

# Isifinyezo Semiphumela Yokuhlolwa Kwemitholampilo

Yomuntu kazana



**Ucwaningo lokufunda ukuthi usebenza ngempumelelo futhi uphephe kangakanani umuthi obizwa nge-bimatoprost osebenza ukwelapha iziguli ezindala ezine-open-angle glaucoma noma i-ocular hypertension**

## Isifinyezo Sesisonke

- Abacwaningi bafuna indlela engcono yokwelapha i-open-angle glaucoma nomfutho wegazi ophezulu (weso).
- Inhloso enkulu yalolu cwaningo kwakuwukufunda ukuthi imithamo emibili ehlukene ye-bimatoprost sustained release (SR) yaqhathaniswa kanjani nokwelashwa nge-timolol, umuthi ovunyiwe wokwehlisa umfutho wamehlo, ukubona ukuthi yikuphi ukwelashwa okwehlisa ngempumelelo umfutho ezigulini ezine-open-angle glaucoma noma i-ocular hypertension.
- I-Bimatoprost SR isebenza ukuhlinzeka ngokulawulwa kwesikhathi eside kokwehliswa komfutho wamehlo, futhi ayidingi ukuthi iziguli zithathe umuthi wansuku zonke.
- Lolu cwaningo lwenzeka kusuka ngoDisemba 2014 kuya kuJulayi 2020 emazweni ayi-15.
- Zingu-528 iziguli ezibambe iqhaza ocwaningweni; Abangu-472 baphothule ucwaningo kwathi abangu-56 abangaluphothula.
- Lolu cwaningo lwahlukaniswa lwaba yizikhathi ze-4: Isikhathi Sokuhlola, Isikhathi Sokuhlansa, Isikhathi Sokwelapha, kanye Nokulandelwa Okwandisiwe.
- Cishe i-61.9% yeziguli (iziguli ezingu-109) eqenjini le-bimatoprost SR eliphakeme, i-48.0% yeziguli (iziguli ezingu-84) eqenjini lomthamo ophansi we-bimatoprost SR, kanti iziguli ezingu-20.8% (iziguli ezingu-36) eqenjini le-timolol zibe nemiphumela emibi ngesikhathi socwaningo.
- Iziguli ezithola i-bimatoprost SR (umthamo ophansi noma ngaphezulu) zibone okungenani ukuthuthuka okuningi ekunciphiseni ukucindezelwa kwamehlo uma kuqhathaniswa neziguli ezithola i-timolol.
- Imiphumela yalolu cwaningo ingasetshenziswa ngabaphenyi ukuqhubekisela phambili ukuthuthukisa lo muthi.
- Uma ubambe iqhaza kulolu cwaningo futhi unemibuzo ngokunakekelwa kwakho ngawodwana, xhumana nodokotela noma nabasebenzi endaweni yocwaningo.

# 1. Imininingwane ejwayelekile mayelana nocwaningo

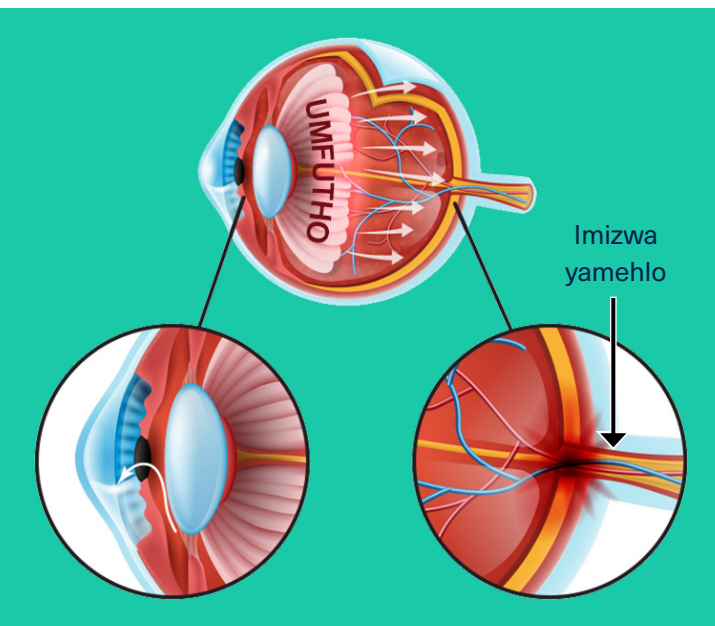
## 1.1. Yayiyini inhloso enkulu yalolu cwaningo?



