IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

CARVETREND 6,25/12,5/25 mg

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S3

IGAMA LOMUTHI

CARVETREND 6,25 mg (amaphilisi)

CARVETREND 12,5 mg (amaphilisi)

CARVETREND 25 mg (amaphilisi)

Carvedilol

ICARVETREND iqukethe ushukela (i*lactose monohydrate* kanye ne*sucrose*), ngokomthamo olandelayo ephilisini ngalinye, ngokulandelana kwawo:

CARVETREND 6,25 mg: (72,25 mg; 5,00 mg)

CARVETREND 12,5 mg: (144,50 mg; 10,00 mg)

CARVETREND 25 mg: (85,00 mg; 60,00 mg)

Ngaphambi kokuba uqale ukusebenzisa iCARVETREND funda ngokucophelela lonke leli pheshana lolwazi

- Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.
- Uma uneminye imibuzo engeziwe, buza udokotela wakho, usokhemisi, umhlengikazi noma omunye umhlinzeki wosizo lwezempilo nokwelashwa.
- ICARVETREND iqondene nawe kuphela futhi inikezwe wena, ngakho-ke ungalokothi wabelane ngayo nabanye abantu. Kungenzeka bona ibalimaze, nakuba nabo benezimpawu ezifana nezakho.

Okuqukethwe kuleli pheshana lolwazi

1. Iyini iCARVETREND futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iCARVETREND
3. Indlela yokusebenzisa iCARVETREND
4. Imithelela engathandeki okungenzeka ibe khona

5. Indlela yokugcina iCARVETREND
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

1. Iyini iCARVETREND futhi isetshenziselwani?

ICarvedilol iyingxenye yeqoqwana lemithi ebizwa ngama*beta-blockers* esebenza ngokuthi ithambise futhi inwebe umgudu wemithambo yegazi. Lokhu kwenza kube lula ukuthi inhliziyo yakho ipompe igazi eliya emzimbeni wakho wonke futhi kunciphisa umfutho wegazi kanye nomthwalo wenhliziyo yakho.

Amaphilisi iCARVETREND asetshenziselwa lokhu:

- Ukwelapha umfutho wegazi ophakeme (*hypertension).* Umfutho wegazi ophakeme ungaholela kwizinhlobo ezihlukahlukene zezifo zenhliziyo. Udokotela ukuyalele ukuthi usebenzise iCARVETREND ngenhloso yokwelula impilo yakho futhi ukuze kuncishiswe nobungozi bokuhlaselwa yisifo senhliziyo kanye nesifo sohlangothi. ICARVETREND ungayisebenzisa kanyekanye neminye imithi eyehlisa umfutho wegazi uma uyalelwe kanjalo ngudokotela wakho.
- Ukudambisa isifo esibhebhethekayo sokuhluleka kwenhliziyo ukupompa igazi ngendlela efanele.
- Ukuvimbela izinhlungu esifubeni (*angina pectoris*). Ngisho usebenzisa umuthi, kumele uqhubeke nokudla kuphela ukudla okunempilo kanye nokuzivocavoca, njengoba uyalelwe ngudokotela wakho.

2. Okumele ukwazi ngaphambi kokuba usebenzise iCARVETREND

Ungalokothi uthathe iCARVETREND:

- Uma umzimba wakho ungezwani nesithako i*carvedilol* noma uma ungezwani nanoma yisiphi esinye isithako samaphilisi iCARVETREND (bheka isigaba 6)
- Mazise udokotela wakho uma unanoma yisiphi isifo esiyisimbelambela/esingamahlalakhona, uma unenkinga yokungagayeki kahle kokudla emzimbeni, noma uma kuneminye imithi

oyisebenzisayo. Izifo ezingamahlalakhona zibandakanya isifo senhliziyo, isifo semithambo yegazi, isifo sesikhumba i*psoriasis* noma inkinga yokusebenza kakhulu kwendlala yegilo.

