Noble Printing Press

File Name : PE310050514_1_ZA_Acti_Lift_20mg_LF_R3

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Pharma Code: 31005 **Paper:** 40gsm Bible **Date:** 21-05-2014 (Front)

SKEDULERINGSTATUS: S5
HANDELSNAAM EN DOSERINGSVORM
ACTI-LIFT 20 mg TABLETTE

SAMESTELLING

Elke filmbedekte tablet bevat sitalopram waterstofbromied gelykstaande aan 20 mg sitalopram. **ACTI-LIFT** bevat ook 114.5 mg lactose monohidraat per tablet.

FARMAKOLOGIESE KLASSIFIKASIE

A1.2 Psigo-analeptika (antidepressante)

FARMAKOLOGIESE WERKING:

Farmakodinamika:

Sitalopram is 'n bisikliese ftalaat-derivaat met 'n antidepressiewe uitwerking. Die uitwerking daarvan is gekoppelaan die selektiewe inhibisie van spesifieke serotonien (5-HT) heropname. Sitalopram blokkeer die heropname van 5-HT primer deur middel van sy (S) enantiomeer, wat lei tot versterking van serotonergiese aktiwiteit in die sentralesenuweestelsel (SSS). Nie sitalopram of sy metaboliete het 'n uitwerking op die heropname van noradrenalien, dopamien en gamma-aminobottersuur (GABA) nie. Sitalopram het weinig of geen antiposaminergiese, antiadrenergiese, antiserotonergiese, antihistaminergiese of anticholinergies eeienskappe.

Farmakokinetika

Biobeskikbaarheid na orale toediening is ongeveer 80% en piek plasmavlakke word gemiddeld binne 4 ure bereik (wissel tussen1 tot 6 ure). Die volume van verspreiding is ongeveer 14 L/kg (wissel tussen 9 tot 17 L/kg). Dit neem 1 tot 2 weke om stabielestaat konsentrasie te bereik. Proteïen binding is ongeveer 80 %. Die gemiddelde eliminasie halfleeftyd is 36 ure (wissel tussen 28 – 42 ure). Sitalopram ondergaan hepatise metabolisme,wat primêr die sitochroom P450 (CYP3A4) en 2C19 (CYP2C19) isoënsieme en tot 'n mindere mate die sitochroom P450 2D6 (CYP2D6) isoënsieme betrek. Die metaboliete inhibeer ook die heropname van serotonien, maar is nie so kragtig soos die stammolekule nie. Sitalopram word hoofsaaklik deur die lewer uitgeskei en die oorblywende metaboliete deur die niere (ongeveer 20 % waarvan 12 % onveranderde medisyne is). Weens 'n verlaagde metabolisme is langer halfleeftye en 'n afname in opruiming by bejaarde pasiënte aangetoon.

INDIKASIES

ACTI-LIFT word aangedui vir die behandeling van:

- Depressie en die voorkoming van terugvalle
- Paniekafwyking met of sonder agorafobie (ruimtevrees)
- Obsessief-kompulsiewe versteuring (OKV)

KONTRA-INDIKASIES:

- Hipersensitiwiteit vir sitalopram of enige van die bestanddele in die formuleering daarvan.
- 'Gelyktydige gebruik met 'n monoamienoksidase-inhibeerder (MAOI). Ten minste 14 dae moet verloop na die gebruik van die MAOI gestaak is, Voordat terapie met **ACTI-LIFT** kan begin.

MAOI's mag slegs gebruik word 7 dae nadat die gebruik van **ACTI-LIFT** gestaak is (sien: **"INTERAKSIES"**).

- Ernstige niersiektes (kreatinien opruiming minder as 20 ml/min).
- Veiligheid en doeltreffendheid tydens swangerskap en laktasie is nog nie vasgestel nie.
- Kinders onder die ouderdom van 18 (sien: **"WAARSKUWINGS"** en **"NEWE- EFFEKTE EN SPESIALE VOORSORGMAATREëLS"**)

