

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI  
UHLA LWEZINHLOBO ZEPHILISI IDYNACAZ MR**

**ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI**

S3

**IDYNACAZ 30 mg MR** engamaphilisi angena kancane kancane isikhathi eside egazini

**IDYNACAZ 60 mg MR** engamaphilisi angena kancane kancane isikhathi eside egazini

**IDYNACAZ 90 mg MR** engamaphilisi angena kancane kancane isikhathi eside agazini

Gliclazide

IDYNACAZ 30 mg MR iqukethe ushukela (*ilactose monohydrate* engama-73,50 mg ephilisini ngalinye).

IDYNACAZ 60 mg MR iqukethe ushukela (*ilactose monohydrate* engama-93,40 mg ephilisini ngalinye).

IDYNACAZ 90 mg MR iqukethe ushukela (*ilactose monohydrate* engama-140,10 mg ephilisini ngalinye).

**Ngaphambi kokuba uqale ukusebenzisa iDYNACAZ MR 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.
- IDYNACAZ MR 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 iDYNACAZ MR futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACAZ MR
3. Indlela yokusebenzisa iDYNACAZ MR

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4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iDYNACAZ MR
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

**1. Iyini iDYNACAZ MR futhi isetshenziselwani?**

IDYNACAZ MR iqukethe *igliclazide* futhi iyingxenye yeqoqwana lemithi ebizwa nge*sulphonylurea antidiabetic medicine*. Isetshenziselwa ukwelapha uhlobo oluthile lwesifo sikashukela olubizwa ngohlobo lwesibili lwesifo sikashukela (*type 2 diabetes*) kubantu abadala uma ukulandela uhlelo lokudla okunempilo, ukuzivocavoca kanye nokwehlisa isisindo somzimba, uma kukodwa, kungenawo amandla anele okugcina ushukela usezingeni elifanelekile egazini.

Uma unohlobo lwesibili lwesifo sikashukela, umthamo we-*insulin* ekhiqizwa ngamanyikwe akho kungenzeka ungabi wumthamo owanele noma kungenzeka ukuthi mhlawumbe umzimba wakho awuyisebenzisi ngendlela efanele i-*insulin* futhi kungenzeka ukuthi udinge i-*insulin* eyengeziwe. IDYNACAZ MR isebenza ngokuthi yenze ukuthi amanyikwe akho akhiphe i-*insulin* eyengeziwe ingene egazini lakho.

**2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACAZ MR**

**Ungalokothi usebenzise iDYNACAZ MR:**

- uma umzimba wakho walana *negliclazide*, *sulphonylureas* (imithi yokwelapha isifo sikashukela), *amasulphonamides* (uhlobo oluthile lwama-antibhayothikhi), noma uma walana nanoma yisiphi esinye isithako seDYNACAZ MR (bheka isigaba 6)
- uma unohlobo lokuqala lwesifo sikashukela (*type 1 diabetes mellitus*) (iziguli eziphethwe wuhlobo lokuqala kwesifo sikashukela azikwazi ukukhiqiza noma ukukhipha i-*insulin* emanyikweni azo)
- uma unamakethone *bodies* kanye noshukela emchamweni wakho (lokhu kungenzeka kusho ukuthi unediabetic keto-acidosis), *idiabetic pre-coma* (isimo esandulela ukuquleka isikhathi

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eside ungaphaphami esibangelwa yisifo sikashukela) noma *diabetic coma* (ukuquleka ungaphaphami okubangelwa yisifo sikashukela)

- uma uphethwe yisifo sesibindi
- uma uphethwe yisifo sezinso
- uma usebenzisa umuthi wokwelapha izifo ezibangelwa wukhunta (*fungal infections*) obizwa ngemiconazole (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neDYNACAZ MR)
- uma uyingane, njengoba lungekho ucwaningo olwenziwe lokucubungula ukuphepha kweDYNACAZ MR ezinganeni
- uma ukhulelwe noma usancelisa umntwana wakho

**Izixwayiso kanye nezinto okumele uziqikelele**

**Qaphela kakhulu uma usebenzisa iDYNACAZ MR:**

Ngaphambi kokuba usebenzise iDYNACAZ MR kumele ukhulume nodokotela wakho. Kumele ulandele uhlelo lokwelashwa olunqunyelwe ngudokotela wakho ukuze ushukela wakho ufinyelele emazingeni afanele egazini. Lokhu kusho ukuthi, ngaphandle nje kokudla amaphilisi, kumele ulandele uhlelo lokudla ukudla okunomsoco, uzivocavoce, futhi uma kudingekile unciphise isisindo somzimba wakho.