- Tshela udokotela uma unomfutho wegazi ophansi, noma unanoma iyiphi inkinga ebangelwa ngama-aleji noma unenkinga yokunqwabelana ngokweqile kwe-esidi emzimbeni wakho (*metabolic acidosis*). Kulezi zimo, udokotela wakho uzokunikeza imiyalelo engeziwe okumele uyilandele.
- Amaphilisi iCARVETREND akumele uwasebenzise uma unesifuba somoya, isifo sokuphefumula (i*chronic obstructive pulmonary disease*), isifo esinamandla sokungasebenzi kahle kwesibindi, inhliziyo eshaya kancane noma ezinye izinkinga eziphathelene nesigqi senhliziyo, isifo esinamandla noma esixinayo sokuhluleka kwenhliziyo ukusebenza ngendlela efanele, umfutho wegazi ophakeme emithanjeni yegazi emaphashini nasenhliziyweni (*pulmonary hypertension*), noma i*pulmonale* (isifo sokuhluleka kwenhliziyo ukupompa igazi eliya emaphashini) noma inkinga yokuhluleka kwenhliziyo ukuthumela igazi ne-oksijini ezithweni ezisemqoka emzimbeni (*cardiogenic shock*).
- Uma unenkinga yenhliziyo, ebizwa nge*variant* noma i*Prinzmetal's angina*, ebonakala ngezinhlungu esifubeni.
- Uma une*phaeochromocytoma* engalashiwe, okuyisimila esikhipha amakhemikhali anjenge*noradrenaline*, adala izimpawu ezinjengokujuluka, ikhanda elibuhlungu, inhliziyo eshaya ngamandla kanye nokuqhaqhazela.
- Uma unenkinga eyenzeka lapho umzimba ukhiqiza i-esidi eningi ngokweqile, futhi ebizwa nge*metabolic acidosis*. Kungenzeka ube nenkinga yokudonsa umoya omncane lapho uphefumula, ongafinyeleli kahle emaphashini, ube nokudideka futhi ukhathale.
- Uma unenkinga yokuphazamiseka okukhulu kwemithambo yakho yegazi, lapho imithambo yegazi incipha futhi inciphise ukuhamba nokugeleza kwegazi eliya emilenzeni nasezingalweni. Kungenzeka uzwe ubundikindiki noma ukunsonsotha ezingalweni zakho nasemilenzeni.
- Uma usebenzisa ama*calcium channel blockers* (isibonelo, i*verapamil* kanye ne*diltiazem*).

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Izingane: Akuqinisekiswanga ukuphepha kwalo muthi ezinganeni.

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iCARVETREND:

- Ekuqaleni kokwelashwa futhi/noma lapho kukhushulwa umthamosillinganiso, kumele ucophelele lapho usukuma uma ngezinyawo, njengoba kungenzeka wehle umfutho wakho wegazi. Kungenzeka uphathwe yisiyezi noma i*vertigo*.
- Kumele ucophelele ikakhulukazi uma unenkinga yokungasebenzi kahle kwenhliziyo, uma usebenzisa noma iyiphi eminye imithi eyehlisa umfutho wegazi.
- Ngaphambi kokuba uhlinzwe noma uhlolelwe ama-aleji, mazise udokotela wakho ukuthi usebenzisa iCARVETREND.

Uma siba sibi isimo sakho, bonisana nodokotela wakho ngokushesha.

Mazise udokotela wakho noma ungoti wezempilo nokwelashwa uma:

- Njengamanje welashwa nge*digitalis* (usebenzisa i*digoxin*).
- Welashelwa i*phaeochromocytoma* (isimila sendlala i-*adrenal gland*).
- Njengamanje usebenzisa i*clonidine* (umuthi osetshenziselwa ukwelapha ikhanda elinkenkethayo, ikakhulukazi ohlangothini olulodwa lwekhanda kanye nokushisa kwesingenhla somzimba okubangelwa wukungena kowesifazane esigabeni sokunqamuka kokuya esikhathini). Ukuyeka ukusebenzisa umuthi wakho i*clonidine* ngenkathi welashwa ngeCARVETREND kungabangela ukukhuphuka kakhulu komfutho wegazi.
- Uhlaselwe yisifo senhliziyo esinamandla futhi esixinayo esidalwe wukungasebenzi kahle kwengosi yangakwesokunxele yenhliziyo.
- Unenkinga yokushaya kwenhliziyo ngokunensa okukhulu (izikhathi ezingaphansi kwama-55 ngomzuzu) emuva kokuqala ukusebenzisa iCARVETREND.
- Njengamanje usebenzisa i*cimetidine* (umuthi wokwelapha isilungulela).
- Ungalokothi uyeke esithubeni nje ukwelashwa ngeCARVETREND uma unenkinga eyaziwayo yokuncipha kwegazi eliya enhliziyweni.