WAARSKUWINGS

ACTI-LIFT moet versigtig gebruik word by:-

- Bejaarde pasiënte – Langer halfleeftye en verminderde opruiming as gevolg van 'n verlaagde metabolisme. 'n laer dosis word vir bejaardes aanbeveel.
- Hepatiese siektes – Opruiming van **ACTI-LIFT** word verminder Versigtige dosistitrering en 'n laer maksimum dosis word aanbeveel.
- Niersiektes – Eliminasie is verminderd. Indien kreatinienopruiming minder as 20 ml/min is, moet **ACTI-LIFT** nie gebruik word nie. (Sien: **"KONTRA- INDIKASIES"**)
- Toevalle of 'n geskiedenis daarvan – Daar bestaan 'n verhoogde risiko van toevalle. **ACTI-LIFT** moet versigtig gebruik word by pasiënte met beheerde epilepsie en moet vermy word by pasiënte waar epilepsie swak beheer word. Versigtigheid moet aan die dag gelê word by pasiënte wat elektrokonvulsie terapie ondergaan
- Manie of 'n geskiedenis van manie – Die toestand mag dalk weer na vore tree. **ACTI-LIFT** moet gestaak word indien die pasiënt die maniese fase betree.
- **ACTI-LIFT** kan die hart stadiger laat klop. Versigtigheid moet aan die dag gelê word by pasiënte met voorafbestaande stadige hartklop.
- Diabetes mellitus – Seldsame gevalle van hipoglukemie is aangemeld.
- **ACTI-LIFT** moet nie gelyktydig met monoamienoksidase inhibeerders, imipramien, ander serotonergistiese medisyne, moklobemied, alkohol, warfarin en simetidien toegedien word nie (sien: **"INTERAKSIES"**).
- Die risiko van serotoniensindroom is seldsaam, maar 'n Potensieël dodelike hiposerotonergiese toestand kan ontstaan indien dit met ander serotonergiese medikasie gekombinee word (sien: **"INTERAKSIES"**) (Toestand kan ontstaan indien dit in kombinasie met ander serotonergiese middels geneem word).

Pasiënte met 'n ernstige depressiewe afwyking, se depressiwiteit en/ of selfmoord gedagtes kan vererger of selfmoord gedrag mag by hulle ontstaan. Hierdie risiko mag voortduur totdat 'n beduidende remissie plaasvind. Dit is egter nog nie vasgestel of antidepressante wel 'n oorsaaklike rol speel in die aanbring van sodanige gedrag nie. Pasiënte wat met **ACTI-LIFT** behandel word, moet noukerig gemonitor word vir kliniese agteruitgang en selfmoordneigings, veral wanneer 'n pasiënt me tterapie begin en wanneer doserings verander word, hetsy of dit vermeerder of verminder word.

As gevolg van die moontlikheid van ko-morbiditeit tussen ernstige depressiewe afwyking en ander psigiatriese en nie-psigiatriese siektes, moe tdieselfde voorsor ggetref word tydens die behandeling van psigiatriese en nie-psigiatriese siektes as wat die geval by ernstige depressiewe afwykings is.

Die volgende simptome is gerapporteer by pasiënte wat met antidepressante soos **ACTILIFT** behandel word vir ernstige depressieweafwyking,sowel as vir ander indikasies soos psigiatriese en nie-psigiatriese siektes: angstigheid, agitasie, paniekaanvalle, slapeloosheid, geïrriteerdheid, vyandigheid (aggressiwiteit, impulsiwiteit, akathisia, hipomanie en manie). Hoewel daar nog nie 'n oorsaak vasgestel is vir die verband tussen die aanvang van sodanige simptome, en of die verergering van depressie en/ of die ontstaan van selfmoordimpulse nie, moet dit oorweeg word om die terapeutiese regime te verander, dit sluit in die moontlike staking van **ACTI-LIFT** by pasiënte in wie die simptome baie erg is, skielik begin het, of waar dit nie deel van die pasiënt se aanvanklike simptome was nie.

Indien daar besluit word om die behandeling met **ACTI-LIFT** te staak, word aanbeveel dat die aanbevole dosis geleidelik verminder word om die moontlikheid van onttrekkingsimptome te voorkom (sien: **"DOSERING EN GEBRUIKSAANWYSINGS").**

Die veiligheid en doeltreffendheid van **ACTI-LIFT** by kinders onder 18 jaar is nog nie vasgestel nie (sien: **"KONTRA-INDIKASIES en NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS").**

INTERAKSIES

- **Monoamienoksidase-inhibeerders (MAOI)** – Gelyktydige gebruik word teen aangedui. Ernstige en potensieël dodelike reaksies soos hipertermie, rigiditeit, mioklonus, outonomiese onstabiliteit met snelle fluktuasie in tekens van lewe en verandering in die geeste toestand van die pasiënt insluitende agitasie wat in delirium kan omsit en selfs koma is aangedui (sien: **"KONTRA-INDIKASIES").**
- **Imipramien** – 'n Toename in die konsentrasie van desimipramien (die aktiewe metaboliete in imipramien) kan voorkom. Dit lyk as of **ACTI-LIFT** nie 'n merkbare toename in plasmavlakke van sommige trisikliese antidepressante veroorsaak nie.
- **Ander serotonergiese medisyne of medisyne met serotonergiese aktiwiteit –** Verhoogde risiko vir die ontwikkeling van die serotoniensindroom wat 'n seldsame, maar potensieël dodelike hiperserotonergiese toestand is.
- **Moklobemied** – Serotoniensindroom het ontwikkel na die gelyktydige inname van moklobemied en **ACTI-LIFT**.
- **Alkohol**– Die uitwerking van alkohol mag vererger word.
- **Warfarin** – Die antikoagulerendewerking van warfarin mag verhoog word.
- **Simetidien** – Die AUC en die maksimum plasmavlakke van **ACTI-LIFT** neem toe as **ACTI-LIFT** saam met simetidien toegedien word.

