kobuso, izindebe zomlomo, ulimu kanye/noma umphimbo, okungenza ukuthi kube nzima ukugwinya
- ukuquleka
- ukuluma kakhulu kwesikhumba (okuhambisana nokumila kwamaqhubu amakhulu emzimbeni), ukuqubuka esikhunjani.

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo, kusho ukuthi kungenzeka ukuthi umzimba wakho awuzwananga neze ne**TEXA ALLERGY SYRUP**. Kungenzeka udinge usizo lokwelashwa oluphuthumayo noma ukulaliswa esibhedlela.

Tshela udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe uma ubona okunye kwalokhu okulandelayo:

- ukudlikiza komzimba ngendlela engalawuleki nokuquleka (amafithi)
- ukushaya kwenhliziyo ngokushesha noma ngendlela engajwayelekile
- imicabango yokuzibulala (okubizwa phecelezi ngesuicidal ideation)
- isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi (ijondisi), isicanucanu, izinhlungu esiswini, ukufikelwa wukukhathala okukhulu kanye nemfiva; izimpawu zenkinga yesibindi.

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Konke lokhu kuyimithelela engathandeki ebucayi futhi enobungozi. Kungenzeka kudingeke ukuba uthole usizo lokwelashwa oluphuthumayo.

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- umphimbo obuhlungu, amafinyila nekhala elilumayo kanye nokuthimula.

Imithelela engathandeki engavamile ukwenzeka:

- isifo segazi, i-anemiya, esihambisana nezimpawu ezinjengokukhathala okukhulu, isikhumba esiphaphathekile, imiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile
- ukopha nokuhuzuka kalula
- ukuzizwa wozela noma unobuthongo, ingcindezi yengqondo, ukudideka, ulaka, inhliziyo encane, ukubona nokuzwa izinto ezingekho, ukungakwazi ukulala (ukungafikelwa ubuthongo)
- ukudikiza kwezicubu zomzimba, ukuqhaqhazela noma ukuthuthumela okungalawuleki
- ukukhathala noma ukuzizwa ubuthakathaka ngendlela engajwayelekile, ukuzizwa ungaphilile emzimbeni wonke
- ukubona ngendlela efiphele noma ukubona into eyodwa sengathi iphindaphindwe kabili, ukukhathala kwamehlo, ubunzima bokugxilisa amehlo, ukupheqa amehlo
- isifo sesiyezi, phecelezi ivertigo (ukuzizwa ungenayo ibhalansi emzimbeni / ikhanda elinomuzwa ozulayo nojikelezayo), ukukhala kwemisindo noma izihlonono ezindlebeni (okubizwa phecelezi ngetinnitus)
- umfutho wegazi ophansi (uzizwe unesiyezi futhi uzwe sengathi uzoquleka, ukuphathwa isiyezi)
- ukuzwakala komsindo ofana nekhwela uma uphefumula udonsa umoya, ukushuba koketshezi emgudwini wokuphefumula (isikhwehlela)



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- isifo sohudo, izinhlungu esiswini, isisu esiqumbile, ukugcwala komoya esiswini, isicanucanu, ukuqunjelwa, umlomo owomile
- imiphumela yokuhlolwa kwesibindi ebonisa okungajwayelekile
- ukuqubuka esikhunjeni noma ezinye izinkinga zesikhumba ezinjengesikhumba esilumayo noma esibomvu, noma ukuzwela kakhulu ekukhanyeni
- ukuqothuka kwezinwele, ukujuluka
- ubuhlungu bemisipha
- ukuphuma komchamo omncane kunalokho okujwayelekile
- izinhlungu noma ukungaphatheki kahle uma uchama
- ukuzichamela embhedeni, ikakhulukazi ukuzichamela kwezingane ebusuku
- ukuzimuka (ukukhuluphala).

Imithelela engathandeki okungaziwa ukuthi ivamise kangakanani ukwenzeka:

- ukukhula kokuthanda nokulangazelela ukudla
- ikhanda elibuhlungu, ukuphathwa isiyenzi
- itwetwe nexhala, uvalo, ukukhohlwa
- amaphupho amabi
- umuzwa wokunsonsotha, ukushisa, ukuncinza (obizwa phecelezi ngamapins and needles), noma ukuba ndikindiki kwesikhumba
- umuzwa wokunambitha okubi emlonyeni
- ukuthuthumela (ukuqhaqhaazela okungalawuleki)
- umqubuko onamabhamuza aqukethe ubovu
- ubuhlungu bamalunga omzimba.

Uma ubona noma iyiphi eminye imithelela engathandeki engabhaliwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

**6. UKUGCINWA NOKUL AHLWA KWETEXA ALLERGY SYRUP:**

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

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Umuthi wugcine endaweni eyomile ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.

Ungawusebenzisi umuthi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe ebhodleleni lawo.

Yiphindisele emuva kusokhemisi wakho yonke imithi engasetshenziswanga.

Ungalokothi ulahle imithi engasetshenziswanga ezinhlelweni zamapayipi okuchitha amanzi noma okuthutha indle (isibonelo, ezindlini zangasese).

**7. UKWETHULWA KWETEXA ALLERGY SYRUP:**

Itholakala ebhodleleni lengilazi, phecelezi, iType 3 amber glass bottle, elinesivalo sepulastikhi esinombala omhlophe esibonisayo uma kukhona oke wazama ukusivula, eliqukethwe kwibhokisana elinemibhalo ngaphandle. Osayizi bokupakisha: 50 ml\*, 100 ml, 150 ml\* kanye nama-200 ml\*.

\*Akubona bonke osayizi bokupakisha abathengiswayo ezindaweni okuthengiswa kuzona imithi.

**8. UKUHLONZWA KWETEXA ALLERGY SYRUP:**

Iwumuthi owuketshezi olucacile noma oluthi malucace olungenawo umbala olunambithekisa futhi lunukise okobhanana.

**9. INAMBA YOKUBHALISWA**

A41/5.7.1/0086

**10. IGAMA, IKHELI LENKAMPANI KANYE NENAMBA YOCINGO YOMNIKAZI**

**WESITIFIKETI SOKUBHALISWA:**

Pharma Dynamics (Pty) Ltd

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**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI  
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**11. USUKU LOKUSHICILELWA:**

Usuku lokubhaliswa: 08 Nhlolanja 2008

Usuku lokugunyazwa kwakamuva: 07 Masingana 2020

**NAMIBIA:**

**NS1** 10/5.7.1/0332

**ZAMBIA:**

**P** 051/004

**MOZAMBIQUE:**

2485