- Uphethwe yisifo sezinso futhi uma kubhebhetheka/kuba kubi kakhulu ukusebenza kwezinso, kumele umazise ngokushesha udokotela wakho.
- Unesifo sikashukela. Kumele uqaphele ukuthi ukusebenzisa iCARVETREND kungadala ukwehla kwamazinga kashukela egazini lakho. Kumele uwuqaphe njalo futhi ngokuqhubekayo ushukela egazini lakho futhi uyiguqule ngendlela efanele imithi oyisebenzisayo yokwelapha isifo sikashukela ukuze ihambisane nesimo sakho.
- Uphethwe yisifo sokuphefumula esiyisimbelambela i*chronic obstructive lung disease*, noma izifo ezidalwa ngama-aleji ezibandakanya imigudu yokuphefumula.
- Unezinkinga zendlala yegilo.
- Unanoma iyiphi inkinga yokuguquka kombala weminwe kanye/noma wezinzwane ngenxa yokuhlangabezana nokuguquka kwezingakushisa (ukubanda noma ukushisa) noma izigameko eziphathelene nemizwa nomphefumulo.
- Unenkinga yokungahambi kahle kwegazi emzimbeni.
- Ufake ama*contact lenses*. Kumele uqaphele ukuthi iCARVETREND kungenzeka inciphise ukwakheka kwezinyembezi futhi yenze ukuthi amehlo ome.
- Uma usebenzisa i*debrisoquine*, umuthi osetshenziselwa ukwehlisa umfutho wakho wegazi.
- Uma unomlando wokuphathwa yizinhlungu esifubeni ngenxa yesifo sokuqina nokuncipha ngokushesha kwemithambo ethumela igazi enhliziyweni yakho (*coronary artery spasm*), njengoba kumele ukuthi iCARVETREND isetshenziswe ngokucophelela uma uphethwe yilesi sifo.
- Uma uphathwa yi*psoriasis* okuyisifo esihlobene nokusetshenziswa kwama*beta-blockers* (imithi yokwehlisa umfutho wegazi).
- Uma uphathwa wukugula okunamandla njengokuvela kwamabhamuza esikhunjeni, emlonyeni, emehlweni kanye nasezithweni zangasese.
- Uma kukhona noma yimuphi owusebenzisayo kule mithi elandelayo: i*verapamil* noma i*diltiazem* noma eminye imithi engama-*anti-dysrhythmic medicines* (imithi yokulawula inkinga yokushaya kwenhliziyo ngesigqi esingahambelani kahle).

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Ukusetshenziswa kweminye imithi neCARVETREND

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

Mtshele udokotela wakho uma kukhona noma yimuphi owusebenzisayo kule mithi elandelayo:

- Ukusebenzisa amaphilisi angeziwe omfutho wegazi noma amaphilisi okunciphisa amanzi emzimbeni kungenzeka kuholele emfuthweni wegazi ophansi.
- I*Digoxin* (esetshenziselwa ukwelapha inkinga yokuhluleka kwenhliziyo ukusebenza ngendlela efanele noma ukushaya kwenhliziyo ngesigqi esingahambelani kahle) ingaholela ekwehleni komfutho wakho wegazi.
- I*Cimetidine* (esetshenziselwa ukwelapha izilonda esiswini, ukunciphisa i-esidi esiswini kanye nesifo sokuyokoza) ingakhuphula umthamo weCARVETREND emzimbeni wakho.
- Iqoqwana lemithi ebizwa ngama*phenothiazines* (esetshenziselwa ukwelapha izifo zengqondo, isibonelo, i*chlorpromazine*, i*fluphenazine*), njengoba ukusebenzisa le mithi kanyekanye neCARVETREND kungawehlisa umfutho wakho wegazi.
- Ukusetshenziswa kweCARVETREND kanyekanye nomuthi wakho wokucindezela amasosha omzimba, i*ciclosporin*, kungenzeka kuholele ekukhuphukeni komthamo we*ciclosporin* emzimbeni wakho futhi lokhu kudinga ukuqashelwa nokubhekisiswa njalo futhi ngokuqhubekayo.
- I*Rifampicin* (esetshenziselwa ukwelapha isifo sofuba) kungenzeka ikhuphule umfutho wakho wegazi.
- Ukusebenza kweCARVETREND kuzoqashelwa futhi kubhekisiswe ngokuqhubekayo ngenkathi usebenzisa i-*amiodarone* (umuthi osetshenziselwa ukwelapha inkinga yokushaya kwenhliziyo ngesigqi esingahambelani kahle) kanyekanye neCARVETREND.
- Amazinga eCARVETREND egazini lakho azoqashelwa futhi abhekisiswe ngokuqhubekayo ngudokotela wakho ngenkathi usebenzisa imithi ebizwa ngama*barbiturates*