Abacwaningi bafuna indlela engcono yokwelapha i-open-angle glaucoma nomfutho ophezulu.

- **I-open-angle glaucoma** uhlobo oluvame kakhulu lwe-glaucoma, isifo samehlo esidala ukuthi ingcindezi yamehlo ibe phezulu kakhulu. Ingcindezi eyandisiwe ingenxa yokwakheka koketshezi esweni, okungaholela ekulimaleni kwemithambo-luvo nokulahleka kombono.
- **I-ocular hypertension** ingcindezi eyandisiwe esweni ngenxa yoketshezi oluningi olungabangelwa izimo zamehlo ezahlukahlukene. Iziguli ezine-hypertension ene-ocular azinakho ukulimala kwe-optic nerve noma ukulahleka kombono; noma kunjalo, bangaba sengozini yokuthola i-glaucoma.

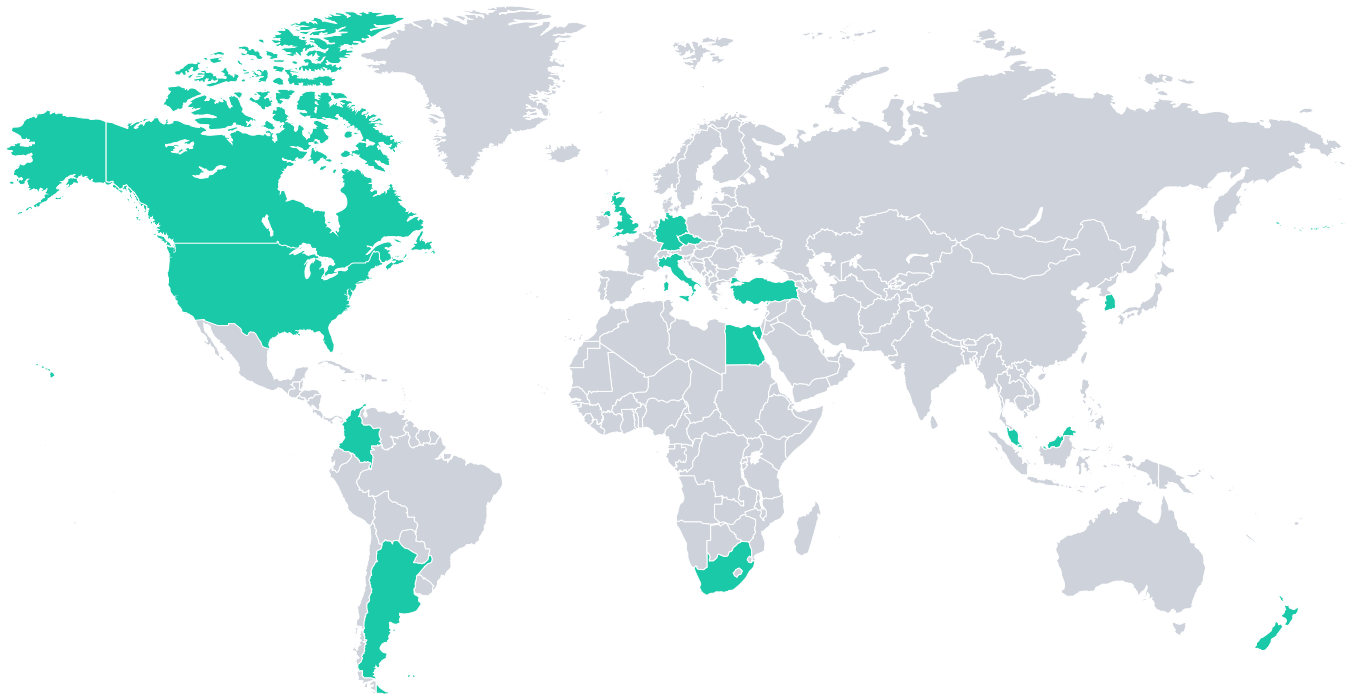
Abaphenyi kulolu cwaningo basebenzise umuthi obizwa nge-bimatoprost SR. I-Bimatoprost SR isebenza ukuhlinzeka ngokulawulwa kwesikhathi eside kokwehliswa kwengcindezi yamehlo futhi ayidingi ukuthi iziguli zithathe umuthi wansuku zonke. Inhloso enkulu yalolu cwaningo kwakuwukufunda ukuthi imithamo emibili ehlukene ye-bimatoprost SR yaqhathaniswa kanjani nokwelashwa nge-timolol, umuthi ovunyiwe wokwehlisa umfutho wamehlo, ukubona ukuthi yikuphi ukwelashwa okwehlisa ngempumelelo umfutho ezigulini ezine-open-angle glaucoma noma i-ocular hypertension. Abaphenyi bahlele lolu cwaningo Njengocwaningo lweSigaba 3, olwenziwa ngokungahleliwe.