SWANGERSKAP EN LAKTASIE

Veiligheid en doeltreffendheid tydens swangerskap en laktasie is nog Nie vasgestel nie. **ACTILIFT** word in die borsmelk uitgeskei.

DOSERING EN GEBRUIKSAANWYSINGS

Depressie

20 mg per dag as 'n enkele dosis. Die dosis mag met weeklikse intervalle deur 20 mg per dag verhoog word tot 'n maksimum dosis van 60 mg, afhangende van die pasiënt se respons.

Angsafwyking

10 mg per dag as 'n enkele dosis vir die eerste week waarna dit tot 20 mg per dag verhoog word. Die dosis mag daarna verder verhoog word indien nodig, maar slegs tot 'n maksimum van 60 mg per dag, afhangend van die pasiënt se respons.

ObsessiefkompulsieweVersteuring:

20 mg per dag as 'n enkele dosis. Die dosis mag in hoeveelhede van 20 mg tot 'n maksimum van 60 mg per dag verhoog word, afhangend van die pasiëntse respons. Indien 'n besluit geneem word om die behandeling met ACTI-LIFT te staak, word aanbeveel dat die dosis geleidelik verminder word om die moontlikheid van onttrekking simptome te voorkom (sien **"WAARSKUWINGS"**).

Spesiale populasies

Bejaardes: 20 mg per dag as 'n enkele dosis. Afhangende van die pasiënt se respons, kan die dosis tot 'n maksimum van 30 mg per dag verhoog word.

Verswaktelewerfunksie: Halveer die dosis.

Verswaktenierfunksie: In gevalle van geringe of matige niersiektes is

Dit nie nodig om die dosis aan te pas nie.

Die aanvangs werking is tussen 2 tot 4 weke. Die behandeling moet vir 'n gepaste tydperk volgehou word (vir tot ses maande) nadat die pasiënt herstel het, om terugvalle te voorkom.

ACTI-LIFT kan met of sonder kos in die oggend of aand geneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS:

Newe-effekte:

Hartsiektes

Gereeld
Palpitasies, bewerasie
Minder gereeld
Bradikardie

Senuweestelselsiektes:

Gereeld
Slaapsteurnisse, parestesie, rustelоosheid, hoofpyn, duiseligheid, moegheid, slaperigheid

Minder gereeld

Agitasie, verwardheid, verswakte konsentrasie, malaise, manie, stuiptrekkings, serotoniensindroom, neuroleptiese kwaadaardige sindroom, akathisia, impulsiwiteit, aggressiwiteit, angstigheid, angsaanvalle, slaaploosheid, geïrriteerdheid, hipomanie.

Metabolisme en Voedingsiektes:

Gereeld

Gewigskommeling

Gastroïntestinale siektes

Gereeld
Naarheid, hardlywigheid, diarree, swak spysvertering, droë mond

Minder gereeld

Salivasie (speekselafskeiding)

Nier- en urienwegsiektes:

Gereeld

Mikturisieversteurings

Minder gereeld

Seksuele disfunksie, ingesluit ejakulasie-afwykings, verlaagde libido, anorgasmie

Hepato-galsiektes:

Minder gereeld

Hepatitis

Muskoskeletale, bindweefsel- en beensiektes:

Dikwels

Astenie/Moegheid

Oogsiektes:

Dikwels

Akkommodasiesteurnisse

Minder gereeld

Midriase

Respiratoriese, toragiese en mediastinale siektes:

Minder gereeld

Nasale stuwing

Vel- en subkutane siektes:

Gereeld

Sweet

Minder gereeld

Veluitslag

Algemene afwykings en toestande by die plek van toediening:

Minder gereeld

Gaap, vyandigheid, selfmoord gedagtes en selfbesering

SpesialeVoorsorgmaatreëls:

- Pasiënte moet aan die begin van terapie noukeurig gemonitor word totdat 'n verbetering in die depressiewe toestand opgemerk word aangesien selfmoord 'n inherent risiko by depressiewe pasiënte is.
- Serotonien-sindroom kom meer algemeen voor nadat 'n pasiënt se dosis verhoog is.
- Indien terapie met **ACTI-LIFT** gestaak moet word, is dit raadsaam om die dosis geleidelik te verminder en sodoende die moontlikheid van onttrekkingsimptome te voorkom.
- Vermy alcohol (sien: **"INTERAKSIES")**
- Die veiligheid en doeltreffendheid in kinder sonder 18 is nog nie vasgestel nie. Kliniese proewe in pasiënte met Ernstige Depressiewe Versteuring, het 'n toename in vyandigheid, selfmoordgedagtes en selfbesering aangetoon.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik:

ACTI-LIFT kan psigomotoriese werkverigtin gbelemmer. Indien pasiënte geaffekteer word, moet hulle nie masjinerie hanteer of bestuur nie

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN:

(Sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS"**)

Simptome van oordosering: Moegheid, swakheid, sedasie, duiseligheid, bewerasie, naarheid, slaperigheid en sinustagikardie.

