IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

MONICOR 60 mg SR

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S3

IGAMAKUHWEBA LOMKHIQIZO KANYE NESIMO SOMTHAMOSILINGANISO

MONICOR 60 mg SR engamaphilisi angena kancane kancane emzimbeni.

Ngaphambi kokuba uqale ukusebenzisa iMONICOR 60 mg SR funda ngokucophelela lonke leli pheshana lolwazi:

- Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.
- Uma unanoma yimiphi eminye imibuzo engeziwe, buza udokotela wakho noma usokhemisi.
- **IMONICOR 60 mg SR** iqondene nawe kuphela futhi inikezwe wena, ngakho-ke ungalokothi wabelane ngayo nabanye abantu. Kungenzeka bona ibalimaze, nakuba nabo benezimpawu ezifana nezakho.

1. OKUQUKETHWE YIMONICOR 60 mg SR

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi-*isosorbide-5-mononitrate*. Iphilisi ngalinye liqukethe i-*isosorbide-5-mononitrate* engama-60 mg.

Ngaphezu kwalokho, iMONICOR 60 mg SR iqukethe izithako ezilandelayo, umsebenzi wazo okungekhona ukwelapha: *Carnauba wax*, *ferric oxide*, *hydroxypropylmethylcellulose*, *macrogol*, *magnesium stearate*, *silica anhydrous colloidal*, *stearic acid*, *talc*, *titanium dioxide*.

IMONICOR 60 mg SR iqukethe ushukela (i*lactose monohydrate* ongama-38,167 mg ephilisini ngalinye) (bheka isigatshana esithi “Ulwazi olubalulekile mayelana nezinye zezithako zeMONICOR 60 mg SR”).

2. IMONICOR 60 mg SR ISETSHENZISELWA LOKHU

IMONICOR 60 mg SR ngamaphilisi owanikezwa ngodokotela ngenhloso yokuvimbela ukuphathwa

yisifo i-*angina pectoris*, okuyisifo esibonakala ngezinhlungu ezinamandla esifubeni ezikuphatha ziphindelela.

3. NGAPHAMBI KOKUTHI USEBENZISE IMONICOR 60 mg SR

Ungalokothi usebenzise iMONICOR 60 mg SR

- uma umzimba wakho ungezwani ne-*isosorbide-5-mononitrate*, nemithi yohlobo lwe-*organic nitrate* noma ungezwani nanoma yiziphi ezinye izithako zeMONICOR 60 mg SR (bheka ingxenye ethi “OKUQUKETHWE YIMONICOR 60 mg SR”)
- uma unomfutho wegazi ophansi kakhulu, unomthamo ophansi wegazi emzimbeni, kunokuncipha okucacile komthamo kwezingqalampilo zegazi ezibomvu emzimbeni, inhliziyo ebuthakathaka ngenxa yokuvaleka kwemithambo yenhliziyo noma ukukhula kwengcindezi ogebhezini lwekhanda ngenxa yokulimala ekhanda noma yokopha ebuchosheni
- uma une-*angle closure glaucoma* (inkinga yokukhula kwengcindezi ehlweni/emehlweni); njengoba iMONICOR 60 mg SR kungenzeka iyikhuphule kakhulu ingcindezi ehlweni
- uma futhi usebenzisa i*sildenafil*, okungumuthi osetshenziselwa ukwelapha indoda engavukelwa, noma engakwazi ukugcina induku yayo ivukile futhi iqinile ukuze ikwazi ukuya kahle ocansini, noma eminye imithi eyenza umsebenzi ofanayo (bheka isigatshana esithi “Ukusebenzisa eminye imithi ngesikhathi esifanayo neMONICOR 60 mg SR”)
- ukwelapha ukuhlaselwa yi-*angina pectoris* kungazelelwe. Udokotela wakho uzokunikeza amaphilisi ashuthekwa ngaphansi kolimi i*nitroglycerin* okumele uwasebenzise kulezi zimo (bheka isigatshana esithi “INDLELA YOKUSEBENZISA IMONICOR 60 mg SR”).

Qaphela kakhulu uma usebenzisa iMONICOR 60 mg SR

- uma uxinwe kakhulu yi*cerebral arteriosclerosis* (inkinga yokuqina kanye/noma ukuba wugqinsi kwezindonga zemithambo emincane yobuchopho) noma unenkinga yomfutho wegazi ophansi kakhulu (bheka isigatshana esithi “Ungalokothi usebenzise iMONICOR 60 mg SR”)

- uma ungondlekile kahle emzimbeni, uma kubuthakathaka kakhulu ukusebenza kwenso yakho noma isibindi, uma kunokuncipha kokusebenza kwendlala i*thyroid gland* noma uma umzimba wakho unezingakushisa eliphansi
- uma une-*angle closure glaucoma* (inkinga yokukhula kwengcindezi ehlweni/emehlweni]); njengoba iMONICOR 60 mg SR kungenzeka iyikhuphule kakhulu ingcindezi ehlweni (bheka isigatshana esithi “Ungalokothi usebenzise iMONICOR 60 mg SR”).