Ngenkathi welashwa ngeDYNACAZ MR kudingekile ukuthi uwabhekisise njalo futhi ngokuqhubekayo amazinga kashukela egazini lakho (futhi uma kunokwenzeka uwaqaphele nasemchamweni wakho), futhi ubhekisise namazinga akho *eglycated haemoglobin* (HbA<sub>1c</sub>).

Evikini lokuqala lokwelashwa, kungenzeka buphakame ubungozi bokuthi ube noshukela ophansi egazini futhi kuyadingeka ukuthi lokhu kuqashelwe futhi kubhekisise ngokuqhubekayo. Izizwombe eziqhubeka isikhathi eside futhi ezibucayi ze*hypoglycaemia* (ushukela ophansi egazini), noma ngabe

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lokhu uyakwazi ukukulawula ngokuthi udle ukudla okunoshukela, kudinga ukwelashwa ngokushesha, ngisho nokulaliswa esibhedlela imbala.

Kungenzeka kube nokwehla kukashukela egazini (*hypoglycaemia*):

- uma uyisiguli, ikakhulukazi esesikhulile ngokweminyaka noma uma uhluleka ukwenza lokho oyalelwe ukuthi ukwenze
- uma ungadli isidlo esifanelekile njalo ngezikhathi zokudla noma uma uvele ungadli lutho weqe izikhathi zokudla
- uma uzile ukudla
- uma ungondlekile kahle emzimbeni
- uma uguqula uhlelo lwakho lokudla
- uma ukhuphula izinga lokuzivocavoca nokunyakazisa umzimba ngaphezu kwelijwayelekile futhi ungatholi izikhuthazimandla (amakhabhohayidirethi) ezilingana nalokhu kukhuphuka kwezinga
- uma uphuza utshwala kakhulu, ikakhulukazi uma weqisa nezikhathi zokudla
- uma unanoma yisiphi isifo esixakile semithambo yegazi (*arteries and veins*), kubandakanya nesifo senhliziyo esinamandla
- uma njengamanje usebenzisa noma uma kamuva nje usanda kuyeka ukusebenzisa imithamosilinganiso ephakeme yamacorticosteroids (okuyimithi esetshenziselwa ukwelapha izinhlungu nokuvuvukala)
- uma unesifo esibangelwa yinkinga yamahomoni (izinkinga zokusebenza kwendlala yegilo, izinkinga ze *pituitary gland* noma ze-*adrenal cortex*)
- uma kunciphe kakhulu ukusebenza kwesibindi sakho noma izinso
- uma usebenzisa, ngesikhathi esifanayo, eminye imithi noma amakhambi emvelo
- uma uphuze umthamosilinganiso weDYNACAZ MR oweqile

Uma unoshukela ophansi egazini kungenzeka ube nezimpawu ezilandelayo:

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ikhanda elibuhlungu, ukulamba kakhulu, isicanucanu, ukuhlanza, ukukhathala komzimba noma kwengqondo, izinkinga zokungalali kahle, ukungahlaliseki, ulaka, ukuhluleka ukugxilisa ingqondo, ukuncipha kwamandla okuhlala uqaphile ubona konke okwenzekayo kanye nokuthatha izinyathelo ngokushesha, ingcindezi yengqondo, ukudideka, izinkinga eziphathelene nokukhuluma noma ukubona kahle, ukuthuthumela, ukuphazamiseka kwezinzwa, isiyenzi kanye nokuba sesimweni sokungakwazi ukuzenzela okuthile nokuzisiza.

Kungenzeka futhi kube nezinkomba nezimpawu ezilandelayo: ukujuluka, isikhumba esimanzi ngenxa yomjuluko, itwetwe nexhala, ukushaya kwenhliziyo ngokushesha noma ngesigqi esingahambelani kahle, umfutho wegazi ophakeme, izinhlungu esifubeni ezifika ngokushesha futhi ungazelele okungenzeka zisabalalele nasezindaweni eziseduzane (*angina pectoris*).

Uma amazinga kashukela egazini eqhubeka nokwehla kungenzeka ube nenkinga yokudideka okukhulu (*delirium*), ube nokudlikizela komzimba, uhluleke ukuzithiba nokulawula imizwa, imicabango nezenzo, ukuphefumula kwakho kungenzeka kube kufushane futhi nokushaya kwenhliziyo yakho kunense, kungenzeka uquleke.

Esikhathini esiningi izimpawu zikashukela ophansi egazini zinyamalala ngokushesha lapho udla ukudla okuthile okunoshukela, amaphilisi eglukhosi/kashukela, amagengqele/amakhyubhu kashukela, ujudi onoshukela, itiyeli elifakwe ushukela. Khumbula ukuthi izinandisi zokuzenzela azisebenzi. Ngakho-ke kumele njalo uhlale uphethe uhlobo lukashukela (amaphilisi eglukhosi, amagengqele/amakhyubhu kashukela). Xhumana nodokotela wakho noma isibhedlela esiseduze nawe uma ukudla ushukela kungakusizi noma uma izimpawu ziphinda ziqala phansi futhi.

