

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

FLEXOCAM 7,5 kanye ne-15 mg

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S3

Amaphilisi iFLEXOCAM 7,5 mg

Amaphilisi iFLEXOCAM 15 mg

Meloxicam

Amaphilisi iFLEXOCAM aqukethe ushukela (iFLEXOCAM 7,5 mg iqukethe ushukela i*lactose monohydrate* ongama-63,0 mg ephilisini ngalinye kanti iFLEXOCAM 15 mg yona iqukethe ushukela i*lactose monohydrate* ongama-126,0 mg ephilisini ngalinye).

Ngaphambi kokuba uqale ukusebenzisa iFLEXOCAM 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.
- IFLEXOCAM 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 iFLEXOCAM futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iFLEXOCAM
3. Indlela yokusebenzisa iFLEXOCAM
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1. Iyini iFLEXOCAM futhi isetshenziselwani?

IFLEXOCAM iyingxenywe yeqoqwana lemithi ebizwa ngama*non-steroidal anti-inflammatory medicines* (NSAIDs) okuyimithi esetshenziselwa ukunciphisa ukuvuvukala kanye nezinhlungu emajoyintini nemisipha yomzimba.

IFLEXOCAM isetshenziselwa ukwelapha:

- *irheumatoid arthritis* (ukuvuvukala emajoyintini omzimba)
- isifo esibuhlungu sokuwohloka koqwanga oluhlanganisa amajoyinti omzimba, phecelezi i-*osteoarthritis* (izinhlungu nokuqina kwamajoyinti omzimba)
- i-*ankylosing spondylitis* (uhlobo oluthile lwe-*arthritis* yomgogodla)
- inkinga yokuhlaselwa yizigameko ezixinayo futhi ezinamandla zesifo sobuhlungu bezinzwa zomzimba obusuka emqolo behle ngomlenze, phecelezi *isciatika* (noma yibuphi ubuhlungu obudalwa wukuvuvukala kwesciatic/hip nerve).

2. Okumele ukwazi ngaphambi kokuba usebenzise iFLEXOCAM

Ungalokothi usebenzise iFLEXOCAM:

- uma umzimba wakho ungezwani nesithako *imeloxicam*, noma uma ungezwani nanoma yisiphi esinye isithako seFLEXOCAM (bheka isigaba 6)
- uma esikhathini esedlule uke waphathwa yinoma yikuphi kulokhu kugula okulandelayo emuva kokuphuza i-*aspirin* noma omunye umuthi wokudambisa izinhlungu:
 - isifuba somoya (ukubefuzela, umuzwa wokucindezeleka esifubeni, ukuphelelwa wumoya)
 - umqubuko esikhunjeni odalwa yi-aleji, phecelezi, *skin hives* (ukuqubuka esikhunjeni/amabala abomvu aqumbile esikhunjeni ahambisana nokuluma okukhulu)
 - *inasal polyps* (ukucinana emakhaleni okubangelwa wukuvuvukala kontwentwesana olusemakhaleni akho), i-*angioedema* (ukuvuvukala ngaphansi kwesikhumba)
 - *irhinitis* enamandla futhi exinayo (amafinyila).