(esetshenziselwa ukwelapha ukudlikizela komzimba ngendlela engalawuleki), i*ketoconazole* (esetshenziselwa ukwelapha ukugula okubangelwa wukhunta (*fungal infections*)), i*fluoxetine* (esetshenziselwa ukwelapha ingcindezi yengqondo), i*haloperidol* (esetshenziselwa ukwelapha izinkinga eziphathelene nokugula kwengqondo) kanye ne-*erythromycin* (okuyi-antibhayothikhi esetshenziselwa ukwelapha ukugula okuhlukahlukene okubangelwa ngamagciwane), njengoba lokhu kungakhulisa noma kunciphise amandla okusebenza kweCARVETREND.

- Amandla okusebenza kwe-*insulin* yakho noma eminye imithi yokwelapha isifo sikashukela ephuzwayo angadala ukuthi lehle izinga likashukela egazini lakho. Kumele uwaqaphe njalo futhi ngokuqhubekayo amazinga kashukela egazini lakho.
- Ukwelashwa nge*clonidine* (esetshenziselwa ukwelapha ikhanda elinkenkethayo, ikakhulukazi ohlangothini olulodwa lwekhanda kanye nokushisa kwesingenhla somzimba okubangelwa wukungena kowesifazane esigabeni sokunqamuka kokuya esikhathini) (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iCARVETREND).
- Ukusebenzisa lo muthi kanyekanye neminye imithi yokwelapha umfutho wegazi enjenge*diltiazem* kanye ne*verapamil* kungenzeka kuholele emfuthweni wegazi ophansi kakhulu kanye nokushaya kwenhliziyo ngokunensa okukhulu.
- Nanoma iyiphi eminye imithi esetshenziselwa ukwelapha umfutho wegazi ophakeme (isibonelo, i*reserpine*, i*guanethidine* noma i*bethanidine*) njengoba ingaholela emfuthweni wegazi ophansi kakhulu kanye nokushaya kwenhliziyo ngokunensa okukhulu.
- Uma uzokwenza ukuhlinzwa okukhulu lapho kuzodingeka khona ukuthi ulaliswe ukuze ungazizwa izinhlungu, kumele umtshele udokotela wakho ukuthi wena uthola ukwelashwa ngeCARVETREND (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iCARVETREND).
- Ukusebenzisa imithi yokuqeda ukuvuvukala kanye nezinhlungu kanyekanye neCARVETREND kungenzeka kukhuphule umfutho wegazi.