Ukuze ugweme imithelela engathandeki yezinkinga zesisu (bheka Imithelela engathandeki), amaphilisi akho kumele uwaphuze ngenkathi udla isidlo sasekuseni/ibhulakufesi.

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Uma kwenzeka uphathwa yimithelela engathandeki ephathelene nesibindi, udokotela wakho kungenzeka awushintshe umuthi wakho.

Uma kunomlando emndenini noma uma wena unolwazi lokuthi uphethwe yisifo esiphathelene nofuzo sokuntuleka kwe*glucose-6-phosphate dehydrogenase (G6PD)* (inkinga yokungasebenzi kahle kwezingqalampilo zegazi ezibomvu), kungenzeka kube nokwehla kwezinga le*haemoglobin* kanye nokucekeleka phansi kwezingqalampilo zegazi ezibomvu (*haemolytic anaemia*). Xhumana nodokotela wakho ngaphambi kokusebenzisa iDYNACAZ MR.

Kungenzeka zingabi khona, noma zingabonakali ngokucacile, noma zivele ngesivinini esiphansi kakhulu izimpawu zikashukela ophansi egazini, noma ungasheshi ukubona ukuthi sehlile izinga likashukela wakho egazini. Lokhu kungenzeka uma uyisiguli esesikhulile ngokweminyaka esisebenzisa imithi ethile (isibonelo, leyo mithi esebenza ohlelweni lwezinzwa zomzimba olubandakanya ubuchopho nomfunkulu kanye nam*beta blockers*).

Kusemqoka ukuthi uthole ukuthi yiziphi izimpawu zikashukela ophansi egazini ezivamise ukukuphatha, ukuze uzelaphe ngokushesha. Kumele futhi ufundise amalungu omndeni wakho mayelana nezimpawu ze*hypoglycaemia* nokuthi zelashwa kanjani.

Izimpawu zikashukela ophakeme egazini (*hyperglycaemia*) kungenzeka zenzeke lapho: igliclazide ingakawehlisi ngokwanele ushukela egazini, lapho ungalulandelanga uhlelo lokwelashwa olunqunyelwe ngudokotela wakho, uma usebenzisa umuthi owenziwe ngekhambi i*St John's wort (Hypericum perforatum)*, noma ezimweni ezikhethekile zokuphathwa yingcindezi yengqondo nomphefumulo. Uma ungaphansi kwezimo zengcindezi yengqondo nomphefumulo (izingozi, ukuhlinzwa noma imfiva, njll.) kungenzeka udokotela wakho akushintshe akwelaphe nge-*insulin*.

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Izimpawu zikashukela ophakeme egazini zingabandakanya ukoma, ukuchama njalo, umlomo owomille, isikhumba esomile esilumayo, izifo zesikhumba kanye nokwehla kwezinga lokusebenza kahle komzimba.

Uma kwenzeka uphathwa yilezi zimpawu, kumele uxhumane nomhlinzeki wakho wosizo lwezempilo nokwelashwa noma usokhemisi.

Emuva kokusebenzisa iDYNACAZ MR isikhathi eside kungenzeka ehle amandla okusebenza kwayo futhi kungenzeka udokotela wakho awukhuphule umthamosilinganiso wakho futhi akucele ukuthi ukhuphule amahlandla nezikhathi zokuqapha nokubhekisisa ngokuqhubekayo amazinga kashukela wakho egazini.

Ukuphazamiseka kwamazinga kashukela egazini kungenzeka lapho unikezwe iDYNACAZ MR ukuthi uyisebenzise kanyekanye nemithi eyingxenywe yeqoqwana lama-antibhayothikhi ebizwa ngama*fluoroquinolones*, ikakhulukazi ezigulini esezikhulile ngokweminyaka. Kulesi simo-ke udokotela wakho uzokukhumbuza ngokubaluleka kokuqapha nokubhekisisa ngokuqhubekayo amazinga kashukela egazini lakho.

Kunamathuba okuthi uphathwe yizinkinga zesikhumba ezibucayi (*itoxic dermal necrolysis* kanye ne-*allergic vasculitis*).

Izimpawu zibandakanya isibhadu esibuhlungu esibomvu esisabalala ngokushesha, ukuxebuka kwesikhumba okungenawo amabhamuza, izindawo ezinesikhumba esingambozekile, ukungaphatheki kahle, imfiva, amachashazi namabadlana anombala osabukhwebezane esikhunjeni, umqubuko obangelwa wukwalana nokudla/nomuthi othile (*hives*), izilonda ezivulekile).