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- uma uke waba nenkinga yokuhluleka kwenhliziyi ukusebenza ngendlela efanele, noma isifo senhliziyi esibangelwa wukuncipha kanye/noma ukuvaleka kwemithambo yegazi ngenxa yekholesteroli, isifo sohlangothi, kanye ne*peripheral arterial disease* okuyinkinga evamile yokugeleza kwegazi lapho kuba nokuncipha kokuhamba nokugeleza kwegazi eliya emilenzeni nasezingalweni ngenxa yokuncipha kwemithambo yegazi
- uma unezilonda esiswini
- uma uxinwe kakhulu yisifo sesibindi
- uma uphethwe yisifo sezinsu noma uma ungaphansi kohlelo lokuhlazwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsu
- uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ukukhulelwa kanye nokuncelisa)
- uma unomlando wokopha esiswini sakho noma emathunjini, noma uma kamuva nje, noma esikhathini esedlule, uke waba nenkinga yezilonda esiswini noma izilonda ezophayo esiswini
- uma odokotela bethole ukuthi wena uphethwe yisifo i*Crohn's disease* noma i*ulcerative colitis* (isifo i*inflammatory bowel disease* esibonakala ngezimpawu ezinjengezinhlungu esiswini nendawo ezungezile kanye nokuqina nokudonseka kwemisipha yesisu, umdidi obuhlungu noma owophayo, okuyisifo esivamise ukuhambisana nohudo olunegazi)
- uma uphethwe nanoma iyiphi inkinga ephathelene nokopha
- uma kamuva nje usanda kuhlinzwa inhliziyi (ngenhloso yokulungisa inkinga yokuncipha noma yokuvaleka kwemithambo yenhliziyi)
- uma uyingane eneminyaka engaphansi kwe-18 ubudala.

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iFLEXOCAM:

IFLEXOCAM kungenzeka ibangele ukuthi ube nezinkinga zenhliziyi kanye/noma zemithambo yegazi, noma ukuqubuka nokuvuvukala kwesikhumba okubangelwa ngama-aleji esikhumba okungambulala nokumbulala umuntu.

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- uma unomlando wokuphathwa yisifo somphimbo (isifo sokuvuvukala komphimbo esihambisana nezimpawu ezinjengezinhlungu lapho ugwinya, isilungulela, isicanucanu, ukuhlanza), isifo *igastritis* (ukuvuvukala kontwentwesana lwesisu) kanye/noma *ipeptic ulcer* (izilonda esiswini), kumele ube ngumuntu oselapheke ngokuphelele ngaphambi kokuthi uqale ukwelashwa ngeFLEXOCAM.
- uma uyisiguli esesikhulile ngokweminyaka, makhulu amathuba okuthi ube nemithelela engathandeki ebangelwa yiFLEXOCAM, ikakhulukazi izinkinga eziphathelele nesisu, izilonda esiswini, lokhu kungabandakanya amathumba (okungambulala nokumbulala umuntu) noma izinkinga zokopha.
- uma unomlando wokuba nenkinga yezilonda esiswini/ukopha, udokotela wakho kungenzeka akuyalele ukuthi uphuze umthamosilinganiso ophansi kakhulu weFLEXOCAM futhi akunikeze eminye imithi engeziwe ngenhloso yokunciphisa umthamo we-esidi ekhiqizwa esiswini sakho futhi ngenhloso yokuvikela untwentwesana lwesisu sakho.
Uma kwenzeka uba nezimpawu zezilonda esiswini noma wopha ngenkathi usebenzisa iFLEXOCAM, kumele uyeke ngokushesha ukuyisebenzisa.
- uma uthatha *iheparin* noma usebenzisa *iwarfarin* (esetshenziselwa ukuvimbela ukushuba nokuguquka kwegazi libe ngamahlule), noma *i-aspirin* noma eminye imithi yokudambisa izinhlungu (*non-steroidal anti-inflammatory medicines - NSAIDs*), njengoba kungafanele ukuthi usebenzise iFLEXOCAM.
- gwema ukusebenzisa iFLEXOCAM kanyekanye neminye imithi yokudambisa izinhlungu nokuqeda ukuvuvukala njengoba lokho kungakhuphula ubungozi bokopha.
- uma udinga umuthi ozodambisa ngokushesha izinhlungu ezinamandla ezikuphethe, iFLEXOCAM ayiwona umuthi olungele lokho.
- lapho ubona umqubuko esikhunjeni sakho, indawana esikhunjeni enesimo sethishu yesikhumba esingajwayelekile (inxeba, isilonda, umqubuko noma ithumba), kumele uyeke ngokushesha ukusebenzisa iFLEXOCAM. Kungenzeka ube nenkinga yokuqubuka nokuvuvukala kwesikhumba okungambulala nokumbulala umuntu.