Behandeling van oordosering:

Behandeling is simptomaties en ondersteunend.

Daar is nie enige spesifieke teenmidddel vir **ACTI-LIFT** nie.

Die maag moet so gou as moontlik deur middel van braking of maaguitspoeling leeggemaak word. Die hart en lewenstekens moet gemonitor word en die pasiënt moet daarna vir ongeveer 24 uur onder mediese toesig gehou word.

IDENTIFIKASIE:

Pienk, ovaalvormige bikonvekse tablette met 'n "G" aan die bokant en 'n"11" aan die onderkant van die halveerlyn op die een aansig van die tablet, en "20" aan die ander kant van die tablet gegraveer.

AANBIEDING:

ACTI-LIFT tablette word in wit ondeursigtige HDPE-bottels met 28, 30, 100 en 500 tablette verpak.

BERGINGSINSTRUKSIES:

Bewaar in 'n diggeslote houer teen of benede 25°C.

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

41/1.2/0297

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:

Glenmark Pharmaceuticals South Africa (Pty) Ltd
Unit 7 and 8 York House,
Tybalt Place
185 Howick Close
Waterfall Business Park
Bekker Street
Vorna Valley
Midrand

DATUM VAN PUBLIKASIEVAN HIERDIE VOUBILJET:

4 Maart 2011

PE310050514-1 ZA

PASIËNTINLIGTINGSBLAD

ACTI-LIFT 20 mg Tablette

Lees hierdie hele blad noukeurig deur voordat u begin om ACTI-LIFT te gebruik.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, vra asseblief vir u dokter of u apteker.
- **ACTI-LIFT** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Skeduleringstatus van die medisinale produk: S5

Eiendomsnaam, sterkte en farmaseutiese vorm

ACTI-LIFT 20 mg TABLETTE

Sitalopramhidrobromied gelykstaande aan sitalopram 20 mg

1. Wat ACTI-LIFT tablette bevat:

- Die aktiewe bestanddeel is sitalopramhidrobromied gelykstaande aan 20 mg sitalopram. Die ander bestanddele is laktosemonohidraat, mikrokristallyne sellulose, povidoon, kruispovidoon, magnesiumstearaat, titaniumdioksied, hidromellose, makrogol en ys teroksiede (rooi en geel).

2. Waarvoor ACTI-LIFT tablette gebruik word:

ACTI-LIFT bevat sitalopram wat aan 'n groep medisyne bekend as antidepressante behoort. **ACTI-LIFT** word vir die behandeling van depressie en voorkoming van 'n terugval, paniekversteuring met of sonder ruimtevrees, en obsessiewe-kompulsiewe versteuring (OKV) gebruik.

3. Voordat u ACTI-LIFT tablette gebruik:

U moet vir u dokter sê as u

- swanger is of dink dat u swanger kan wees.
- medisyne gebruik wat aan die klas bekend as monoamienoksidaseremmers (MAOR's) behoort of dit in die voorafgaande 14 dae gestaak het.
- dit vir u moeilik is om motor te bestuur of masjinerie te hanteer.

U moet ACTI-LIFT tablette nie gebruik nie as

- U hipersensitief (allergies) teenoor sitalopram of enige van die ander bestanddele van **ACTI-LIFT** tablette is.
- U niere nie so goed werk as wat hulle moet nie.

Wees besonder versigtig met ACTI-LIFT tablette

As u nierprobleme het, moet u dit vir u dokter sê voordat u **ACTI-LIFT** tablette gebruik.

Swangerskap en borsvoeding

Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

As u swanger is of u baba borsvoed terwyl u hierdie medisyne gebruik, moet u asseblief u dokter, apteker of ander gesondheidsorgdeskundige om advies vra.

Gebruik van ander medisyne saam met ACTI-LIFT tablette

As u ander medisyne op gereelde basis gebruik, waaronder aanvullende of tradisionele medisyne, kan die gebruik van **ACTI-LIFT** tablette saam met hierdie medisyne ongewensde interaksies veroorsaak. Sê asseblief vir u dokter, apteker of ander gesondheidsorgdeskundige as u enigeen van die volgende gebruik:

- Monoamienoksidaseremmers
- Imipramien
- Moklobemied
- Selegilien
- Sumatriptaan

4. Hoe om ACTI-LIFT tablette te gebruik:

Gebruik ACTI-LIFT tablette altyd presies soos wat u dokter vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Vir behandeling van depressie is die aanbevole dosis 20 mg per dag. Die tablette kan in die oggend of aand en nie noodwendig saam met voedsel nie, gedrink word. U dokter kan die dosis, indien nodig, tot 60 mg verhoog.

Vir die behandeling van paniekversteuring is die aanbevole dosis 10 mg vir die eerste week voordat dit na 20 mg verhoog word.

