# ISishwankathelo seziPhumo zoLingo lwezoNyango

## Uphononongo olujonga ukhuseleko lwebaloxavir marboxil ebantwaneni abaneinfluenza abangaphantsi konyaka om-1 (miniSTONE-1)

Jonga ekupheleni kwesi ishwankathelo ukuze ufumane isihloko esipheleleyo sophononongo.

## Malunga nesishwankathelo

Esi sisishwankathelo seziphumo zolingo lwezonyango (ekuthiwa 'luphononongo' kolu xwebhu) – esibhalelwe:

- amalungu oluntu kunye
- nabantu abathathe inxaxheba kuphononongo

Esi sishwankathelo sisekelwe kulwazi olwaziwayo ngexesha lokubhala.

Uphononongo luqale ngoJanuwari ka-2019 lwaze lwagqitywa ngoJulayi ka-2023. Esi sishwankathelo sibhalwe emva kokuba luphelile uphononongo.

Akukho phononongo lunye lunokusixelela yonke into malunga neengozi kunye neenzuzo zeyeza. Kuthatha abantu abaninzi kumaphononongo amaninzi ukufumanisa yonke into ekufuneka siyazi. Iziphumo ezivela kolu phononongo zinokohluka kwezivela kwamanye amaphononongo ngeyeza elinye.

- **Oku kuthetha ukuba kufuneka ungenzi izigqibo ngokusekelwe kwesi sishwankathelo sinye – thetha nogqirha wakho ngalo lonke ixesha phambi kokwenza naziphi na izigqibo zonyango emntwaneni wakho**

### Isiqulatho sesishwankathelo


1. Ulwazi jikelele malunga nolu phononongo
2. Ngubani othathe inxaxheba kolu phononongo?
3. Kwenzeke ntoni ngexa lophononongo?
4. Bezithini iziphumo zophononongo?
5. Luluncedo njani uphando olu phononongo?
6. Ingaba zikhona izicwangciso zamanye amaphononongo?
7. Ndingalufumana phi ulwazi oluthe vetshe?


## Siyabulela ebantwini abathathe inxaxheba kolu phononongo

Abantu abathathe inxaxheba bancede abaphandi ukuphendula imibuzo ebalulekileyo malunga neinfluenza kunye neyeza eliphononongiweyo (ibaloxavir marboxil), elinokuba neenzuzo kuluntu jikelele.

## Ulwazi olungundoqo malunga nolu phononongo

- Olu phononongo lwenzelwe ukubona ukuba ingaba ibaloxavir marboxil ikhuselekile na ukuba isetyenziswe ebantwaneni abangaphantsi konyaka om-1
- Olu phononongo luquke abantwana abangama-48 kumazwe asi-7 (eCosta Rica, eFinland, eMexico, ePoland, eMzantsi Afrika, eSpain nase-USA)
- Okufunyaniswe kuphando okungundoqo kukuba ibaloxavir marboxil ikhuselekile ebantwaneni ababudala bungaphantsi konyaka om-1 ukuba bayithathe njengoko kunjalo ebantwaneni abadadlana nabantu abadala
- Namnye kubantwana abathathe inxaxheba obe neziphumo ebezingalindelekanga ezimandundu ebezinxulumene nebaloxavir marboxil

## 1. Ulwazi jikelele malunga nolu phononongo

### Kutheni lusenziwa nje olu phononongo?

I-Influenza, ekuthiwa ngumkhuhlane kananjalo, sisifo esixhaphakileyo esibangwa lusulelo yintsholongwane yomkhuhlane. Iimpawu ezixhaphakileyo ziquka umkhuhlane, ukukhohlela, umqala obuhlungu, iingqaqambo zomzimba nokudinwa.