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- IFLEXOCAM kungenzeka ibe nokuhlobana nokukhuphuka kobungozi bokuhlaselwa yisifo senhliziyo (“*myocardial infarction*”) noma isifo sohlangothi. Maningi amathuba okuthi lokhu kwenzeke kuwena uma usuwusebenzise isikhathi eside lo muthi. Ungalokothi weqise kumthamosilinganiso onconyiwe noma weqise esikhathini esibekiwe sokwelashwa ngalo muthi.
- uma unanoma iyiphi kulezi zinkinga ezilandelayo eziphathelene nemithambo yenhliziyo noma yegazi, tshela udokotela wakho: umfutho wegazi ophakeme, amazinga ekholesteroli aphakeme, isifo sika-shukela, futhi uma ungumuntu obhemayo, njengoba lokhu kungakhuphula amathuba okuhlaselwa yisifo senhliziyo noma isifo sohlangothi. Uma unenkinga yenhliziyo engasebenzi kahle, umfutho wegazi ophakeme noma esinye isifo okungenzeka sibebhetheke noma sibe sibi kakhulu ngenxa yokugcwala koketshezi emzimbeni (ukunqwabelana ngokweqile koketshezi emzimbeni), tshela udokotela wakho. Kuyenzeka kube nokubonakala kwenkinga yokugcwala nokunqwabelana koketshezi ezigulini ezisebenzisa iFLEXOCAM.
- uma unenkinga yezinso noma yesibindi noma usebenzisa imithi engama-*diuretic* (amaphilisi amanzi) noma unenkinga yokuphelelwa amanzi emzimbeni, kumele kuqashelwe futhi kubhekisiswe ngokucophelela ukusebenza kwezinso zakho.
- uma uyisiguli esesikhulile ngokweminyaka futhi unesifo sokungasebenzi kahle kwenhliziyo, phecelezi *congestive heart failure* (lapho inhliziyi yakho ingalipompi igazi elanele eliya emzimbeni wakho), uma usebenzisa imithi yokwelapha *hypertension* (umfutho wegazi ophakeme) noma uma unokuncipha komthamo wegazi (*hypovolaemia*) okubangelwa wukuhlinzwa osanda kukwenza, ukulahlekelwa yigazi, ukusha okubi noma ukuphuza uketshezi oluncane kunomthamo woketshezi ofanele.
- uma odokotela bethole ukuthi unamazinga aphakeme *potassium* egazini lakho.
- uma unezinkinga zezinso futhi usebenzisa umuthi obizwa nge-*pemetrexed* (okungumuthi osetshenziselwa ukwelapha umdlavuza), tshela udokotela wakho ukuze awuguqule ngendlela efanele umthamosilinganiso weFLEXOCAM.

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- uma usebenzisa iFLEXOCAM, kungenzeka ifihle izimpawu zokutheleleka ngesifo (isibonelo, imfiva).
- ukusebenzisa iFLEXOCAM njalo futhi ngokuqhubekayo ezinyangeni ezintathu zokugcina zokukhulelwa kungenzeka kudale umfutho wegazi ophakeme ngokuxakile emithanjeni yegazi yamaphaphu omntwana okungenza kube nzima ukumpompeka kwegazi lingene emaphashini, futhi lokho kungabambezele noma kwelule isikhathi sokubeletha.
- uma usebenzisa *lithium* (umuthi wokuzinzisa isimo sengqondo nomphefumulo).
- uma ungumuntu onesifo sikashukela, amazinga akho *epotassium* kumele aqashelwe futhi abhekisiswe ngokuqhubekayo.
- uma unezinkinga zendlala yegilo.
- uma uneminyaka engaphansi kwe-18 ubudala.
- uma unesifuba somoya.