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- I-*isoprenaline* (esetshenziselwa ukwehlisa isivinini sokushaya kwenhliziyo, isifuba somoya noma ukuvimbeleka/ukubambezeleka kwemiyalezo kagesi elawula ukushaya kwenhliziyo) engaholela ekuncipheni kwamandla okusebenza kahle kweCARVETREND.
- I*hydralazine* (esetshenziselwa ukwelapha umfutho wegazi ophakeme) kanye notshwala kungaholela ekwehleni komfutho wegazi.
- I*quinidine*, *disopyramide*, *lignocaine*, *procainamide* kanye ne*phenytoin* okusetshenziselwa ukwelapha inkinga yokungasebenzi kahle kwenhliziyo.
- Ukusebenzisa imithi eyizikhuthazi (i-*adrenaline* noma i*noradrenaline*) ukwelapha ukushaya kwenhliziyo ngokunensa noma inkinga yokuvimbeleka/ukubambezeleka kwemiyalezo kagesi elawula ukushaya kwenhliziyo, noma yokunciphisa ukuhamba nokugeleza kwegazi eliya ezandleni nasezinyaweni zakho, kungahlehlisa futhi kuphazamise ukusebenza komuthi wakho wokwelapha umfutho wegazi.
- Kungenzeka uthole ukuthi umfutho wegazi wehla kakhulu kunokwejwayelekile uma usebenzisa lo muthi kanyekanye nemithi yokuqeda nokuvimbela ukugula okudalwa ngama-aleji (equkethe ama*phenothiazines*).
- Iqoqwana lemithi ebizwa ngama*nitrates* (esetshenziselwa ukwelapha izinhlungu esifubeni, isibonelo, i*nitroglycerine*), njengoba kungenzeka le mithi yehlise umfutho wakho wegazi.
- Kungenzeka anciphe amandla eCARVETREND okwehlisa umfutho wegazi uma ungowesifazane osebenzisa izivimbelanzalo eziqukethe i-*oestrogen* noma ama*corticosteroids* (okuyimithi esetshenziselwa ukwelapha ukuvuvukala).
- I-*ergotamine* (umuthi osetshenziselwa ukwelapha ikhanda elinkenkethayo, ikakhulukazi ohlangothini olulodwa lwekhanda).
- Kungaba kuhle ukuthi imithi esetshenziselwa ukunciphisa ukushaya kwenhliziyo ingasetshenziswa kanyekanye neCARVETREND.
- Ukusebenzisa iCARVETREND kanyekanye nemithi ekhuphula ukuhamba nokugeleza kwegazi eliya enhliziyweni kunganciphisa umfutho wakho wegazi ngaphezu kwalokho okulindelekile.

- Kumele umazise udokotela wakho uma njengamanje usebenzisa imithi yokukhuthaza kanye nokubuyisela ukushaya kwenhliziyo yakho esimweni esijwayelekile. Lokhu kungenzeka kwehlise kakhulu ukushaya kwenhliziyo.

Ukuphuza iCARVETREND nokudla kanye nophuzo

ICARVETREND kumele uyiphuze emuva kokudla, uyehlise ngamanzi futhi kungaba kuhle uma uyiphuza ngesikhathi esifanayo nsukuzonke.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Uma ukhulelwe noma uncelisa umntwana wakho, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iCARVETREND ukuze uthole ukwelulekwa.

Ukukhulelwa: Akuqinisekiswanga ukuphepha kweCARVETREND kwabesifazane abakhulelwe futhi akumele isetshenziswe kubona.

Ukuncelisa: Njengoba i*carvedilol* idluliseka ingene obisini lwebele, akumele isetshenziswe ngumuntu oncelisayo.

Ukushayela kanye nokusebenzisa imishini:

ICARVETREND ingadala isiyezi, izinkinga eziphathelene nokungakuboni kahle emehlweni, ikhanda elibuhlungu kanye nokukhathala kakhulu.

Akulula ukubikezela njalo ukuthi iCARVETREND izoba nomthelela ongakanani emisebenzini yansukuzonke yesiguli. Iziguli kumele ziqinisekise ukuthi aziyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho sezibonile ukuthi iCARVETREND iziphatha kanjani emzimbeni.

ICARVETREND iqukethe ushukela wobisi, i*lactose,* kanye noshukela wezitshalo, i*sucrose*

ICARVERTREND iqukethe ushukela wobisi. Iziguli ezinezifo zofuzo eziyivelakancane zokuhluleka komzimba ukugaya ushukela wobisi noma olunye uhlobo lukashukela olubizwa nge*galactose* akumele zisebenzise iCARVETREND. Uma uke watshelwa ngudokotela wakho ukuthi umzimba

wakho uyahluleka ukubekezelela nokugaya izinhlobo ezithile zikashukela, xhumana nodokotela wakho ngaphambi kokusebenzisa iCARVETREND.
ICARVETREND iqukethe ushukela wobisi kanye noshukela wezitshalo okungaba nomthelela ekulawulekeni koshukela egazini lakho uma ungumuntu onesifo sikashukela.

3. Isetshenziswa kanjani iCARVETREND

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela.
Kumele njalo iCARVETREND uyisebenzise ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Udokotela wakho nguyena ozonquma mayelana nobude besikhathi sokwelashwa. Ungalokothi uguqule imithamosilinganiso yakho noma uyeke ukwelashwa ungakaqali ngokubonisana nodokotela wakho. ICARVETREND kumele uyiphuze emuva kokudla, uyehlise ngamanzi futhi kungaba kuhle uma uyiphuza ngesikhathi esifanayo nsukuzonke.