- **Ucwaningo lweSigaba 3** lucwaningo ukwelashwa okusha okungavela enanini elikhulu leziguli ezinesimo noma isifo. Kulolu cwaningo lweSigaba 3, odokotela abacwaningayo babheka izinzuzo ze-bimatoprost SR kuqhathaniswa ne-timolol ezigulini ezine-open-angle glaucoma noma i-ocular hypertension. Odokotela abacwaningayo baphinde babheka noma imiphi imiphumela emibi okungenzeka ukuthi iziguli bezinayo ngemuva kokwelashwa nge-bimatoprost SR noma i-timolol. Imiphumela emibi yizehlakalo zokwelapha ezibhekwa odokotela bocwaningo ukuthi okungenani ihlobene nemithi yocwaningo/ukwelashwa.
- Uhlelo lwekhompyutha lwalusetshenziselwa ukwenza ngokungahleliwe (ngengozi) ukubeka iziguli eqenjini elilodwa lezokwelapha elingu-1 kwangu-3. Le nqubo ibizwa ngokuthi **ukufakwa ngokungahleliwe**, esiza ukwenza amaqembu afane futhi anciphise umehluko phakathi kwamaqembu.

## 1.2. Ucwangingo lwenziwe nini futhi kuphi?

Lolu cwangingo lwenzeka kusuka ngoDisemba 2014 kuya kuJulayi 2020 kula mazwe alandelayo: I-Argentina, Canada, Colombia, Czechia, Egypt, Germany, Italy, Malaysia, New Zealand, Singapore, South Africa, South Korea, Turkey, United Kingdom kanye ne-United States.



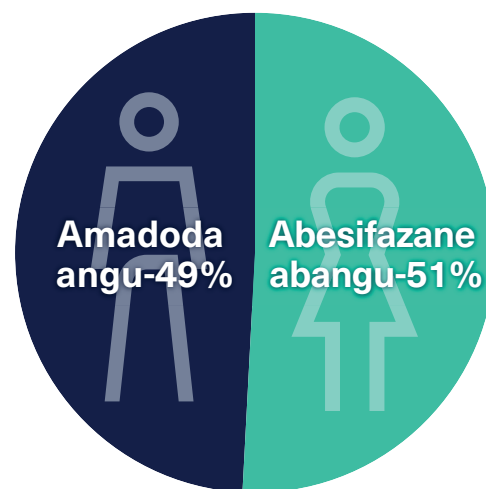
## 2. Yiziphi iziguli ezifakiwe kulolu cwangingo?

Inani leziguli zabantu abadala ezingama-528 ezine-open-angle glaucoma noma i-ocular hypertension zibambe iqhaza ocwangingweni. Ezigulini ezingama-528, ezingama-472 ziphothule ucwangingo kanti ezingama-56 aziphothulanga.

Kwakunenani elilinganayo lamadoda (49%) nabesifazane (51%) ocwangingweni. Iziguli zazisukela eminyakeni engu-19 kuya kwengu-90 ubudala. Isilinganiso seminyaka yeziguli ocwangingweni sasiyiminyaka engu-62.6.