Ukusetshenziswa kweminye imithi neFLEXOCAM

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

- I-*aspirin* kanye neminye imithi yokuqeda ukuvuvukala nezinhlungu: kungenzeka ikhuphule inkinga yokucela kwezilonda esiswini kanye/noma yokopha.
- Imithi yokuvimbela ukuguquka kwegazi libe ngamahlule noma imithi “yokunciphisa ukushuba kwegazi”, enjenge*warfarin*, *clopidogrel*, *ticlopidine* noma *heparin*, kanye nemithi ecubuza amahlule egazi (*amathrombolytics* / imithi yama-*anti-platelet*), njengoba le mithi kungenzeka ikhuphule ubungozi bokopha.
- Imithi ebizwa ngamaselective *serotonin re-uptake inhibitors* esetshenziselwa ukwelapha isifo sengcindezi yengqondo kungenzeka ikhuphule ubungozi bokopha.
- *Lithium* (umuthi wesifo sengqondo osetshenziselwa ukwelapha izinkinga zesimo sengqondo nomphefumulo), njengoba iFLEXOCAM kungenzeka iphazamise indlela osebenza ngayo

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umuthi wakho.

- *Methotrexate* (esetshenziselwa ukwelapha izimila, izifo zesikhumba ezibucayi kakhulu kanye ne-*active rheumatoid arthritis*), njengoba iFLEXOCAM kungenzeka ikhuphule amandla okusebenza alo muthi.
- Uma owesifazane esebenzisa iFLEXOCAM, kuyancipha ukuvimbeleka kahle kwenzalo ngezivimbela ezishuthekwa ngaphakathi esibeletweni, ama-*intrauterine devices (IUDs)*, futhi kumele asebenzise nezinye izindlela ezengeziwe zokuvimbela inzalo.
- Imithi esetshenziselwa ukwelapha umfutho wegazi ophakeme, kubandakanya namadiuretics (amaphilisi amanzi), njengoba iFLEXOCAM kungenzeka inciphise amandla okusebenza kwale mithi futhi udokotela wakho kungenzeka kudingeke ukuthi akubhekisise futhi akuqaphe ngokuqhubekayo ukusebenza kwezinsizo zakho.
- *Probenecid* (esetshenziselwa ukulawula isifo igawuthi) kungenzeka ikhuphule amandla okusebenza kweFLEXOCAM.
- *Cholestyramine* (esetshenziselwa ukwehlisa amazinga ekholesteroli) kungenzeka inciphise amandla okusebenza kweFLEXOCAM.
- *Ciclosporin* noma *itacrolimus* (esetshenziswa emuva kokufakelwa isitho somzimba noma esetshenziselwa ukwelapha ukugula okunamandla okuphathelele nezinkinga zesikhumba, *rheumatoid arthritis* noma *inephrotic syndrome*) kungenzeka iphazamise indlela ezisebenza ngayo izinso zakho.
- *Deferasirox* (esetshenziselwa ukwelapha amazinga aphakeme esakhamzimba i-ayoni egazini) kungenzeka ikhuphule ubungozi bokopha kanye nezilonda esiswini.
- *Pemetrexed* (esetshenziswa ekwelapheni umdlavuzi), njengoba kungadingeka ukuthi luguqulwe uhlelo lomthamosilinganiso wakho weFLEXOCAM.
- Imithi ephuzwayo yokwelapha isifo sikashukela, enjengamasulphonealureas kanye nenateglinide.
- Amacorticosteroids (asetshenziselwa ukwelapha izifo ezihlukahlukene zokuvuvukala noma zezinkinga zesikhumba) kungenzeka akhuphule ubungozi bezilonda esiswini kanye nokopha.

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Ukuphuza iFLEXOCAM nokudla kanye nophuzo:

IFLEXOCAM kumele iphuzwe nokudla futhi yehliswe ngengilazi yamanzi.

Utshwala kungenzeka bukhuphule ubungozi bokuthi wophe, uma ubuphuza ngesikhathi esifanayo lapho usebenzisa iFLEXOCAM.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Uma ukhulelwe noma usancelisa umntwana wakho, noma uma ucabanga ukuthi mhlawumbe ukhulelwe noma uma uhlela ukuthola umntwana, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iFLEXOCAM.