Ukuphuza iMONICOR 60 mg SR nokudla kanye nophuzo

- IMONICOR 60 mg SR ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.
- Amaphilisi iMONICOR 60 mg SR ungawaqhephula uwahlukanise kabili, kodwa akumele uwahlafune noma uwagaye, futhi kumele uwehlise ngamanzi awuhhafu wengilazi.

Ukukhulelwa kanye nokuncelisa:

- UNGALOKOTHI USEBENZISE IMONICOR 60 mg SR uma ukhulelwe, noma uma usola sengathi ukhulelwe noma uma usancelisa, njengoba kungaziwa ukuthi iphephile yini iMONICOR 60 mg SR kumuntu okhulelwe noma oncelisayo.

Uma ukhulelwe noma uncelisa, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iMONICOR 60 mg SR.

Ukushayela kanye nokusebenzisa imishini:

- IMONICOR 60 mg SR kungenzeka ikuphazamise ungakwazi ukushayela kahle imoto nokusebenzisa umshini. Qaphela kakhulu uma uzizwa unesiyezi, ukhathele noma wozela ngenkathi usebenzisa iMONICOR 60 mg SR**,** ikakhulukazi uma uyisebenzisa kanyekanye neminye imithi yokwehlisa umfutho wegazi.

Ulwazi olubalulekile mayelana nezinye zezithako zeMONICOR 60 mg SR:

- IMONICOR 60 mg SR iqukethe ushukela wobisi i*lactose*. Uma wazi noma usola sengathi umzimba wakho uyahluleka ukubekezelela kanye nokugaya ushukela wobisi bonisana nodokotela wakho ngaphambi kokusebenzisa iMONICOR 60 mg SR.

Ukusebenzisa eminye imithi ngesikhathi esifanayo neMONICOR 60 mg SR:

- Kumele ngaso sonke isikhathi umazise umhlinzeki wakho wosizo lwezempilo nokwelashwa uma kukhona nanoma yimiphi eminye imithi oyisebenzisayo.
  (Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)
- uma uhlose ukuphuza utshwala noma eminye imithi ebangela ukunwebeka kwemithambo yegazi, lokho kungenza ukuthi wehle ngokweqile umfutho wegazi.

Uma usebenzisa lokhu:

- i*sildenafil* kanye neminye imithi esetshenziselwa ukwelapha indoda engavukelwa noma engakwazi ukugcina induku yayo ivukile futhi iqinile ukuze ikwazi ukuya kahle ocansini,
- amanye ama-*antihypertensive agents* (imithi esetshenziselwa ukwelapha umfutho wegazi ophakeme),
- utshwala,

bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Akuyona yonke imithi okungenzeka iphazamisane nokusebenza kweMONICOR 60 mg SR esohlwini olubhalwe lapha ngenhla.

4. INDLELA YOKUSEBENZISA IMONICOR 60 mg SR:

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela.

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

MONICOR 60 mg SR

Kumele njalo iMONICOR 60 mg SR uyiphuze ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Phuza iphilisi leMONICOR 60 mg SR elilodwa nsukuzonke, ekuseni. Lo mthamosilinganiso ungakhushulwa ube ngamaphilisi eMONICOR 60 mg SR amabili aphuzwa kanye nsukuzonke, ekuseni. Uma usaqala ukwelashwa ungaphuza uhhafu wephilisi leMONICOR 60 mg SR nsukuzonke, ekuseni, futhi lokhu kumele ukwenze ezinsukwini zokuqala ezimbili kuya kwezine ukuze unciphise amathuba okuphathwa yikhanda elibuhlungu. Amaphilisi iMONICOR 60 mg SR ungawaqhephula uwahlukanise kabili, kodwa akumele uwahlafune noma uwagaye, futhi kumele uwehlise ngamanzi awuhhafu wengilazi.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeMONICOR 60 mg SR. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba isifo esikuphethe kungenzeka sidlondlobale, sibe sibi kakhulu.

Uma ubona sengathi iMONICOR 60 mg SR inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi. IMONICOR 60 mg SR ingasetshenziswa yodwa noma isetshenziswe ngokuhlanganyela neminye imithi yokulawula i-*angina pectoris*.