Abantu abaninzi baye bachache emkhuhlaneni ngeveki ngaphandle kwemfuno yokubona ugqirha. Ngamanye amaxesha, umkhuhlane unokukhokelela kwizigulo ezimandundu ngokungaphaya (iingxaki) ezifana nokudumba/ukukrala kwemiphunga (inyumoniya) okanye ityhefu egazini (ukutyhefeka). Umkhuhlane ixesha lininzi uchaphazela abantwana, kwaye kunokwenzeka babe neengxaki ukodlula abantu abadala.

Kukho amayeza amaninzi athengwa ngaphandle kommiselo anokusetyenziswa ukunyanga iimpawu zomkhuhlane, kodwa la awawunyangi unobangela – usulelo lweentsholongwane. Unyango olulwa iintsholongwane oluyihlasela ngqo intsholongwane yomkhuhlane. Lona unokulufumana kugqirha okanye usokhemesti. Nyaka ngamnye, izigidi zabantu kwihlabathi jikelele zifuna unyango lomkhuhlane.

IBaloxavir marboxil lunyango olulwa iintsholongwane lweinfluenza olusebenza ngokwahlukileyo kwezinye izibulala ntsholongwane. Ibonakalise ukuba iyasebenza ekunyangeni umkhuhlane ebantwini abadala nabantwana ubuncinane abanonyaka om-1 ubudala. Olu phononongo lujonga ukuba ikhuseleke kangakanani ibaloxavir marboxil ebantwaneni abangaphantsi konyaka om-1.

### Ibileliphi iyeza eliphononongwayo?

Iyeza ekuthiwa yi ‘baloxavir marboxil’ lilo ebekujoliswe kulo kolu phononongo

- Indlela elibizwa ngayo ithi ‘ba-lox-av-ear mar-box-il’
- IBaloxavir marboxil isebenza ngokunqanda intsholongwane yomkhuhlane ekubeni yenze iikopi zayo emzimbeni
- Oku kunokuthetha ukuba awukho mandundu kangako umkhuhlane kwaye abantwana bachacha ngokukhawuleza xa benyangwa ngebaloxavir marboxil

## Yintoni abafuna ukuyifumanisa abaphandi?

**Umbuzo ongundoqo ebebefuna ukuwuphendula abaphandi ibingulo:**
Ngabantwana abangaphi ababe neziphumo ebezingalindelekanga (iingxaki zezonyango ezenzeka ngexa lophononongo) ngenxa yonyango lwebaloxavir marboxil?

## Ibiluhlobo luni lophononongo olu?

Olu phononongo ibiluphononongo'lweSigaba 3'. Oku kuthetha ukuba lwandisiwe lusuka kumaphononongo angaphambili ukufumanisa malunga neziphumo ebezingalindelekanga zebaloxavir marboxil ebantwaneni abangaphantsi konyaka om-1. Kunokwenziwa isigqibo sokuba ingaba lungavunywa na unyango ukuba oogqirha balunike abantwana abancinci kakhulu.

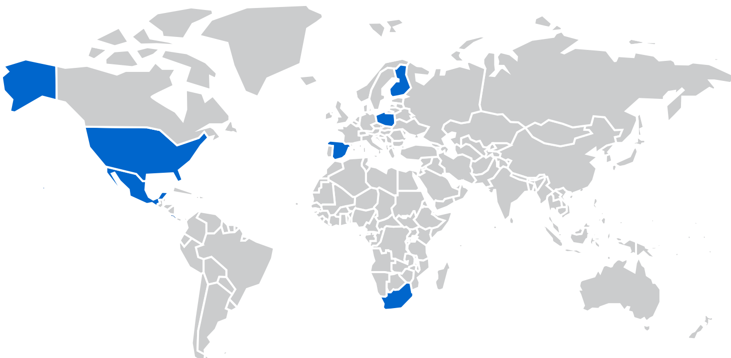
Olu ibiluphononongo'olungafihlwanga'. Oku kuthetha ukuba bonke abantu abathatha inxaxheba kuphononongo kunye noogqirha bophononongo bebelazi iyeza lophononongo elinikwe abantwana.