Akumele usebenzise iFLEXOCAM ngenkathi ukhulelwe. Kungenzeka ilimaze umntwana wakho ongakazalwa futhi iphazamise nokubeletha kwakho kahle ngendlela ejwayelekile.

IFLEXOCAM kungenzeka ingene obisini lwebele, njengoba nemithi efanayo nayo iyaye ingene obisini lwebele. Uma usebenzisa iFLEXOCAM akumele uncelise umntwana wakho.

Akulungile neze ukuthi iFLEXOCAM isetshenziswe ngowesifazane ozama ukukhulelwa, owesifazane onobunzima ukuthi akhulelwe noma owesifazane okwenziwa ukuhlolwa okuthile kuyena njengoba lo muthi ungaphazamisa ukuba kwakhe esimweni esikahle sokuzala nokuthola abantwana noma kubambezele ukuphuma kweqanda esizalweni sakhe.

Ukushayela kanye nokusebenzisa imishini

IFLEXOCAM ingadala ukozela noma ukufiphala kwamehlo.

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

IFLEXOCAM iqukethe ushukela wobisi *i/lactose*.

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IFLEXOCAM iqukethe ushukela wobisi. Iziguli ezinezifo zofuzo eziyivelakancane zokuhluleka komzimba ukugaya ushukela wobisi noma olunye uhlobo lukashukela olubizwa nge*galactose* akumele zisebenzise iFLEXOCAM.

IFLEXOCAM iqukethe ushukela wobisi ongaba nomthelela ekulawulekeni koshukela egazini lakho uma ungumuntu onesifo sikashukela.

3. Isetshenziswa kanjani iFLEXOCAM

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

Umthamosilinganiso ophelele wansukuzonke weFLEXOCAM ngama-15 mg.

Kubantu abadala:

Umthamosilinganiso ojwalelekile yilona:

Ukwelapha i-*acute sciatica*: Ngama-7,5 mg kanye nsukuzonke. Uma bungabi khona ubungcono umthamosilinganiso ungakhushulwa ube ngama-15 mg ngosuku.

Ukwelapha i-*ankylosing spondylitis*: Ngama-15 mg kanye nsukuzonke.

Ukwelapha i-*osteoarthritis*: Ngama-7,5 mg kanye nsukuzonke. Umthamosilinganiso ungakhushulwa ube ngama-15 mg uma kudingekile.

Ukwelapha i-*rheumatoid arthritis*: Ngama-15 mg kanye nsukuzonke. Umthamosilinganiso wunciphise uma kunokwenzeka (inqobo nje uma kubonakala ukuthi amaphilisi asawenza kahle umsebenzi wawo emzimbeni).

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeFLEXOCAM. Uma ubona sengathi iFLEXOCAM inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

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Uma uphuze iFLEXOCAM 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 wamaphilisi oweqile kungenzeka zibandakanye lokhu:

- ukuzizwa unobuthongo noma ukhathele, isicanucanu, ukuhlanza, izinhlungu esiswini kanye nokopha. Ezimweni ezimbi kakhulu umthamosilinganiso oweqile ungasolelela ekutheni ube nenkinga yomfutho wegazi ophakeme, ukuhluleka kwezinsiso ukusebenza, ukuhluleka kwesibindi ukusebenza, ukuquleka isikhathi eside ungaphaphami, ukudlikizela komzimba okungalawuleki kanye nokuhluleka kwenhliziyo ukusebenza ngendlela efanele.

Uma kwenzeka ukhohlwa ukuphuza iFLEXOCAM

Uma kwenzekile wakhohlwa ukuphuza iFLEXOCAM, yiphuze ngokushesha emuva kokukhumbula ukuthi kumele uyiphuze. Uma sekusondele isikhathi sokuphuza umthamosilinganiso olandelayo, ungabe usawuphuza lowo mthamosilinganiso ongawuphuzanga futhi uqhubeke uphuze iFLEXOCAM njengokujwayelekile ngesikhathi esilandelayo esibekiwe. Ungalokothi uphuze imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iFLEXOCAM

Ungalokothi uyeke ukusebenzisa lo muthi ungakaqali ngokukhuluma nodokotela wakho.