Kubantu abadala:

Ukwelapha umfutho wegazi ophakeme:

- Umthamosilinganiso okumele uwuphuze uma usaqala ukwelashwa yiphilisi elilodwa elingama-12,5 mg kanye ngosuku (ekuseni) noma iphilisi elilodwa elingama-6,25 mg kabili ngosuku (ekuseni nakusihlwa). Udokotela kungenzeka awukhuphule umthamosilinganiso wakho uyofinyelela ephilisini elilodwa elingama-25 mg kabili ngosuku.

Ukwelapha Isifo Sokuhluleka Kwenhliziyo Ukupompa Igazi Ngendlela Efanele:

- Umthamosilinganiso okumele uwuphuze uma usaqala ukwelashwa ngama-3,125 mg kabili ngosuku, okungenani kuze kuphele izinsuku eziyi-14. Emuva kwalokho umthamosilinganiso uzokhushulwa njalo okungenani emuva kwezinsuku eziyi-14 uyofinyelela kuma-6,25 mg kabili ngosuku, uphinde futhi ukhushulwe ube ngama-12,5 mg kabili ngosuku bese kuthi ekugcineni ukhushulelwe kuma-25 mg kabili ngosuku. Kusazoqhubeka ukwelashwa okwejwayelekile

nge*digitalis*, noma ngama*diuretics* noma nge-*ACE-inhibitor*. Udokotela uzokhuphula umthamosilinganiso kuphela uma umzimba wakho ubonisa ubungcono nokuzwana kwawo kahle nalo muthi owelashwa ngawo.

Ukwelashwa kwezinhlungu esifubeni:

- Umthamosilinganiso okumele uwuphuze uma usaqala ukwelashwa ngama-12,5 mg kabili ngosuku bese ukhushulwa ngemuva kwezinsuku ezimbili ube ngama-25 mg kabili ngosuku.

Ukwelashwa kwabantu abanenkinga yokungasebenzi kahle kwengosi yangakwesokunxele yenhliziyo kodwa-ke engahambisani nezinkinga ezengeziwe futhi ezixakile zokungasebenzi kahle kwenhliziyo:

- Udokotela wakho uzonquma ukuthi ungakanani umthamosilinganiso ofanelekile azokunikeza wona futhi uzosiqapha futhi asibhekisise ngokuqhubekayo isimo sakho ngenkathi welashwa ngeCARVETREND.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeCARVETREND. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba lokho kungaba nemithelela emibi kakhulu enhliziyweni yakho. Uma ubona sengathi iCARVETREND inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Uma uphuze iCARVETREND 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.

Izimpawu zomthamosilinganiso oweqile kungenzeka zibandakanye lokhu:

- Ukweqisa kancane kumthamosilinganiso kungaholela ekutheni ube nomfutho wegazi ophansi (okuhambisana nesiyezi noma i*vertigo*; kungenzeka futhi uquleke) kanye nenhliziyo eshaya

kancane. Ngokuvamile esimweni esinjalo kwanele ukunciphisa umthamosilinganiso futhi kungaba wusizo ngisho nokuyeka okwesikhashana ukusebenzisa lo muthi.

- Ukweqisa kakhulu kumthamosilinganiso kungaphazamisa kakhulu ukuhamba nokugeleza kwegazi emzimbeni, ukuphefumula, ukusebenza kwenhliziyo kanye nokuhlala komuntu ephapheme, ebona konke okwenzekayo. Udokotela uzothatha izinyathelo ezifanele zokwelapha izinkomba nezimpawu zomthamosilinganiso oweqile.

Ngenkathi ulinde usizo lokwelashwa, futhi uma uphapheme ungaqulekile, zama ukuphalaza ukuze ukhiphe lokho okusesiswini. Lala phansi, wehlise ikhanda, izinyawo zithi ukuphakama kancane. Uma isiguli siqulekile, silalise ngohlangothi futhi ungazami ukusiphalazisa.