## Lwenziwe nini kwaye phi uphononongo?

Uphononongo luqale ngoJanuwari ka-2019 lwaze lwagqitywa ngoJulayi ka-2023. Esi sishwankathelo sibhalwe emva kokuba luphelile uphononongo.

Uphononongo lwenziwe kumaziko ophononongo ali-15 emazweni asi-7 aboniswe kwimaphu elandelayo:

- ECosta Rica
- EFinland
- EMexico
- IPoland
- South Africa
- ISpain
- I-USA

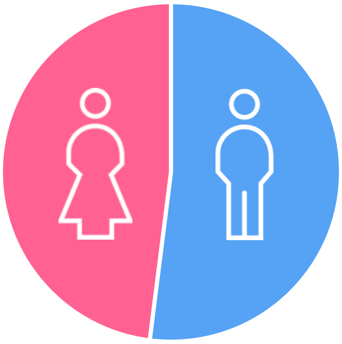


## 2. Ngubani othathe inxaxheba kolu phononongo?

Kolu phononongo, ngabantwana abangama-48 abangaphantsi konyaka abanomkhuhlane okanye usulelo olubufana nomkhuhlane abathathe inxaxheba.

**48%**

Ama-23 kubantwana abangama-48 abathathe inxaxheba



**52%**

Ama-25 kubantwana abangama-48 abathathe inxaxheba

**Uluhlu lobudala: ngaphantsi konyaka om-1**

Abantwana bangathatha inxaxheba kuphononongo ukuba:

- Bebengaphantsi konyaka om-1 ubudala
- Abazali/abagcini babo bavumile ukuba banokuyithatha inxaxheba kuphononongo
- Bafunyaniswe ngoxilongo ukuba banomkhuhlane ngokusekelwe kwisigqibo sikagqirha seempawu kunye nesiphumo sovavanyo esithi ukhona umkhuhlane
- Bebenesiphumo sovavanyo esithi abanayo i-COVID-19 kwiintsuku ezi-2 zokubona ugqirha
- Babone ugqirha kwiintsuku ezi-4 zokuba neempawu zomkhuhlane

Abantwana abanako ukuthatha inxaxheba kuphononongo ukuba:

- Bafuna unyango lomkhuhlane (okanye esinye isigulo) esibhedlele
- Banikwe olunye unyango olunokuchaphazela indlela esebenza ngayo ibaloxavir marboxil
- Babelekwe phambi kwexesha, okanye ubunzima babo bebungaphantsi kwe-2.5kg

## 3. Kwenzeke ntoni ngexa lophononongo?

Ngexa lophononongo, bonke abantwana abathathe inxaxheba banikwe ithamo elinye lebaloxavir marboxil njengeenkozwana ezixutywe namanzi ngomlomo. Umthamo onikiweyo ubuxhomekeke kubunzima babo bomzimba.

Xa luqqityiwe uphononongo, abazali okanye abagcini babantwana abathatha inxaxheba baceliwe ukuba babuyele kumaziko abo ophononongo ngezihlandlo zotyelelo ezingaphaya – ukukhangela impilo xa iyonke yaba bantwana. Jonga ngezantsi ukubona ulwazi oluthe vetshe malunga nento eyenzekileyo kuphononongo.

**Ukhetho lwabantwana abaza kuthatha inxaxheba kuphononongo** → **Abantwana abangama-48 benikwa ithamo elinye lebaloxavir marboxil** → **Oogqirha bayaqhuba ukukhangela impilo yabantwana abathathe inxaxheba, ukuya kwiintsuku**