4. Imithelela engathandeki okungenzeka ibe khona

IFLEXOCAM kungenzeka ibe nemithelela engathandeki emzimbeni.

Akuyona yonke imithelela engathandeki ebikiwe yeFLEXOCAM equkethwe kuleli pheshana lolwazi.

Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi

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ongathandeki emzimbeni ngenkathi usebenzisa iFLEXOCAM, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iFLEXOCAM 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.

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

- *ibronchospasm* noma isifuba somoya (ukukhwehlela, ukuphefumula kanzima, ukuphefumula okunomsindo, iphika, umuzwa wokucindezeleka esifubeni, ukubefuzela)
- ukuba khona kwegazi emchamweni wakho (amanzi)
- ukushaya kwenhliziyi ngamandla noma ngokushesha (*tachycardia*)
- izinhlungu esifubeni (*angina*), ukushaya kwenhliziyi ngesigqi esingahambelani kahle noma ngokushesha (*amapalpitations*, umfutho wegazi ophakeme noma umfutho wegazi ophansi), umuzwa onkenkethayo esifubeni sakho noma ezingalweni
- isifo sokuhluleka kwenhliziyi ukusebenza ngendlela efanele (isifo senhliziyi, esihambisana nephika kanye nokuvuvukala kobuso, izinyawo noma ingxenye esezansi yemilenze, okubangelwa wukugcwala nokunqwabelana koketshezi emzimbeni)
- umbala womchamo wakho uba mnyama, uzizwe ukhathele, ugula futhi ungakuthandi ukudla

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- ukuvuvukala kunoma iyiphi ingxenye yomzimba
- ukukhipha indle ebomvu, esatiyela, njengoba lokhu kungenzeka kube wuphawu lwezilonda ezophayo esiswini
- ukuvuvukala kwesibindi (*hepatitis*) okubonakala ngezimpawu ezinjengezinhlungu esiswini nendawo ezungezile, ukukhathala kakhulu, isicanucanu, imfiva, ukuguquka kwamehlo noma isikhumba kube nombala ophuzi, futhi okubizwa ngejondisi
- isifo sohlangothi (ubundikindiki obenzeka kungalindelekile ebusweni, engalweni noma emlenzeni, ikakhulukazi ohlangothini olulodwa lomzimba)
- ukuvela kwamabhamuza, ukuxebuka noma ukopha kunoma iyiphi ingxenye yesikhumba sakho okungenzeka kuhambisane nomqubuko noma kungahambisani nomqubuko (kubandakanya izindebe zomlomo, amehlo, umlomo, ikhala, izitho zangasese, izandla noma izinyawo zakho), izimpawu ezinjengezomkhuhlane (imfiva, ukuzwa amakhaza kanye nemisipha yomzimba enkenkethayo) okuyizimpawu zesifo sesikhumba esibucayi esibangelwa wukungezwani komzimba nomuthi othile (esibizwa nge *Steven Johnson Syndrome/toxic epidermal necrolysis (TEM)*) esingambulala nokumbulala umuntu
- umqubuko esikhunjeni noma izisihla zesikhumba ezingajwayelekile eziyindilinga enombala ophinki/obomvu futhi ephaphathekile phakathi nendawo okungenzeka kulume, kube nezimpephelezi noma kugcwale uketshezi ngaphakathi. Umqubuko kungenzeka uvele ikakhulukazi ezintendeni zesandla noma ngaphansi kwezinyawo zakho. Lokhu kungaba yizimpawu ze-aleji yesikhumba ebucayi kakhulu ebizwa nge-'*erythema multiforme*'
- ukuchama umchamo omncane kunalokho okujwayelekile kuwena lapho uchama
- amanani axakile futhi angajwayelekile ezingqalampilo zegazi ezimhlophe kanye namaplathelethi, ukopha noma imihuzuko engajwayelekile, umphimbo obuhlungu, imfiva kanye nokuzwa amakhaza
- ukudideka nokuphazamiseka kwengqondo okwenza ungazi ukuthi ukuphi, ungasazi isikhathi, ungasazi ukuthi ungubani nokuthi kwenzekani eduze kwakho, ukuguquka kwesimo sengqondo nomphefumulo, ingcindezi yengqondo