Udokotela wakho kungadingeka ukuthi enze ukuhlolwa/amathesti ukuze aqaphe isimo sakho ngaphambi kokwelashwa noma ngenkathi welashwa.

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Akuqinisekiswa ukuphepha kanye nokusebenza kahle kweDYNACAZ MR ezinganeni (bheka isigatshana esithi Ungalokothi usebenzise iDYNACAZ MR).

**Ukusetshenziswa kweminye imithi neDYNACAZ MR**

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

Imithi elandelayo iyabukhuphula ubungozi bokuphathwa yi *hypoglycaemia*, ngisho nobungozi bokuquleka isikhathi eside ungaphaphami futhi akumele isetshenziswe:

- umuthi oqukethe *imiconazole* (osetshenziselwa ukwelapha ukugula okubangelwa wukhuntha) (bheka isigatshana esithi Ungalokothi usebenzise iDYNACAZ MR).

Imithi noma imikhiqizo elandelayo kungenzeka yenze ukuthi ehle kakhudlwana kunokwejwayelekile amazinga kashukela egazini lakho uma iphuzwa kanyekanye neDYNACAZ MR futhi akulungile neze ukuthi isetshenziswe:

- *iphenylbutazone* (esetshenziselwa ukwelapha izinhlungu nokuvuvukala)
- utshwala bukhuphula ubungozi bokuphathwa yi *hypoglycaemia* (ushukela ophansi egazini) kanye nokuquleka isikhathi eside ungaphaphami. Kumele ubugweme utshwala kanye nemithi equkethe i-alkhoholi.

Kungenzeka aqine amandla eDYNACAZ MR okwehlisa ushukela egazini futhi kungenzeka ube nezinkomba zamazinga kashukela ophansi egazini uma usebenzisa omunye wale mithi elandelayo:

- *isulphinpyrazone* (umuthi wokwelapha igawuthi)
- ama-*anabolic steroids* (ihomoni eyi-*steroid* ekhuthaza ukukhula kwemisipha yomzimba) kanye nama-*androgens* (ihomoni yobulili besilisa kanye nezicibunjalo zowesilisa eziphathelene nezocansi nenzalo)



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- imithi ethile esetshenziselwa ukwelapha umfutho wegazi ophakeme kanye nesifo senhliziyo ebizwa ngama *ACE inhibitors* (*icaptopril, enalapril, quinidine, quinine* kanye ne *clonidine*), kanye nama-*antidysrhythmics* (*disopyramide*)
- imithi esetshenziselwa ukwelapha umfutho wegazi ophakeme kanye nokuhluleka kwenhliziyo ukusebenza ngendlela efanele (*amabeta blocker, ACE-inhibitor* anjenge *captopril*, noma i-*enalapril*)
- ama-antibhayothikhi (*chloramphenicol, sulphonamides, quinolones, tetracyclines, clarithromycin*)
- imithi ethile yokwelapha ingcindezi yengqondo enjenge *fluoxetine* (*monoamine-oxidase inhibitors*)
- imithi ethile esetshenziselwa ukwelapha ukugula okubangelwa wukhunta, enjenge *ketconazole, itraconazole, voriconazole, fluconazole*
- umuthi wokucindezela uthando lokudla i *fenfluramine*
- *irantidine* kanye ne *cimetidine* (imithi esetshenziselwa ukwelapha isilungulela)
- ama *fibrates* (anjenge *clofibrate*) asetshenziselwa ukwelapha ikholesteroli ephakeme
- i-*insulin* kanye neminye imithi yokwelapha isifo sikashukela ephuzwayo (enjenge-*acarbose, metformin, thiazolidinediones, GLP-1 receptor inhibitors*)
- imithi ethile esetshenziselwa ukwelapha izinhlungu nokuvuvukala (ama *NSAID* kanye nama *salicylates*)
- ama *beta-blockers* (imithi esetshenziselwa ukulawula isigqi sokushaya kwenhliziyo, ukwelapha izinhlungu esifubeni (*angina*), kanye nokunciphisa umfutho wegazi ophakeme) kungenzeka akhuphule ithuba lokuthi ube nenkinga kashukela ophakeme noma ophansi egazini. Futhi kungenzeka afihle izimpawu zikashukela ophansi egazini.