U dokter kan die dosis, indien nodig, tot 60 mg verhoog.

Vir die behandeling van obsessiewe kompulsiewe versteuring is die aanbevole aanvanklike dosis 20 mg. Dit kan, indien nodig, met inkremente van 20 mg tot 60 mg daagliks verhoog word.

Vir bejaarde pasiënte is die aanbevole daaglikse dosis 20 mg en dit kan afhangende van die pasiënt tot 30 mg verhoog word.

Vir pasiënte met swak lewerfunksie moet die dosis gehalveer word.

Vir pasiënte met ligte tot matige swak nierfunksie hoef die dosis nie aangepas te word nie.

As u meer ACTI-LIFT tablette gedrink het as wat u moes

Sommige van die volgende simptome kan voorkom as u meer tablette drink as wat u moes: Moegheid, swakheid, sedasie, duiseligheid, bewerasie, naarheid en lomerigheid.

Raadpleeg u dokter of apteker onmiddellik in geval van oordosering. As nie een beskikbaar is nie, kry hulp van die naaste hospitaal of vergiftigingsentrum.

As u vergeet het om u ACTI-LIFT tablette te drink

As u 'n dosis oorgeslaan het, drink u tablet sodra u onthou. As dit egter amper tyd vir die volgende dosis is, moet u nie 'n dubbele dosis drink om vir die oorgeslane individuele dosis op te maak nie.

5. Moontlike newe-effekte:

Soos enige ander medisyne kan **ACTI-LIFT** tablette newe-effekte en wel die volgende veroorsaak:

Algemene newe-effekte is

- Hoofpyn, sweet, moegheid, bewerigheid, gewigstoename/verlies
- Hartkloppings, slaapversteurings, rustelоosheid
- Naarheid, diarree, slegte spysvertering, droë mond
- Hardlywigheid
- Dowwe visie
- Versteuring in urinering

Newe-effekte wat soms voorkom, is

- Ongesteldheid, gaap, stadige hartklop
- Agitasie, verwardheid, swak konsentrasie, lae libido, versteurings in ejakulasie, gebrek aan orgasme
- Salivasie, veluitslag, toe neus
- Konvulsies, rustelоosheid, impulsiwiteit, aggressiwiteit, angs, paniekaanvalle, ge brek aan slaap, geïrriteerdheid, hipomanie
- Hepatitis
- Gaap, vyandigheid, selfmoordgedagtes en selfbesering

Nie alle newe-effekte wat vir **ACTI-LIFT** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger terwyl u **ACTI-LIFT** gebruik, moet u u dokter, apteker of ander gesondheidsdeskundige om advies raadpleeg.

Invloed op die vermoë om motor te bestuur of masjinerie te gebruik:

ACTI-LIFT kan die vermoë belemmer vir die uitvoering van take wat vaardigheid vereis. Indien aangetas, moet hierdie pasiënte nie masjinerie hanteer of 'n motor bestuur nie.

6. Bewaring en wegdoening van ACTI-LIFT tablette:

Hou alle medikasie buite bereik en sig van kinders.
Bewaar in diggeslote houers by of benede 25 °C.
Hierdie medisyne moet nie na die vervaldatum op die houer gebruik word nie.
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

7. Aanbieding van ACTI-LIFT tablette:

ACTI-LIFT tablette is beskikbaar in wit, ondeursigtige HDPE-bottels met 28, 30, 100 of 500 tablette.

8. Identifikasie van ACTI-LIFT tablette:

Pienk, ovaalvormige, bikonvekse tablette met "G" aan die een kan en "11" aan die ander kant van die breeklyn op die een kant van die tablet gegraveer en met "20" op die ander kant.

9. Registrasienommer:

41/1.2/0297

10. Naam en adres van houer van registrasie:

Glenmark Pharmaceuticals South Africa (Pty) Ltd
Unit 7 and 8 York House,
Tybalt Place
185 Howick Close
Waterfall Business Park
Bekker Street
Vorna Valley
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SCHEDULING STATUS: S5

PROPRIETARY NAME AND DOSAGE FORM

ACTI-LIFT 20 mg TABLETS

COMPOSITION

Each film-coated tablet contains citalopram hydrobromide equivalent to citalopram 20 mg.

ACTI-LIFT also contains 114.5 mg of lactose monohydrate per tablet.

PHARMACOLOGICAL CLASSIFICATION

A 1.2 Psychoanaleptics (antidepressants)

PHARMACOLOGICAL ACTION

Pharmacodynamics:

Citalopram is a bicyclic phthalane derivative with antidepressant effect. Its effect is linked to the selective inhibition of specific serotonin (5-HT) reuptake. Citalopram, primarily through its (S)- enantiomer, blocks 5-HT reuptake, leading to potentiation of serotonergic activity in the central nervous system (CNS). Neither citalopram nor its metabolites have an effect on noradrenaline, dopamine and GABA reuptake. Citalopram has little or no antidopaminergic, antiadrenergic, antiserotonergic, antihistaminergic or anticholinergic properties.