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- isifo *ipancreatitis* (ukuvuvukala kwamanyikwe) (izimpawu zaso kungenzeka zibandakanye ubuhlungu engxenyeni yesisu engasenhla, obusabalalayo buze buyofinyelela emhlane; isisu esikhukhumele futhi esinezindawo ezibuhlungu lapho usithinta noma usicindezela; isicanucanu nokuhlanza, imfiva kanye nenhliziyo eshaya ngamandla)
- ukuvuvukala kwethumbu elikhulu esiswini (isifo sohudo, ngokuvamile esinendle enegazi noma enombala omnyama, izinhlungu esiswini kanye nemfiva)
- izinhlungu ezinamandla futhi ezibeleseyo esiswini nendawo ezungezile.

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:

- i-anemiya (kungenzeka uzizwe ubuthakathaka futhi ubukeke uphaphathekile)
- ikhanda elibuhlungu, isiyezi, inzululwane
- ukungezwa ezindlebeni
- ukuvuvukala kwengxenywe esezansi yemilenze yakho, izandla, izingalo, izinyawo, amaqakala kanye nemilenze
- isifo sohudo, ukuqunjelwa, izinhlungu esiswini, ukugula noma ukuzizwa sengathi uyagula, inkinga yokungagayeki kahle kokudla, isilungulela
- ukuqubuka esikhunjeni noma ezinye izinkinga zesikhumba, ukuluma kwesikhumba
- ukukhathala noma ukuba buthakathaka ngendlela engajwayelekile.

Imithelela engathandeki engavamile ukwenzeka:

- Imiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile
- ukukhula noma ukuncipha kothando lokudla, ukuzimuka noma ukuncipha emzimbeni
- ukozela, ukungalali kahle, amaphupho amabi
- isifo sokuvuvukala kontwentwesana olumboze ubuchopho nomfunkulu, phecelezi i-aseptic

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meningitis (izimpawu zaso zibandakanya imfiva, ukuzwa amakhaza, isisu esibuhlungu, ikhanda elinkenkethayo, ukuphelelwa wuthando lokudla kanye nokuhlanza)

- ukuphazamiseka kokusebenza kahle kwamehlo, amehlo afiphele noma ezinye izinkinga zamehlo
- *ivertigo* (ukuzizwa ungenayo ibhalansi emzimbeni / ikhanda elinomuzwa ozulayo nojikelezayo), ukukhala kwemisindo noma izihlonono ezindlebeni
- ukufikelwa wukushisa okukhulu esikhunjeni nasebusweni, ukuzwela kakhulu kwesikhumba ekukhanyeni, ukujuluka
- umfutho wegazi ophakeme, umfutho wegazi ophansi (ikhanda elibuhlungu, izinkinga zokungaboni kahle, amehlo afiphele, ukushaya kwenhliziyo ngesigqi esingahambelani kahle)
- umlomo owomile, umuzwa wokunambitha oxakile futhi ongajwayelekile, umphimbo obuhlungu, isilungulela, ukugcwala ngokweqile komoya esiswini (umsuzo)
- umlomo noma umphimbo ovuvukele noma obuhlungu, izilonda esiswini noma emathunjini, isifo *icolitis* (ukuvuvukala kukapopopo noma isifo *iCrohn's disease*), okungenzeka kubhebhethetheke futhi kube kubi kakhulu
- imiphumela yokuhlolwa kokusebenza kwesibindi ebonisa okuxakile futhi okungajwayelekile
- ukukhipha amanzi (umchamo) amancane noma amaningi kunalokho okujwayelekile kuwena, imiphumela yokuhlolwa kokusebenza kwezinsu ebonisa okuxakile futhi okungajwayelekile
- ukubambezeleka kokuphuma kweqanda esizalweni sowesifazane
- umuzwa wokunsonsotha, ukushisa, ukuncinza (obizwa phecelezi ngamapins and needles), noma ubundikindiki.