Amandla e *glucoside* okwehlisa ushukela egazini kungenzeka ehle futhi kungenzeka akhuphuke amazinga kashukela egazini uma omunye wale mithi elandelayo usetshenziswa kanyekanye ne DYNACAZ MR:

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- *idanazol* esetshenziselwa ukwelapha izinkinga eziphathelene namabele, ukopha kakhulu kowesifazane ngenkathi esesikhathini kanye ne-*endometriosis* ayikulungele neze ukusetshenziswa kanyakanye neDYNACAZ MR. Uma uhluleka ukugwema lo muti, kumele kube nokubhekiswa nokuqashelwa njalo futhi ngokuqhubekayo koshukela emchamweni wakho nasegazini. Kungadingeka ukuthi uguqulwe umthamosilinganiso wakho weDYNACAZ MR
- *i-epinephrine (adrenaline)*, imithi yesifuba somoya (*salbutamol, terbutaline*), imithi yokukhwehlela nomkhuhlane equkethe *iephedrine* kanye ne*pseudoephedrine*
- *amacorticosteroids* (imithi efana ne*cortisone* esetshenziselwa ukwelapha ukuvuvukala)
- *amacalcium channel blockers, clonidine, diazoxide* (imithi yemithambo yegazi nenhliziyo esetshenziselwa ukwelapha izinkinga zenhliziyo)
- *ichlorpromazine* (imithi eyehlisa ixhala noma elalisayo futhi esetshenziselwa ukwelapha isicanucanu noma ukuhlanza)
- *ilithium* (esetshenziselwa ukwelapha izinhlobo ezithile zengcindezi yengqondo)
- *amathiazide diuretics* (okungamaphilisi amanzi)
- umuthi wesithuthwane (isifo sokuwa) onjenge*phenytoin*
- *iglucagon* (ihomoni elekelela ukuguqulwa kwe*glycogen* ibe yi*glucose*)
- amahomoni abesifazane i-*oestrogen* kanye ne*progesterone*
- imithi yokwelapha izifo ezibangelwa ngamagciwane *irifampicin* kanye ne-*isoniazid*
- amahomoni endlala yegilo
- *amagluocorticoids* (asetshenziselwa ukulekelela umzimba ukuthi ugaye amakhabhohayidirethi, amaphrotheyini kanye namafutha)
- imithi yokwelapha isifuba somoya noma esetshenziswa ngenkathi owesifazane ebeletha (i-*intravenous salbutamol, ritodrine* kanye ne*terbutaline*).

Inkinga yokuphazamiseka kukashukela egazini (ushukela wegazi ophansi kanye noshukela wegazi ophakeme) ingenzeka lapho imithi eyingxenywe yeqoqwana lama-antibhayothikhi ebizwa

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ngama*fluoroquinolones* isetshenziswa kanyekanye neDYNACAZ MR, ikakhulukazi ezigulini esezikhulile ngokweminyaka.

IDYNACAZ MR kungenzeka ikhuphule amandla emithi engama-*anticoagulants* (imithi enciphisa ukushuba nokuphenduka kwegazi libe ngamahlule isibonelo, i*warfarin*). Kungadingeka ukuthi uguqulwe umthamosilinganiso wakho wama-*anticoagulant*.

**Ukuphuza iDYNACAZ MR nokudla kanye nophuzo:**

IDYNACAZ MR kumele iphuzwe nokudla. Iphilisi kumele uligwinye lonke liphelele, ulehlise ngamanzi awuhhafu wengilazi futhi kumele uliphuze ngaphambili nje kancane kokudla isidlo sasekuseni esiphelele noma isidlo sokuqala sosuku. Akumele weqise isidlo emuva kokuphuza amaphilisi. Akulungile ukuphuza utshwala ngoba kungenzeka bukuguqule ngendlela engalindelekile ukulawuleka kukashukela wakho egazini.

**Ukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana**

Uma ukhulelwe noma uncelisa, noma uma ucabanga ukuthi mhlawumbe ukhulelwe noma uma uhlela ukuthola umntwana, bonisana nodokotela wakho, usokhemisi noma omunye umhlinzeki wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise lo muthi.

Ungalokothi usebenzise iDYNACAZ MR uma ukhulelwe noma uma usancelisa umntwana wakho (bheka isigatshana esithi Ungalokothi usebenzise iDYNACAZ MR).

**Ukushayela kanye nokusebenzisa imishini:**

Kungenzeka amandla akho okuhlala uqaphile ubona konke okwenzekayo kanye nokuthatha izinyathelo ngokushesha aphazanyiswe yi*hypo-* noma *hyperglycaemia*, ikakhulukazi lapho usaqala ukwelashwa noma lapho uguqula imithamosilinganiso. Kumele uzazi izimpawu ze*hypoglycaemia* (ushukela ophansi egazini) ezibandakanya isiyenzi, ukuhluleka ukugxilisa kahle ingqondo, ukudideka, ukozela kanye namehlo afiphele.