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weCARVETREND:
Uma kwenzekile wakhohlwa ukuphuza umuthi wakho, phuza umthamosilinganiso wakho onqunyiwe ngokushesha emuva kokukhumbula ukuthi kumele uwuphuze. Kodwa-ke, uma sekusondele isikhathi sokuphuza umthamosilinganiso olandelayo, ungabe usawuphuza lowo mthamosilinganiso ongawuphuzanga kodwa esikhundleni salokho uphinde futhi uqale ukuphuza umthamosilinganiso ojwayelekile ngesikhathi esibekiwe. Ungalokothi uphuze imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iCARVETREND
Ungalokothi uyeke esithubeni nje ukusebenzisa amaphilisi ngoba lokho kungadala imithelela emibi kakhulu enhliziyweni yakho.
Esikhundleni salokho umthamosilinganiso kumele uncishiswe kancane kancane esikhathini esiyizinsuku eziyisikhombisa kuya kweziyi-14. Imithi yakho kumele uyisebenzise njalo futhi ngokuqhubekayo njengoba ekuyalelile udokotela wakho.
Uma sekuphele izinsuku ezingaphezu kwe-14 uyekile ukusebenzisa iCARVETREND, ukwelashwa kumele kuqalwe ngomthamosilinganiso ophansi kunayo yonke.

4. Imithelela engathandeki okungenzeka ibe khona

Akuyona yonke imithelela engathandeki ebikiwe yeCARVETREND equkethwe kuleli pheshana lolwazi. Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa iCARVETREND, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

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

- ukuvuvukala kwezandla, izinyawo, amaqakala, ubuso, izindebe, umlomo noma umphimbo okungenza kube nzima ukugwinya noma ukuphefumula
- ukuqubuka noma isikhumba esilumayo
- ukuquleka
- isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi, futhi esibizwa ngejondisi
- ukwehla kakhulu komfutho wegazi.

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze neCARVETREND oyisebenzile. 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:

- ukushaya kwenhliziyo ngokunensa okukhulu noma ukushaya kwenhliziyo ngesigqi esingahambelani kahle (izikhathi ezingaphansi kwama-55 ngomzuzu)
- ukuchama ngokweqile
- izinhlungu esifubeni
- ukuphazamiseka kokusebenza kwamehlo

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

CARVETREND 6,25/12,5/25 mg

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- isikhumba esiphaphathekile, nokuzizwa ubuthakathaka futhi uphelelwa wumoya
- ukuzimuka (ukukhuluphala) ngokushesha
- izinkinga zesisu ezinjengokuphelelwa wuthando lokudla, isisu esihambisayo/esikhiphayo, isicanucanu kanye nokuhlanza, ukuphathwa yisisu
- umfutho wegazi ophansi ohambisana ne*vertigo* noma isiyezi (ikakhulukazi lapho usukuma uma ngezinyawo)
- umfutho wegazi ophakeme
- ukuvuvukala
- ukutheleleka ngamagciwane kwamaphaphu nomgudu wokuphefumula
- ukushaya kwenhliziyo kancane
- ukukhathala kakhulu
- ikhanda elibuhlungu
- ubuhlungu emajoyintini noma emisipheni yomzimba
- amazinga aphakeme kashukela egazini noma ikholesteroli ephakeme, ubunzima bokulawula amazinga kashukela egazini uma ungumuntu onesifo sikashukela
- inkinga yokungaboni kahle emehlweni kanye namehlo abuhlungu, omile, alumayo
- ukuzizwa udabukile isikhathi eside
- ukuphefumula kanzima, okuhambisana nokubefuzela
- izandla noma izinyawo ezibandayo
- ubundikindiki kanye nezinhlungu emilenzeni nasezinyaweni
- izinhlungu emzimbeni wonke.

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
CARVETREND 6,25/12,5/25 mg

Imithelela engathandeki engavamile ukwenzeka:

- ukopha okungajwayelekile noma imihuzuko
- izinhlungu esifubeni noma ukungaphatheki kahle esifubeni
- ukungakwazi ukukhipha indle njalo
- imiphumela yokuhlolwa kokusebenza kwesibindi ebonisa okuxakile futhi okungajwayelekile
- izifo ezibangelwa wukungezwani komzimba wakho nemithi noma okunye okungama-aleji
- umuzwa osanaliti onsonsothayo ama*pins and needles*
- ukuzizwa udidekile
- ubunzima bokulawula isinye sakho, ikakhulukazi uma ungowesifazane
- ukungaqhanyelwa kanye nokuhluleka ukuhlala uqhanyelwe uze uqede ukwenza ucansi
- izimpawu zomkhuhlane
- izinkinga zesikhumba ezibangelwa ngama-aleji ezinjengama-*hives*, ukuluma kwesikhumba nomqubuko, ukujuluka kakhulu kunokwejwayelekile
- umlomo owomile kanye namehlo omile (okungakunika izinkinga uma ungumuntu ofaka ama*contact lens*)
- ukuqothuka kwezinwele.