Le mitholela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- izilonda esiswini, phecelezi, *peptic ulcer* (ubuhlungu obushisayo/obuvuthayo kwingxenye yesisu emaphakathi noma engasenhla obuzwakala esikhathini esiphakathi kwesidlo sakho esedlule kanye nesidlo esilandelayo noma ebusuku)
- ubunyumba/ukungabi nanzalo kowesifazane.

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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, usokhemisi noma umhlengikazi. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngohlelo xhumano 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 kweFLEXOCAM. Futhi ungathumela i-imeyili ngqo enkampanini, pharmacovigilance@pharmadynamics.co.za, ngenhloso yokuqinisekisa ukuphepha komkhiqizo.

5. Indlela yokugcina iFLEXOCAM

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.

Yivikele ekukhanyeni.

Izingqwenjana eziyizigcinimaphilisi 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

Okuqukethwe yiFLEXOCAM

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Isithako sokwelapha esiyinhloko esiqukethwe ephilisini ngalinye leFLEXOCAM 7,5 yimeloxicam engama-7,5 mg.

Isithako sokwelapha esiyinhloko esiqukethwe ephilisini ngalinye leFLEXOCAM 15 yimeloxicam engama-15 mg.

Ezinye izithako yilezi:

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous, sodium citrate.

7. Indlela ebukeka ngayo iFLEXOCAM kanye nalokho okuqukethwe ephaketheni layo

Amaphilisi iFLEXOCAM 7,5 anombala ophuzi ngokukhanyayo, ayindingilizi, aqumbile nhlangothi zombili, anonqenqema olutshekile oluqoshwe umbhalo onohlamvu B kanye nenamba 18 ohlangothini olulodwa kanti ngakolunye uhlangothi akubhaliwe lutho.

Amaphilisi iFLEXOCAM 15 anombala ophuzi ngokukhanyayo, ayindingilizi, aqumbile nhlangothi zombili, anonqenqema olutshekile oluqoshwe umbhalo onohlamvu B kanye nenamba 19 engxenyeni ngayinye yephilisi ehlukaniswe wumugqa onqamula phakathi ohlangothini olulodwa lwephilisi kanti ngakolunye uhlangothi akubhaliwe lutho.

Amaphilisi iFLEXOCAM 7,5 agcinwe emaphaketheni aqukethe izigcinamaphilisi zePVC/PVdC ezingabonisi ngokucacile okuqukethwe ngaphakathi ezakhiwe nge-aluminium eqinile eziqukethe amaphilisi angama-30 (imisweswana yamaphilisi ayi-10) ezifakwe kwibhokisana.

Amaphilisi iFLEXOCAM 15 agcinwe emaphaketheni aqukethe izigcinamaphilisi zePVC/PVdC ezingabonisi ngokucacile okuqukethwe ngaphakathi ezakhiwe nge-aluminium eqinile eziqukethe amaphilisi ayi-10 noma angama-30 (imisweswana yamaphilisi ayi-10) ezifakwe kwibhokisana.

8. Umnikazi Wesitifiketi Sokubhaliswa

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

FLEXOCAM 7,5 kanye ne-15 mg

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9. Leli pheshana lolwazi lagcina ukubuyekezwa mhla ziyi-

13 kuNhlaba 2022

10. Inamba yokubhaliswa

FLEXOCAM 7,5: A38/3.1/0497

FLEXOCAM 15: A38/3.1/0498

FLEXOCAM 7,5:

NAM: 06/3.1/0205 BOT: BOT1101978

FLEXOCAM 15:

NAM: 06/3.1/0204 BOT: BOT1101977A

BOT: BOT1101977B