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Akulula ukubikezela njalo ukuthi iDYNACAZ MR izoba nomthelela ongakanani emisebenzini yansukuzonke yesiguli. Kumele uqinisekise ukuthi awuyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho usubonile ukuthi iDYNACAZ MR ikuphatha kanjani emzimbeni.

**IDYNACAZ MR iqukethe ushukela wobisi, *ilactose*.**

IDYNACAZ MR iqukethe ushukela wobisi. Uma uke watshelwa ngudokotela wakho ukuthi umzimba wakho uyahluleka ukubekezelela izinhlobo ezithile zikashukela, xhumana nodokotela wakho ngaphambi kokusebenzisa lo muthi.

**3. Isetsheziwa kanjani iDYNACAZ MR**

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

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeDYNACAZ MR. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba kungenzeka zibuye izimpawu zoshukela ophakeme egazini. Uma ubona sengathi iDYNACAZ MR inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso ofanelekile azokunikeza wona emuva kokubukisisa ukuthi umzimba wakho uphatheke kanjani emuva kokusebenzisa lo muthi futhi emuva kokubheka izinga likashukela egazini lakho. Iphilisi kumele uligwinye lonke liphelele, ungalihlafuni, futhi kumele ulehlise ngamanzi awuhhafu wengilazi ngaphambili nje kancane kokudla isidlo sasekuseni esiphelele noma isidlo sokuqala sosuku (futhi kungaba kuhle uma uliphuza ngesikhathi esifanayo nsukuzonke). Akumele weqise isidlo emuva kokuphuza amaphilisi. Amaphilisi

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iDYNACAZ MR 90 mg ungawahlukanisa abe yizingxenye ukuqinisekisa ukuthi uwaphuza ngendlela oyalelwe ngayo ngudokotela wakho.

*Kubantu abadala:*

Umthamosilinganiso onconyiwe yiphilisi elilodwa kuya kwamane angama-30 mg noma amaphilisi amabili angama-60 mg (umthamosilinganiso ophelele ngama-120 mg) okusho ukuthi ama-30 kuya kuma-120 mg athathwa njengomthamosilinganiso owodwa nsukuzonke, ophuzwa nesidlo sasekuseni. Uma kuqaliswa uhlelo lokwelapha ngenhlanganisela yemithi lapho iDYNACAZ MR isetshenziswa kanyekanye *nemetformin*, *i-alpha glucosidase inhibitor*, *i-thiazolidinedione*, *idipeptidyl peptidase-4 inhibitor*, *iGLP-1 receptor agonist* noma *i-insulin*, udokotela wakho uzonquma ukuthi ungakanani umthamosilinganiso azokunikeza wona oqondene nomuthi ngamunye azokunikeza wona.

*Ukuguqulwa komthamosilinganiso:*

Uma amazinga kashukela wakho egazini, ngaphambi kokudla, engehlanga ngendlela egculisayo, udokotela wakho kungenzeka awukhuphule ngokuqhubekayo umthamosilinganiso uyofinyelela kuma-60, ama-90 noma ama-120 mg ngosuku (amaphilisi amabili kuya kwamane angama-30 mg). Udokotela uzokuyalela ukuthi uzowukhuphula kanjani umthamosilinganiso wakho, kodwa ngokuvamile inani lamaphilisi kumele ulikhuphule okungenani njalo emuva kwenyanga eyodwa. Umthamosilinganiso wansukuzonke akumele ube ngaphezu kwama-120 mg.

*Izingane:*

Akuqinisekiswa ukuphepha kanye nokusebenza kahle kwe-DYNACAZ MR ezinganeni namabhungu namatshitshi, ngakho-ke akumele neze isetshenziswe ezinganeni.

**Uma uphuze iDYNACAZ MR engaphezulu kwaleyo okumele uyiphuze**

Uma kwenzekile waphuza umthamosilinganiso oweqile, bonisana nodokotela wakho noma

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usokhemisi. Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu.

Izimpawu zomthamosilinganiso wamaphilisi oweqile kungenzeka zibandakanye lokhu:

Ushukela ophansi egazini (futhi okubizwa nge*hypoglycaemia*)

Izimpawu zingaba ngcono noma zelapheke ngokuthi ngokushesha udle ushukela (amagengqele amane kuya kwayisithupha) noma uphuze isiphuzo esinoshukela, ulandelise ngokudla okulula okuphelele noma ngesidlo soqobo esiphelele. Uma isiguli siqulekile tshela udokotela wakho ngokushesha futhi ufonele abezimo eziphuthumayo. Kumele lokhu ukwenze futhi uma kukhona othile, isibonelo ingane, ophuze lo mkhiqizo engahlosile. Iziguli eziqulekile akumele zifunzwe ukudla noma isiphuzo.