Ukubamba iqhaza kulolu cwangingo, iziguli bekufanele zibe ne-open-angle glaucoma noma i-ocular hypertension esweni ngalinye elidinga ukwelashwa. Uma womabili amehlo esiguli ehlangabezana nezidingo zokungena ocwangingweni, iso elinengcindezi ephakeme yeso labelwa njengeso locwangingo. Iziguli kwakudingeka ziyeke ukuthatha imishanguzo yazo ejwayelekile yokwehlisa ingcindezi ngenkathi zisocwangingweni.

Iziguli ezazike zabamba iqhaza ocwangingweni lwe-Allergan zisebenzisa i-bimatoprost SR azikwazanga ukubamba iqhaza kulolu cwangingo. Iziguli bezingakwazi futhi ukubamba iqhaza uma zinezinye izifo noma ukungajwayelekile kweso okungabeka isiguli engcupheni noma kuphazamise ukuqedwa kocwangingo.



### 3. Yimiphi imithi eyacwaningwa?

Umuthi kulolu cwaningo ubizwa nge-bimatoprost SR. I-Bimatoprost SR isimila esincane esincibilika ngokwemvelo esweni. Lokhu kufakwa kuqukethe umuthi i-bimatoprost. I-Bimatoprost SR ibekwe endaweni ephakathi kwe-cornea (ingxenye ecacile yeso) kanye ne-iris (ingxenye enemibala yeso). Ngemuva kokuthi i-bimatoprost SR ibekwe esweni, umuthi ukhishwa kancane bese ukufakelwa kuncibilika kancane kancane.

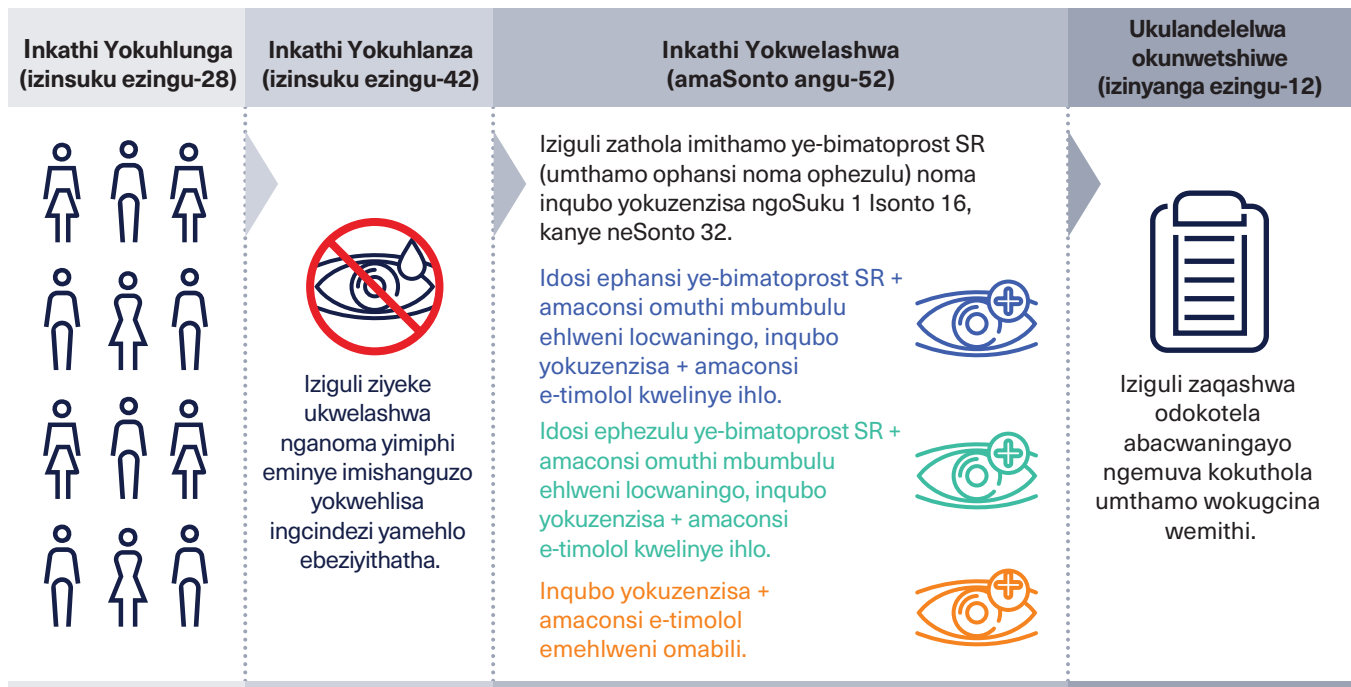
Lolu cwaningo lwahlukaniswa lwaba yizikhathi ze-4: Isikhathi Sokuhlola, Isikhathi Sokuhlansa, Isikhathi Sokwelapha, kanye Nokulandelwa Okwandisiwe. Ngesikhathi Sokuhlolwa, odokotela bokucwaninga bakhetha iziguli ezihlangabezana nazo zonke izidingo zocwaningo oluhleliwe. Ngesikhathi Sokugeza, iziguli ziyeke ukwelashwa nganoma yimiphi eminye imishanguzo yokwehlisa ingcindezi yamehlo ebiziphuza.