Pharmacokinetics

Oral bioavailability is about 80 % with maximum plasma levels being reached in 4 hours (range 1 to 6 hours). Volume of distribution is about 14 L/kg (range 9 to 17 L/kg). Time to reach steady state concentration is 1 to 2 weeks. Protein binding is about 80 %. Elimination half-life is 36 hours (range 28 – 42 hours). Citalopram undergoes hepatic metabolism primarily involving the cytochrome P450 (CYP3A4) and 2C19 (CYP2C19) isoenzymes and to a small extent cytochrome P450 2D6 (CYP2D6) isoenzymes. The metabolites also inhibit the reuptake of serotonin, but are less potent than the parent molecule. Citalopram is excreted mainly via the liver with the remainder via the kidneys (approximately 20 % of which 12 % is unchanged medicine). Longer half-lives and decreased clearance due to a reduced rate of metabolism has been demonstrated in the elderly.

INDICATIONS

ACTI-LIFT is indicated for the treatment of

- Depression and prevention of relapse
- Panic disorder with or without agoraphobia.
- Obsessive-compulsive disorder (OCD)

CONTRA-INDICATIONS:

- Hypersensitivity to citalopram or any of the ingredients in the formulation.
- Concurrent use with a monoamine oxidase inhibitor (MAOI). At least 14 days should elapse between discontinuing the MAOI and initiating therapy with **ACTI-LIFT**. MAOIs should not be introduced for 7 days after discontinuation of **ACTI-LIFT** (see **"INTERACTIONS"**).
- Severe renal impairment (creatinine clearance less than 20 ml/min)
- Safety and efficacy in pregnancy and lactation has not been established
- Children under the age of 18 years (see **"WARNINGS"** and **"SIDE EFFECTS AND SPECIAL PRECAUTIONS"**)

WARNINGS:

ACTI-LIFT should be used with caution in:-

- Elderly patients – Longer half-life and decreased clearance due to a reduced rate of metabolism. A lower dose is recommended in the elderly.
- Hepatic impairment – Clearance of **ACTI-LIFT** is reduced. Cautious dosage titration and a lower maximum dose are recommended.
- Renal impairment – Elimination is decreased. If creatine clearance is less than 20 ml/min **ACTI-LIFT** should not be used. (See **"CONTRA INDICATIONS"**)
- Seizures or history thereof – There is an increased risk of seizures. **ACTI-LIFT** should be used with caution in patients with controlled epilepsy and be avoided in patients with poorly controlled epilepsy. Care is advised in patients receiving electroconvulsive therapy.
- Mania or history of mania – Condition may be re-activated. **ACTI-LIFT** should be discontinued if the patient enters the manic phase.
- **ACTI-LIFT** may cause a reduction in heart rate. Caution is advised in patients with preexisting slow heart rates.
- Diabetes mellitus – Rare occurrences of hypoglycaemia have been reported.
- **ACTI-LIFT** should not be used with monoamine oxidase inhibitors; imipramine; other serotonergic medicines; moclobemide; alcohol; warfarin; and cimetidine (see **"INTERACTIONS"**).
- Risk of serotonin syndrome, a rare but potentially fatal hyperserotogenic state, if combined with other serotonergic medicines (see **"INTERACTIONS"**).

Patients with major depressive disorder may experience worsening of their depression and or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicines in inducing such behaviour has not been established. Patients being treated with **ACTI-LIFT** should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy, or at anytime of dose changes, either increases or decreases.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric disorders and non-psychiatric disorders.

The following symptoms have been reported in patients being treated with antidepressants such as **ACTI-LIFT** for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness, impulsivity, akathisia, hypomania, and mania). Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing **ACTI-LIFT**, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient`s presenting symptoms.

If the decision is made to discontinue treatment with **ACTI-LIFT**, it is recommended that the dose should be decreased gradually to prevent the possibility of withdrawal symptoms (see **"DOSAGE AND DIRECTIONS FOR USE"**).

Safety and efficacy in children under 18 years of age have not been established (see **"CONTRA-INDICATIONS** and **SIDE EFFECTS AND SPECIAL PRECAUTIONS"**).

INTERACTIONS:

- **Monoamine oxidase inhibitors (MAOI)** – Concurrent use is contra-indicated. Serious and potentially fatal reactions have occurred such as: hyperthermia, rigidity, myoclonus, autonomic instability with rapid fluctuation of vital signs and mental status changes including extreme agitation progressing to delirium and coma (see **"CONTRAINDICATIONS"**).
- **Imipramine** – An increase in the concentration of desimipramine (the active metabolite of imipramine) may occur. It appears that **ACTI-LIFT** does not cause a marked increase in plasma levels of some tricyclic antidepressants.
- **Other serotonergic medicines or medicines with serotonergic activity** – Increased risk of developing the serotonin syndrome, a rare but potentially fatal hyperserotonergic state.
- **Moclobemide** – Serotonin syndrome has developed after taking moclobemide and **ACTI-LIFT**.
- **Alcohol** - The effects of alcohol may be increased.
- **Warfarin** – the anticoagulant activity of warfarin may be increased
- **Cimetidine** – the AUC and the maximum plasma concentration of **ACTI-LIFT** are increased when **ACTI-LIFT** is administered concurrently with cimetidine.