## 4. Bezithini iziphumo zophononongo?

**Umbuzo ongundoqo:** Ngabantwana abangaphi ababe neziphumo ebezingalindelekanga zonyango lwebaloxavir marboxil?

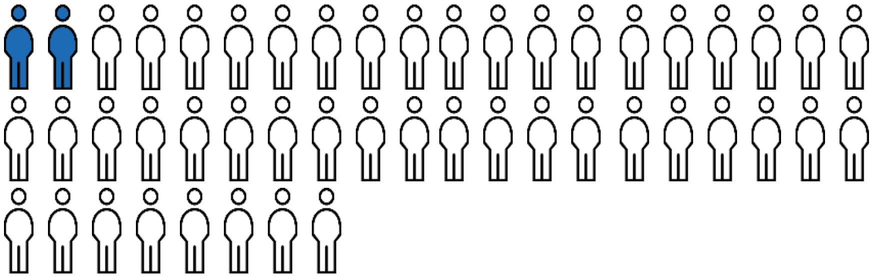
Iziphumo ebezingalindelekanga ziingxaki zezonyango ezenzeka ngexa lophononongo.

Iziphumo ebezingalindelekanga ezingekho mandundu ziingxaki zezonyango (ezifana nokuziva unesiyezi) ngexa lophononongo. Iziphumo ebezingalindelekanga ezimandundu zezo zibanga ukulaliswa esibhedlele okungacetywanga (okanye ukulaliswa esibhedlele ixesha elide kunelo belicetyiwe) okanye ezinokubeka ubomi esichengeni, ezibanga ukuba nokukhubazeka okanye ukusweleka. Kuphela ziziphumo ebezingalindelekanga oogqirha abacinga ukuba bezinxulumene neyeza lophononongo ezibonisiweyo.

Ayingabo bonke abantwana ababe nesiphumo ebesingalindelekanga kolu phononongo.

Akukho namnye kubantwana abathathe inxaxheba obe neziphumo ebezingalindelekanga ezimandundu ebezinxulumene nonyango lophononongo.

Kubantwana abangama-48 kolu phononongo, aba-2 (4%) babe neziphumo ebezingalindelekanga ezingekho mandundu ekucingwa ukuba bezinxulumene nonyango. Ezi ziphumo bezingalindelekanga zozibini bezilurhudo.



**Ngabantwana aba-2 kwabangama-48 ababe neziphumo ebezingalindelekanga ezingekho mandundu ekucingwa ukuba bezinxulumene**

Ngexa lophononongo, akukho namnye kubantwana abanyangwe ngebaloxavir marboxil oye wasweleka ngenxa yeziphumo ebezingalindelekanga ezinokuba bezinxulumene neyeza lophononongo.

Akukho namnye kubantwana abanyangwe ngebaloxavir marboxil oyekileyo ukunikwa iyeza lophononongo ngenxa yeziphumo ebezingalindelekanga.

Eli candelo libonisa iziphumo ezingundoqo kuphela ezivela kolu phononongo. Ungafumana ulwazi oluthe vetshe malunga neziphumo zophononongo kwiiwebhusayithi ezisekupheleni kwesi sishwankarthelo (jonga kwiCandelo 7).

## 5. Luluncedo njani uphando olu phononongo?

Ulwazi oluthiwe thaca apha luvela kuphononongo olunye lwabantwana abangama-48 abangaphantsi konyaka om-1 abanomkhuhlane. Ezi ziphumo zincede abaphandi bafunde ngokungaphaya ngomkhuhlane nebaloxavir marboxil, oko okunokukhokela kunyango olungcono kuluntu jikelele.

Okufunyanisiweyo okungundoqo kuphononongo kukuba ibaloxavir marboxil ikhuselekile jikelele ebantwaneni abangaphantsi konyaka om-1 kwaye khange kube khona ziphumo bezingalindelekanga zinxulumene nonyango. Oku kuyahambelana nokhuseleko olwaziwayo lwebaloxavir marboxil ebantwaneni abadadlana, abantwana abafikisayo nabantu abadala.