Esikhathini Sokwelashwa, uhlelo lwekhompyutha lwalusetshenziselwa ukwenza ngokungahleliwe (ngengozi) ukubeka iziguli eqenjini elilodwa kwele-3:

1. Iziguli eziseqenjini lokuqala zithole umthamo ophansi we-bimatoprost SR kanye namaconsi omuthi mbumbulu amehlo esweni locwaningo kanye nenqubo yokuzenzisa (ngaphandle kokufakwa okufakelwayo) kanye nokwehla kwamehlo kwe-timolol kwelinye iso.
2. Iziguli eziseqenjini lesibili zithole umthamo ophakeme we-bimatoprost SR kanye ne-eye placebo eye eye esweni locwaningo kanye nenqubo yokuzenzisa kanye namaconsi e-timolol asemehlweni kwelinye iso.
3. Iziguli eziseqenjini lesithathu zithole inqubo yokuzenzisa kanye ne-timolol eye eye iso ngalinye. Lokhu kusho ukuthi iziguli eziseqenjini lesithathu zithole kuphela i-timolol, futhi alukho olunye ukwelashwa.

Iziguli zathola imithamo ye-bimatoprost SR noma inqubo yokuzenzisa ngoSuku 1, Isonto 16, nangesonto 32.

Ngesikhathi Sokulandelwa Okunwetshiwe, iziguli zaziqashwe ngodokotela abacwaningayo ngemuva kokuthola umthamo wokugcina wemithi yocwaningo. Umdwebho ongezansi ukhombisa ukuthi ucwaningo luhlelwe kanjani.



## 4. Yayiyini imiphumela emibi?

Imiphumela engemihle yimicimbi yezokwelapha engadingeki ebithathwa ngudokotela ocwaningayo ukuthi okungenani ihlobene nomuthi wocwaningo.

Umpfumela oseceleni ubucayi uma uholela ekufeni, usongela impilo, ubeka isiguli esibhedlela, ugcina isiguli esibhedlela isikhathi eside, noma ubangela ukukhubazeka okuhlala isikhathi eside.

Cishe i-6.3% yeziguli (iziguli eziyi-11) eqenjini le-bimatoprost SR eliphakeme, i-2.9% yeziguli (iziguli ezi-5) eqenjini lethamo eliphansi le-bimatoprost SR, futhi azikho iziguli eqenjini le-timolol ezinemiphumela emibi kakhulu ngesikhathi socwaningo.

Cishe i-9.1% yeziguli (iziguli eziyi-16) eqenjini eliphakeme le-bimatoprost SR, i-2.3% yeziguli (iziguli ezi-4) eqenjini lethamo eliphansi le-bimatoprost SR, kanti i-1.2% yeziguli (iziguli ezi-2) eqenjini le-timolol ziyeke ukuthatha ucwaningo. umuthi ngenxa yemiphumela emibi ngesikhathi socwaningo.

Asikho isiguli esashona ngesikhathi socwaningo ngenxa yemiphumela engemihle.

Ithebula elingezansi likhombisa imininingwane ngemiphumela emibi emibi iziguli ezinayo ocwaningweni, kanye nemiphumela emibi eziguli ezinayo eziholele ekutheni isiguli siyeke umuthi wocwaningo.