QAPHELA:

Amaphilisi iMONICOR 60 mg SR akumele asetshenziselwe ukwelapha inkinga yokuhlaselwa yi-*angina pectoris* kungazelelwe.

Uma uphuze iMONICOR 60 mg SR engaphezulu kwaleyo okumele uyiphuze:

Uma kwenzekile waphuza umthamosilinganiso oweqile, bonisana nodokotela wakho noma usokhemisi. Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu. Ngenkathi uyobonisana nodokotela, phatha leli pheshana lolwazi kanye nawo wonke amaphilisi asele ukuze azi ukuthi yimaphi amaphilisi owasebenzisile.

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso wakho weMONICOR 60 mg SR:

Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

5. IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA:

IMONICOR 60 mg SR kungenzeka ibe nemithelela engathandeki emzimbeni. Akuyona yonke imithelela engathandeki ebikiwe yalo muthi equkethwe kuleli pheshana lolwazi. Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa iMONICOR 60 mg SR, xhumana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iMONICOR 60 mg SR futhi utshele udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe:

- ukuqubuka noma isikhumba esilumayo
- ukuquleka
- ukufikelwa wukushisa nobubomvu ebusweni.

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze neMONICOR 60 mg SR oyisebenzile. Kungenzeka kudingeke ukuba uthole usizo lokwelashwa oluphuthumayo.

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

- ukushaya kwenhliziyo ngokushesha futhi ngesigqi esingahambelani kahle, ikhanda elibuhlungu, ukuphefumula kanzima.

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

- ukuhlanza, ukufiphala kwamehlo, ikhanda elibuhlungu kakhulu futhi elilokhu libelesele isikhathi eside; ubuhlungu bemisipha yomzimba, isisu esihambisayo/esikhiphayo
- inkinga yegazi edala ukuguquka kombala wesikhumba uthi mawufane nombala oluhlaza okwesibhakabhaka, ukukhathala, isiyezi, umfutho wegazi ophansi, isicanucanu, ukungahlaliseki/ukungabi nasinqe.

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

Imithelela engathandeki elandelayo yona kungenzeka ingadingi ukuthi uthole usizo lokwelashwa futhi kungenzeka iziphelele ngokwayo ngenkathi uqhubeka nokwelashwa:

- ikhanda elibuhlungu noma umfutho wegazi ophansi obonakala ngokuthi uzizwe unesiyezi nesicanucanu.

6. UKUGCINWA NOKULAHLWA KWEMONICOR 60 mg SR:

- YONKE IMITHI KUMELE UYIGCINE ENDAWENI EZINGAFINYELELI KUYONA IZINGANE.
- Yigcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.
- Amaphilisi wagcine esitsheni sawo afike naso.
- Wavikele ekukhanyeni.
- Sigcine sivalwe ngci isitsha samaphilisi.
- Ungawasebenzisi amaphilisi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe kwilebula/kuqwenjana oluyisigcinamaphilisi noma kwibhokisana.
- Yiphindisele emuva kusokhemisi wakho yonke imithi engasetshenziswanga.
- Ungalokothi ulahle imithi engasetshenziswanga ezinhlelweni zamapayipi okuchitha amanzi noma okuthutha indle (isibonelo, ezindlini zangasese).

7. UKWETHULWA KWEMONICOR 60 mg SR:

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

MONICOR 60 mg SR

Amaphilisi iMONICOR 60 mg SR agcinwe esitsheni sepulastiki esimhlophe esivaleka ngci esiqukethe amaphilisi angama-30.

IMONICOR 60 mg SR ifakwe futhi kwizingqwenjana ezingumsweswana eziyizigcinamaphilisi ezakhiwe ngefoyela le-*aluminium* eliqinile elinombala osiliva kanye nontwentwesana lwe*PVC/PVDC* olubonisa lokho okungaphakathi, eziqukethe amaphilisi ama-3 X 10 angaphakathi kwebhokisana.

8. UKUHLONZWA KWEMONICOR 60 mg SR:

Amaphilisi **iMONICOR 60 mg SR** ngamaphilisi ayindingiliza anombala okhilimu, anomugqa onqamula phakathi nhlangothi zombili, abhalwe inamba “60” ohlangothini olulodwa.

9. INAMBA YOKUBHALISWA:

A37/7.1.4/0340

10. IGAMA NEKHELI LOMNIKAZI WESITIFIKETI SOKUBHALISWA:

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11. USUKU LOKUSHICILELWA:

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Usuku lokugunyazwa kwakamuva: 03 Masingana 2020

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

MONICOR 60 mg SR

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