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

Ukubika imithelela engathandeki

Uma uphathwa yimithelela engathandeki, khuluma nodokotela wakho noma usokhemisi. Lokhu kubandakanya ngisho naleyo mithelela engathandeki okungenzeka ikuphathe kodwa engabhaliwe kuleli pheshana. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngokusebenzisa ifomu lokubika imithelela engathandeki (“**6.04 Adverse Drug Reporting Form**”), elitholakala ku-inthanethi ngaphansi kwemibhalo namaphepha ashicileliwe abakwa-SAHPRA:

https://www.sahpra.org.za/Publications/Index/8. Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweCARVETREND.

5. Indlela yokugcina iCARVETREND

- Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.
- Yigcine endaweni epholile futhi eyomile (ezingeni lokushisa elingama-30 °C noma ngaphansi kwalokho).
- Ungalokothi ufake amaphilisi kwesinye isitsha ngoba kungenzeka axubane. Izingqwenjana eziyizigcinamaphilisi zigcine kwibhokisana lamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba asetshenziswe.
- Ungawasebenzisi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe kwibhokisana lawo.
- Yiphindisele emuva kusokhemisi wakho yonke imithi engasetshenziswanga.
- Ungalokothi ulahle imithi engasetshenziswanga ezinhlelweni zamapayipi okuchitha amanzi noma okuthutha indle (isibonelo, ezindlini zangasese).

6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

Okuqukethwe yiCARVETREND

Iphilisi ngalinye leCARVETREND 6,25 mg liqukethe i*carvedilol* engama-6,25 mg.

Iphilisi ngalinye leCARVETREND 12,5 mg liqukethe i*carvedilol* engama-12,5 mg.

Iphilisi ngalinye leCARVETREND 25 mg liqukethe i*carvedilol* engama-25 mg.

7. Ezinye izithako yilezi:

Collo*idal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, povidone,* ushukela wezitshalo.

8. Indlela ebukeka ngayo iCARVETREND kanye nalokho okuqukethwe ephaketheni layo

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

CARVETREND 6,25/12,5/25 mg

CARVETREND 6,25 mg: Iyiphilisi elimhlophe, elimise okweqanda, eliqumbile kancane nhlangothi zombili, elinomugqa onqamula phakathi ohlangothini olulodwa futhi ngakolunye uhlangothi elinophawu S2.

CARVETREND 12,5 mg: Iyiphilisi elimhlophe, elimise okweqanda, eliqumbile kancane nhlangothi zombili, elinomugqa onqamula phakathi ohlangothini olulodwa futhi ngakolunye uhlangothi elinophawu S3.

CARVETREND 25 mg: Iyiphilisi elimhlophe, eliyindingiliza, eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, elinomugqa onqamula phakathi ohlangothini olulodwa.

ICARVETREND itholakala emaphaketheni ayizigcinamaphilisi ze-*OPA/AL/PVC* nefoyela le-*aluminium* eziqukethe amaphilisi angama-30.

9. Umnikazi Wesitifiketi Sokubhaliswa

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10. Leli pheshana lolwazi lagcina ukubuyekezwa mhla ziyi-

13 kuZibandlela 2019

11. Inamba yokubhaliswa

CARVETREND 6,25 mg: S3 37/7.1.3/0276

CARVETREND 12,5 mg: S3 37/7.1.3/0277

CARVETREND 25 mg: S3 37/7.1.3/0278

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

CARVETREND 6,25/12,5/25 mg

CARVETREND 6,25 mg:	NAM NS2 08/7.1.3/0105
CARVETREND 12,5 mg:	NAM NS2 08/7.1.3/0104
CARVETREND 25 mg:	NAM NS2 08/7.1.3/0103
CARVETREND 6,25 mg:	BOT S2 BOT1101790
CARVETREND 12,5 mg:	BOT S2 BOT1101791
CARVETREND 25 mg:	BOT S2 BOT1101792
CARVETREND 6,25 mg:	ZAM POM 7580/12
CARVETREND 12,5 mg:	ZAM POM 7581/12