Ucwaningo Selulonke			
	Bimatoprost SR Iqembu Ledosi Epezulu (Iziguli ezingu-176)	I-Bimatoprost SR Iqembu Ledodi Ephansi (Iziguli ezingu-175)	Iqembu le-Timolol (Iziguli ezingu-173)
Inani leziguli ezinemiphumela emibi kakhulu	11 (6.3% weziguli)	5 (2.9% weziguli)	0 (0.0% weziguli)
Imiphumela emibi kakhulu			
• Ukulahleka kweseli ye-cornea (ukulahleka kweseli ye-corneal)	1-8 (4.5%)	3 (1.7%)	0 (0.0%)
• Ukuvuvukala kwe-cornea (i-corneal edema)	2 (1.1%)	1 (0.6%)	0 (0.0%)
• Ukuwohloka kwe-cornea (ukubola kwamakhaza)	0 (0.0%)	1 (0.6%)	0 (0.0%)
• Ukwakheka kwamanzi kwi-macula (i-macular edema)	1 (0.6%)	0 (0.0%)	0 (0.0%)
Inani leziguli eziyeke ukuthatha imithi yocwaningo ngenxa yemiphumela engemihle	16 (9.1%)	4 (2.3%)	2 (1.2%)
Izizathu zokuma	Ukuwohloka kwe-cornea, i-corneal disorder, ukulahleka kweseli kwe-cornea, ukuthinta kwe-corneal (lapho ilensi yeso ithinta i-cornea), ukufakwa kwethuluzi lokulethwa kwemithi yocwaningo, ukunyuka kwengcindezi yamehlo, ukuvuvukala kwe-iris (ingxenye enemibala yeso) kanye umzimba we-ciliary (isakhiwo esiyindilinga esizungeze iso) (iridocyclitis), ukuvuvukala kwe-iris (iritis), ukungabekezelelani okulula (i-photophobia), ukuzwa kwezinto zangaphandle emehlweni, ukuvuvukala kwe-cornea	Ukuwohloka kwe-cornea, ukuphazamiseka kwemiphunga okungamahlakhona, ukuphathwa okungafanele komkhiqizo esweni, ukuvuvukala kwe-cornea	Ukusabela okweqile komuthi (umuthi wegazi opezulu wemithi), iso elibomvana (conjunctivitis)

Cishe i-61.9% yeziguli (iziguli ezingu-109) eqenjini le-bimatoprost SR eliphakeme, i-48.0% weziguli (iziguli ezingu-84) eqenjini lomthamo ophansi we-bimatoprost SR, kanti iziguli ezingu-20.8% (iziguli ezingu-36) eqenjini le-timolol zibe nemiphumela emibi ngesikhathi socwaningo. Ithebula elingezansi likhombisa imininingwane ngemiphumela emibi ejwayelekile (okungenani ezigulini eziyi-11 noma ngaphezulu kunoma yiliphi iqembu lokwelashwa) kulolu cwawano. Imiphumela emibi kakhulu yanda ukwanda kokugeleza kwegazi kuye iso kanye nokulahleka kweseli kwe-cornea.

<b>Ucwaningo Selulonke</b>			
	<b>Bimatoprost SR Iqembu Ledosi Ephazulu (Iziguli ezingu-176)</b>	<b>Bimatoprost SR Iqembu Ledosi Ephansi (Iziguli ezingu-175)</b>	<b>Iqembu Le-Timolol (Iziguli 173)</b>
Inani leziguli okungenani ezinomphumela owodwa omubi	109 (61.9% yeziguli)	1-84 (48.0% yeziguli)	36 (20.8% yeziguli)
Imiphumela emibi ejwayelekile			
Ukwanda kokugeleza kwegazi kuye esweni (i-conjunctival hyperemia)	48 (27.3%)	37 (21.1%)	10 (5.8%)
Ukulahleka kweseli kwe-cornea	40 (22.7%)	11 (6.3%)	0 (0.0%)
Ubuhlungu beso	18 (10.2%)	10 (5.7%)	6 (3.5%)
Ukuvuvukala kwe-cornea	17 (9.7%)	4 (2.3%)	0 (0.0%)
Imithambo yegazi ephukile esweni (i-conjunctival hemorrhage)	12 (6.8%)	12 (6.9%)	11 (6.4%)
Ukuzwa kwento yangaphandle emehlweni	12 (6.8%)	10 (5.7%)	2 (1.2%)
Ukubekwelelana ukukhanya	11 (6.3%)	8 (4.6%)	0 (0.0%)

Kuwo wonke ucwaningo, iziguli eziseqenjini lethosi eliphakeme le-bimatoprost SR zithole imiphumela emibi kakhulu uma kuqhathaniswa neziguli ezithola umthamo ophansi we-bimatoprost SR noma i-timolol.