PREGNANCY AND LACTATION:

Safety and efficacy in pregnancy and lactation has not been established. **ACTI-LIFT** is excreted into the breast milk.

DOSAGE AND DIRECTIONS FOR USE:

Depression

20 mg a day as a single dose. Dosage may be increased by 20 mg a day at intervals of at least one week to a maximum of 60 mg depending on the patient`s response.

Panic Disorder

10 mg a day as a single dose for the first week then increasing to 20 mg a day. The dose may be increased thereafter as required to a maximum of 60 mg a day depending on the patient`s response.

Obsessive-Compulsive Disorder:

20 mg a day as a single dose. This dose can be increased by 20 mg increments to a maximum of 60 mg a day depending on the patient`s response.

If the decision is made to discontinue treatment with **ACTI-LIFT**, it is recommended that the dose should be decreased gradually to prevent possibility of withdrawal symptoms (see **"WARNINGS"**).

Special populations:

Elderly: 20 mg a day as a single dose. Depending on the patient`s response, the dose can be increased to a maximum of 30 mg a day.

Reduced hepatic function: Dose should be halved.

Reduced renal function: Dose adjustment is not necessary in cases of mild or moderate renal impairment.

The onset of action is seen within 2 to 4 weeks. Treatment should be continued for an appropriate length of time (up to six months) after recovery in order to prevent relapse. **ACTI-LIFT** may be taken with or without food in the morning or evening.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-Effects:

Cardiac disorders:

Frequent
Palpitations, tremor
Less frequent
Bradycardia

Nervous system disorders:

Frequent
Sleep disturbances, paraesthesia, restlessness, headache, dizziness, fatigue, somnolence.
Less frequent
Agitation, confusion, impaired concentration, malaise, mania, convulsions, serotonin syndrome, neuroleptic malignant syndrome, akathisia, impulsivity, aggressiveness, anxiety, panic attacks, insomnia, irritability, hypomania.

Metabolism and Nutrition disorders:

Frequent
Weight changes

Gastrointestinal disorders:

Frequent
Nausea, constipation, diarrhoea, dyspepsia, dry mouth
Less frequent
Salivation

Renal and Urinary disorders:

Frequent
Micturition disorders
Less frequent
Sexual dysfunction including ejaculation disorder, decreased libido, anorgasmia

Hepato-biliary disorders:

Less frequent
Hepatitis

Musculoskeletal, connective tissue and bone disorders:

Frequent
Asthenia

Eye disorders:

Frequent
Accommodation disturbances
Less frequent
Mydriasis

Respiratory, thoracic and mediastinal disorders:

Less frequent
Nasal congestion

Skin and subcutaneous disorders:

Frequent
Sweating
Less frequent
Rash

General disorders and administration site conditions:

Less frequent
Yawning, hostility, suicidal ideation and self-harm.

SPECIAL PRECAUTIONS:

- Patients should be monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patients.
- Serotonin syndrome is more likely to occur after an increase in dose.
- If therapy with **ACTI-LIFT** is to be discontinued, it is recommended that the dose is decreased gradually in order to prevent the possibility of a withdrawal syndrome.
- Avoid alcohol (see **"INTERACTIONS"**)
- Safety and efficacy in children under 18 years of age have not been established. In clinical trials in Major Depressive Disorder, there were increased reports of hostility and suicide–related adverse events such as suicidal ideation and self-harm.

Effect on the ability to drive and use machines:

ACTI-LIFT may impair performance of skilled tasks. If affected these patients should not operate machinery or drive.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**)

Symptoms of overdose: Tiredness, weakness, sedation, dizziness, tremor, nausea, somnolence and sinus tachycardia.

Treatment of overdose:

Treatment is symptomatic and supportive. There is no specific antidote to **ACTI-LIFT**.

The stomach should be emptied as soon as possible by emesis or gastric lavage. Monitoring of cardiac and vital signs necessary and medical surveillance is advisable for about 24 hours.

IDENTIFICATION:

Pink, oval shaped, biconvex tablets with "G" engraved on one side and "11" on the other side of the bisect on one face of the tablet and other face of the tablet being engraved with"20".

PRESENTATION:

ACTI-LIFT Tablets are packed in white opaque HDPE bottles containing 28, 30, 100 and 500 tablets.