Akukho phononongo lunye lunokusixelela yonke into malunga neengozi kunye neenzuzo zeyeza. Kuthatha abantu abaninzi kumaphononongo amaninzi ukufumanisa yonke into ekufuneka siyazi. Iziphumo ezivela kolu phononongo zinokohluka kwezivela kwamanye amaphononongo ngeyeza elinye.

- **Oku kuthetha ukuba kufuneka ungenzi izigqibo ngokusekelwe kwesi sishwankathelo sinye – thetha nogqirha wakho ngalo lonke ixesha phambi kokwenza naziphi na izigqibo zonyango emntwaneni wakho.**

## 6. Ingaba zikhona izicwangciso zamanye amaphononongo ebantwaneni?

Asaqhubeka amaphononongo ngebaloxavir marboxil.

ICENTERSTONE luphononongo olujonga isiphumo sebaloxavir marboxil ekunqandeni ukunwenwa komkhuhlane ebantwini abane-5 ukuya kuma-64 eminyaka ubudala.

IPEBBLESTONE luphononongo lwebaloxavir marboxil ebantwaneni abano-1 ukuya kwi-11 leminyaka ubudala, olujonga ukunganyangeki kwentsholongwane yeinfluenza, apho utshintsho lwenzeka khona ngaphakathi kwintsholongwane olunokwenza lungasebenzi ngempumelelo unyango lwesibulala ntsholongwane.

Ulwazi oluthe vetshe malunga nala maphononongo lunokufunyanwa ku:

- https://clinicaltrials.gov/study/NCT03969212
- https://clinicaltrials.gov/ct2/show/NCT06094010

## 7. Ndingalufumana phi ulwazi oluthe vetshe?

Ungafumana ulwazi oluthe vetshe malunga nolu phononongo (miniSTONE-1) kwiiwebhusayithi ezixelwe ngezantsi:

- https://clinicaltrials.gov/ct2/show/results/NCT03653364
- https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-002154-70/FI
- https://forpatients.roche.com/ en/trials/infectious-diseases/influenza/study-to-assess-the-safety--pharmacokinetics--and-effic-62594.html

### Ngubani endinokumqhagamshelana naye ukuba ndinemibuzo malunga nolu phononongo?

Ukuba unayo nayiphi imibuzo engaphaya emva kokufunda esi sishwankathelo:

- Yiya kwiqonga leziGulane kwaye ugcwalise ifomu yoqhagamshelwano – https://forpatients.roche.com/ en/trials/infectious-diseases/influenza/study-to-assess-the-safety--pharmacokinetics--and-effic-62594.html
- Qhagamshelana nommeli kwiofisi yakho yengingqi yeRoche

Ukuba umntwana wakho uthathe inxaxheba kolu phononongo kwaye ukuba unayo nayiphi na imibuzo malunga neziphumo:

- Thetha nogqirha wakho wophononongo

Ukuba unemibuzo malunga nonyango lomntwana wakho:

- Thetha nogqirha ojongene nonyango lomntwana wakho

### Ngubani oququzelele kwaye wahlawulela olu phononongo?

Olu phononongo luququzelelwe kwaye lwahlawulelwa yi-F. Hoffmann-La Roche Ltd, ikomkhulu layo liseBasel, eSwitzerland.

## Isihloko esipheleleyo sophononongo kunye nolunye ulwazi oluchongayo

Isihloko esipheleleyo solu phononongo sesi: "UPhononongo lokuHlola uKhuseleko, iPharmacokinetics, kunye nokuSebenza kweBaloxavir Marboxil kubaThathi Nxaxheba abangabaNtwana abaPhilileyo ukuSuka ekuZalweni ukuya kuNyaka om <1 abaneeMpawu ezibuFana nezeInfluenza".

Olu phononongo lwaziwa njenge miniSTONE-1'.

- Inombolo yeprotokoli yolu phononongo ngu: CP40559
- Isazisi seClinicalTrials.gov kolu phononongo sesi: NCT03653364
- Inombolo ye-EudraCT yolu phononongo yile: 2018-002154-70