## 5. Beyiyini imiphumela isiyonke yocwaningo?

Ucwaningo luphothulwe njengoba bekuhleliwe futhi kwaboniswa ukuthi i-bimatoprost SR inganciphisa ngempumelelo ukucindezelwa kwamehlo ezigulini ezine-open-angle glaucoma noma i-ocular hypertension. Imiphumela yocwaningo ikhombise ukuthi iziguli ezithola i-bimatoprost SR (umthamo ophansi noma ophakeme) zibone okungenani ukuthuthuka okuningi ekunciphiseni ukucindezelwa kwamehlo uma kuqhathaniswa neziguli ezithola i-timolol kusukela ekuqaleni kocwaningo kuya kwiviki 2, iviki 6 kanye neviki 12 ukwelashwa.

Iziguli eziseqenjini lomthamo ophakeme we-bimatoprost SR zithole imiphumela emibi kakhulu uma kuqhathaniswa neziguli ezithola umthamo ophansi we-bimatoprost SR noma i-timolol.

## 6. Ucwangingo luzisize kanjani iziguli nabacwangingi?

Ucwangingo luzisize abacwangingi ukuthi bafunde kabanzi ngokuphepha nokusebenza kwe-bimatoprost SR ekwelapheni iziguli ezine-open-angle glaucoma ne-ocular hypertension. Kukhombisile ukuthi womabili amanani (aphezulu naphansi) we-bimatoprost SR akhombise ukusebenza okufana ne-timolol ekwehliseni ingcindezi yamehlo ngeviki 2, Isonto 6, kanye neViki le-12 lokwelashwa. I-Bimatoprost SR inganikeza ukwelashwa okuqhubekayo, okuhlala isikhathi eside kweziguli ezine-open-angle glaucoma ne-ocular hypertension, futhi ayidingi ukuthi iziguli zithathe umuthi wansuku zonke.

Lesi sifinyezo sikhombisa kuphela imiphumela evela kulolu cwangingo, engahluka kunemiphumela yezinye izingcwangingo. Ukutholwe kulolu cwangingo kungasetshenziswa kolunye ucwangingo ukufunda ukuthi iziguli ziyasizwa yini yi-bimatoprost SR.

## 7. Ngabe kukhona okuhlelwayo ngocwangingo oluzayo?

Ucwangingo oluningi lwe-bimatoprost SR luyaqhubeka.

## 8. Ngubani oxhase lolu cwangingo?

Lolu cwangingo lwaluxhaswe yi-AbbVie. Lesi sifinyezo sibuyekezelwe ukufundwa yiqembu elimele iziguli.

## 9. Ngingalutholaphi ulwazi oluthe xaxa mayelana nalolu cwangingo?

Isihloko Socwangingo	Ukusebenza Nokuphepha kwe-Bimatoprost SR ezigulini ezine-Open-angle Glaucoma noma i-Ocular Hypertension (The Efficacy and Safety of Bimatoprost SR in Patients With Open-angle Glaucoma or Ocular Hypertension)
Inombolo Yephrothokholi	192024-092
Clinicaltrials.gov	NCT02250651 <a href="https://clinicaltrials.gov/ct2/show/NCT02250651?term=NCT02250651&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT02250651?term=NCT02250651&amp;draw=2&amp;rank=1</a>
EudraCT	2014-003186-24 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003186-24">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003186-24</a>
Umxhasi Wocwangingo	AbbVie, Inc. Ucingo: +1 800-633-9110 I-imeyili: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

## Siyabonga

I-AbbVie ifuna ukubonga bonke ababambiqhaza ngesikhathi sabo nangomzamo wabo owenze lolu cwangingo lwenzeka.

Abababambiqhaza bocwangingo lwezempilo basiza ukuqhubekisela phambili isayensi!