STORAGE INSTRUCTIONS:

Store in tightly closed container, at or below 25 °C

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

41/1.2/0297

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Glenmark Pharmaceuticals South Africa (Pty) Limited
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

04 March 2011

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Patient Information Leaflet

ACTI-LIFT 20 mg Tablets

Read all of this leaflet carefully before you start taking ACTI-LIFT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ACTI-LIFT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling Status of the medicinal product: S5

(Proprietary) name, strength and pharmaceutical form:

ACTI-LIFT 20 mg Tablets

Citalopram hydrobromide equivalent to citalopram 20 mg

1. What ACTI-LIFT tablets contain:

- The active substance is citalopram hydrobromide 20 mg equivalent to Citalopram 20 mg. The other ingredients are lactose monohydrate, microcrystalline cellulose, povi done, crospovidone, magnesium stearate, titanium dioxide, hydromellose, macrogol and iron oxides (red and yellow).

2. What ACTI-LIFT tablets are used for:

ACTI-LIFT contains citalopram which belongs to a group of medicines called anti-depressants.

ACTI-LIFT is used for the treatment of depression and prevention of relapse, panic disorder with or without agoraphobia and obsessive compulsive disorder (OCD).

3. Before you take ACTI-LIFT tablets:

You should tell your doctor

- If you are pregnant or think you might be pregnant.
- If you are taking medicines belonging to a group of medicines called Monoamine Oxidase Inhibitors (MAOIs) or 14 days after discontinuation.
- If you have impaired ability to drive or operate machinery.

Do not take ACTI-LIFT tablets

- If you are hypersensitive (allergic) to citalopram or any of the other ingredients in **ACTI-LIFT** tablets.
- If your kidney is not working as well as it should.

Take special care with ACTI-LIFT tablets

If you suffer from kidney problems, inform your doctor before taking **ACTI-LIFT**

Pregnancy and breast-feeding

Safety in pregnancy and during lactation has not been established.
If you are pregnant or breast feeding your baby while taking **ACTI-LIFT,** please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with ACTI-LIFT tablets

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ACTI-LIFT** tablets with these medicines may cause undesirable interactions. Please tell your doctor, pharmacist or other healthcare professional, if you are taking any of the following:

- Monoamine Oxidase Inhibitors
- Imipramine
- Moclobemide
- Selegiline
- Sumatriptan

4. How to take ACTI-LIFT tablets:

Always take **ACTI-LIFT** tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

For treatment of depression, the recommended dose is 20 mg daily. The tablets may be taken in the morning or evening, not necessarily with food. Your doctor may increase the dose to 60 mg daily if necessary.

For treatment of panic disorder, the recommended dose is 10mg for the first week before increasing the dose to 20 mg. Your doctor may increase the dose to a maximum of 60 mg, if necessary.

For the treatment of Obsessive Compulsive disorder, the recommended initial dose is 20 mg.

This may be increased in increments of 20 mg to 60 mg daily if necessary.

Elderly patients, the recommended daily dose is 20 mg, and may be increased to 30 mg dependant on the patient.

Patients with reduced liver function, the dosage should be halved

Patients with mild to moderate impaired kidney function, there is no need to adjust the dosage.

If you take more ACTI-LIFT tablets than you should

Some of the following symptoms may appear if you take more tablets than you should:

Tiredness, weakness, sedation, dizziness, tremor, nausea and somnolence.

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take ACTI-LIFT tablets

If you miss a dose, take your tablet as soon as you remember. But if it almost time for the next dose, do not take a double dose to make up for forgotten individual doses.

5. Possible side-effects:

As with any other medicine, **ACTI-LIFT** tablets may cause the following side effects:

Commonly reported side effects are:

- Headache, sweating, fatigue, tremor, weight loss/weight gain
- Palpitations, sleep disturbances, restlessness
- Nausea, diarrhoea, dyspepsia, dry mouth
- Constipation
- Blurred vision disturbances
- Urination disorders

Uncommon side-effects are:

- Malaise, yawning, slow heartbeat
- Agitation, confusion, impaired concentration, decreased libido, ejaculation disorder, lack of orgasm
- Salivation, rash, nose congestion
- Convulsions, restlessness, impulsivity, aggressiveness, anxiety, panic attacks, lack of sleep, irritability, hypomania
- Hepatitis
- Yawning, hostility, suicidal ideas and self-harm

Not all side-effects reported for **ACTI-LIFT** are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

ACTI-LIFT may impair performance of skilled tasks. If affected, do not operate machinery or drive.

6. Storing and disposing of ACTI-LIFT tablets:

Keep all medicines out of the reach and sight of children.
Store in tightly closed containers, at or below 25 °C
Do not use after the expiry date stated on the carton
Return all unused medicine to your pharmacist
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. Presentation of ACTI-LIFT tablets:

ACTI-LIFT tablets are available in white opaque HDPE bottles, containing 28, 30, 100 and 500

8. Identification of ACTI-LIFT tablets:

Pink, oval shaped, biconvex tablets with "G" engraved on one side and "11" on other side of the bisect on one face of the tablet and other face of the tablet being engraved with "20"

9. Registration number:

41/1.2/0297

10. Name and address of registration holder:

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