Kumele uqinisekise ukuthi ngaso sonke isikhathi kunomuntu othile owazisiwe ngaphambilini ongafonela udokotela uma kwenzeka kuvela isimo esiphuthumayo.

**Uma kwenzeka ukhohlwa ukuphuza iDYNACAZ MR**

Uma kwenzekile wakhohlwa ukuphuza umthamosilinganiso weDYNACAZ MR, waphuze ngokushesha amaphilisi akho emuva kokukhumbula ukuthi kumele uwaphuze, bese emuva kwalokho uqhubeka nokuphuza iDYNACAZ MR ngesikhathi esijwayelekile. Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Kusemqoka ukuphuza umuthi wakho nsukuzonke ngoba phela umuthi ophuzwa nsukuzonke usebenza kangcono.

**Uma uyeka ukusebenzisa iDYNACAZ MR**

Ukuyeka ukusebenzisa lo muthi kungadala ukukhuphuka koshukela egazini (*hyperglycaemia*) okukhuphula ubungozi bokuphathwa yizifo nezinkinga ezibangelwa yisifo sikashukela esingalawulekile kahle.

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**4. Imithelela engathandeki okungenzeka ibe khona**

Akuyona yonke imithelela engathandeki ebikiwe yeDYNACAZ MR efakiwe kuleli pheshana lolwazi.

Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa iDYNACAZ MR, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iDYNACAZ MR 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

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithethelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze ne-DYNACAZ MR 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:

- i *Stevens-Johnson syndrome* noma ezinye izinkinga zesikhumba ezibucayi kakhulu (eziqala ngokubonakala kwezimpawu ezinjengezomkhuhlane, kulandelwe wumqubuko obuhlungu obomvu noma osabukhwebezane ngokombala osabalalayo kanye namabhamuza)
- ushukela ophansi egazini — i *hypoglycaemia* (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iDYNACAZ MR ukuze ubone uhlu lwezimpawu)
- inkinga yokuhluleka kwesibindi ukusebenza ngendlela efanele (izinkomba zibandakanya ukuguquka kwesikhumba namehlo kube nombala ophuzi (ijondisi) kanye nezinhlungu engxenyeni yesisu engasenhla ngakwesokudla)

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- izinkinga zezinso (ukuphuma komchamo omningi kunalokho okujwayelekile kuwena lapho uchama noma ukuchama njalo)

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:

- ikhanda elibuhlungu, isiyezi, ukozela
- ukuqunjelwa, isifo sohudo, izinhlungu esiswini noma ukungaphatheki kahle, ukuqina nokudonseka kwemisipha yesisu okubuhlungu, ukuvalekelwa noma ukuvulekelwa yinhliziyi, isilungulela, isisu esiqumbile, ukugcwala komoya esiswini (umsuzo), ukuzimuka, isicanucanu, ukuhlanza, ukuguquka komuzwa wokunambitha (umuzwa wokunambitha osansimbi, phecelezi, *metallic taste*).

Imithelela engathandeki engavamile ukwenzeka:

- ukwehla kwenani lezingqalampilo egazini okuholela kwimiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile kubandakanya ne-anemiya
- amazinga esodium ephansi egazini, isifo sokuzizacisa
- ukubona ngendlela efiphele, ukungaboni kahle emehlweni okulokhu kuqhubeka njalo nokuba kubi
- ukungasebenzi kwesibindi kahle nangendlela ejwayelekile (indle enombala wobumba, umchamo omnyama, umzimba olumayo, ukuphelelwa wuthando lokudla, amehlo anombala ophuzi noma isikhumba esinombala ophuzi).

Le mithethelela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- umqubuko obangelwa wukwalana nokudla/nomuthi othile (*hives*), isikhumba esilumayo, ukuvuvukala kwesikhumba, ukuqubuka, ukushintsha kombala wesikhumba ube bomvu, ukuzwela kakhulu ekukhanyeni, isikhumba esomile, isikhumba esinamabhamuza noma



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esixebukayo, ukuncipha kogqinsi lwesikhumba, isikhumba esiphaphathekile, ukuhuzuka okungajwayelekile

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. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngohleloxhumano lwe-inthanethi ukubazisa ngokuphatheka kabi okubangelwa wumuthi othile, ngokulandela lelinki elandelayo:

<https://www.sahpra.org.za/Publications/Index/8>

Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweDYNACAZ MR. Futhi ungathumela i-imeyili ngqo enkampanini, [pharmacovigilance@pharmadynamics.co.za](mailto:pharmacovigilance@pharmadynamics.co.za), ngenhloso yokuqinisekisa ukuphepha komkhiqizo.

**5. Indlela yokugcina iDYNACAZ MR**

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine endaweni eyomile ezingeni lokushisa elingama-30 °C noma ngaphansi kwalokho. Yivikele ekukhanyeni.

Izingqwenjana eziyizigcinamaphilisi kumele zigcinwe 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**

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**Okuqukethwe yiDYNACAZ MR**

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi*gliclazide*.

DYNACAZ 30 mg MR: Iphilisi ngalinye elingena kancane kancane isikhathi eside egazini liqukethe *igliclazide* engama-30 mg. Iphilisi ngalinye elingama-30 mg liqukethe ushukela (*lactose monohydrate* engama-73,50 mg ephilisini ngalinye).

DYNACAZ 60 mg MR: Iphilisi ngalinye elingena kancane kancane isikhathi eside egazini liqukethe *igliclazide* engama-60 mg. Iphilisi ngalinye elingama-60 mg liqukethe ushukela (*lactose monohydrate* engama-93,40 mg ephilisini ngalinye).

DYNACAZ 90 mg MR: Iphilisi ngalinye elingena kancane kancane isikhathi eside egazini liqukethe *igliclazide* engama-90 mg. Iphilisi ngalinye elingama-90 mg liqukethe ushukela (*lactose monohydrate* engama-140,10 mg ephilisini ngalinye).

**7. Ezinye izithako yilezi**

DYNACAZ 30 mg MR:

*Calcium carbonate, colloidal silica dioxide, hypromellose, lactose monohydrate, magnesium stearate.*

DYNACAZ 60 mg MR kanye neDYNACAZ 90 mg MR:

*Hypromellose, lactose monohydrate, magnesium stearate, silica colloidal anhydrous.*

**8. Indlela ebukeka ngayo iDYNACAZ MR kanye nalokho okuqukethwe ephaketheni layo**

DYNACAZ 30 mg MR: Ingamaphilisi anombala omhlophe kuya kumbala ocishe ube mhlophe, amise okweqanda, aqumbile kancane nhlangothi zombili (anobude obungama: 11 mm x ububanzi obungama-5,5 mm) anonqenqema olutshekile.

DYNACAZ 60 mg MR: Ingamaphilisi anombala omhlophe kuya kumbala ocishe ube mhlophe, amise okweqanda, aqumbile kancane nhlangothi zombili angama-13 mm.

DYNACAZ 90 mg MR: Ingamaphilisi anombala omhlophe kuya kumbala ocishe ube mhlophe, anesakhiwo esisagobongwana, aqumbile nhlangothi zombili angama-17 - 17,5 mm anemigqa emibili enqamula phakathi ezungeze iphilisi.

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Umugqa onqamula phakathi wenzelwe kuphela ukuthi iphilisi ligwinyeke kalula hhayi ukuthi lihlukaniswe libe yimithamosilinganiso elinganayo.

Amaphilisi iDYNACAZ 30 mg MR agcinwe kumaphakeshana aqukethe izingqwenjana eziyizigcinamaphilisi akhiwe nge-*Aluminium/PVC* aqukethe amaphilisi ayi-10 kuqwenjana oluyisigcinamaphilisi olungumsweswana ngalunye; ibhokisana ngalinye elinombhalo ngaphandle liqukethe amaphilisi angama-60.

Amaphilisi iDYNACAZ 60 mg MR agcinwe kwizingqwenjana eziyizigcinamaphilisi ezingumsweswana ezakhiwe nge-*OPA/Al/PVC* ecacile kanye nefoyela le-*aluminium*. Amaphilisi angama-28 (2 x 14) noma angama-30 (2 x 15) azofakwa kwibhokisana likakhadibhodi.

Amaphilisi iDYNACAZ 90 mg MR agcinwe kwizingqwenjana eziyizigcinamaphilisi ezingumsweswana ezakhiwe nge-*OPA/Al/PVC* kanye nefoyela le-*aluminium*. Izingqwenjana eziyizigcinamaphilisi ezingumsweswana eziqukethe amaphilisi angama-30 noma angama-60 noma angama-90 zizofakwa kwibhokisana likakhadibhodi.

**9. Umnikazi Wesitifiketi Sokubhaliswa**

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**10. Leli pheshana lolwazi lagcina ukubuyezwa mhla ziyi-**

15 kuNhlangulana 2021

**11. Inamba yokubhaliswa**

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DYNACAZ 30 mg MR: A42/21.2/0249

DYNACAZ 60 mg MR: A48/21.2/1184

DYNACAZ 90 mg MR: A53/21.2/0083

DYNACAZ 30 mg MR **Namibia:** NAM NS2

12/21.2/0110