Pharmacode position may change as per the supplier's m/c requirement

APPROVED
Samantha , 2022/11/29 ,13:58:27

LENIO P1532543

LENIO P1532543

AUROGEN

SKEDULERINGSTATUS

SUID-AFRIKA: S5

NAMIBIË: NS3

EIENDOMSNAAM (en doseervorm):
LENIO 20 mg (tablet)
LENIO 30 mg (tablet)

SAMESTELLING:
LENIO 20 mg:
Elke filmbedekte tablet bevat paroksetienhidrochloriedhemihidraat ekwivalent aan 20 mg paroksetien. Bevat suiker: 10 mg laktose.

LENIO 30 mg:
Elke filmbedekte tablet bevat paroksetienhidrochloriedhemihidraat ekwivalent aan 30 mg paroksetien. Bevat suiker: 15 mg laktose.

Die ander bestanddele in **LENIO** is anhidriese kalsiumhidrogeenfosfaat, kalsiumhidrogeenfosfaatdihidraat, magnesiumstearaat en natriumstyselglikolaat.

Die dekmateriaal vir **LENIO 20 mg** bevat hipromellose, poliëtileenglikol 400, polisorbaat 80 en titaandioksied (C.I. Nr: 77891).

Die dekmateriaal vir **LENIO 30 mg** bevat FD&C blou # 2/indigo karmienaluminiumlak (C.I. Nr: 73015). hipromellose, poliëtileenglikol 400, polisorbaat 80 en titaandioksied (C.I. Nr: 77891).

FARMAKOLOGIESE KLASSIFIKASIE:
A 1.2 Psigo-analeptika (Antidepressante)

FARMAKOLOGIESE WERKING:
Paroksetien is 'n selektiewe serotonienheropnameïnhibeerder (SSHI). Daar word geglo dat die antidepressanteffek van paroksetien verband hou met sy serotonergiese neurotransmissie.

Farmakokinetika:
Na orale toediening word paroksetien geredelik vanuit die maagdermkanaal geabsorbeer. Die absorpsie word nie deur die teenwoordigheid van voedsel, melk of teensuurmiddels beïnvloed nie. Paroksetien is hoogs proteïengebonde (95 %) en ondergaan uitgebreide eerstedeurgang-metabolisme in die lewer waar dit gedeeltelik deur sitochroom P450 2D6 (CYP2D6) gemetaboliseer word. Die metaboliete blyk klinies onaktief te wees. Die eliminasiehalfleeftyd is ongeveer 24 uur. maar daar bestaan egter 'n groot wisseling tussen indiwidue. In die meeste pasiënte word die platokonsentrasie binne 7 tot 14 dae bereik. Paroksetien word deur die niere (ongeveer 64 %) en feses (ongeveer 36 %) uitgeskei, hoofsaaklik as onaktiewe metaboliete.

INDIKASIES:
- Depressie.
- Obsessiewe kompulsiewe afwyking (OKA).
- Sosiale fobie.
- Paniekafwyking.

KONTRA-INDIKASIES:
- Hipersensitiwiteit teen paroksetien of enige van die bestanddele van **LENIO**.
- Monoamienoksidaseïnhibeerders (MAOIs): **LENIO** behoort nie in kombinasie met MAOIs binne 2 weke na die staking van behandeling mets MAOIs gebruik te word nie. MAOIs behoort nie voor twee weke na die staking van terapie met **LENIO** ingestel te word nie.
- Kinders jonger as 18 jaar oud (sien "**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**" en "**NEWE EFFEKTE**").
- Toediening saam met tioridasien.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
Veiligheid en effektiwiteit in kinders jonger as 18 jaar oud is nie vasgestel nie (sien "**KONTRA-INDIKASIES**" en "**NEWE EFFEKTE**").

Pasiënte met erge depressiewe afwyking, beide volwassenes en kinders, kan agteruitgang van depressie en die ontwikkeling van selfmoordidees en -gedrag ondervind, of hulle antidepressante gebruik, aldan nie. Hierdie risiko kan voortduur totdat beduidende remissie plaasvind. 'n Oorsaaklike rol van antidepressantmedikasie in die indusering van sulke gedrag is egter nie vasgestel nie. Pasiënte wat met **LENIO** behandel word behoort nietemin vir die kliniese agteruitgang van selfmoordgedagtes, veral aan die begin van 'n kursus terapie, of enige tyd wanneer daar 'n dosisverandering (toename of afname) plaasvind, dopgehou te word.

Weens die moontlikheid van ko-morbiditeit tussen erge depressiewe afwyking en ander psigiatriese en nie-psigiatriese afwykings, behoort dieselfde voorsorgsmaatreëls wanneer pasiënte met erge depressiewe afwyking behandel word, geneem te word wanneer pasiënte met ander psigiatriese en nie-psigiatriese afwyking behandel word.

Die volgende simptome is in pasiënte wat met antidepressante vir erge depressiewe afwyking, asook vir ander indikasies, beide psigiatriese en nie-psigiatries behandel word, waargeneem: angs, agitasie, paniekaanvalle, slaaploosheid, geïrriteerdheid, vyandigheid, aggressiwiteit, impulsiwiteit, akatisie, hipomanie en manie. Alhoewel 'n oorsaaklike skakel tussen die ontwikkeling van sulke simptome en die agteruitgang van depressie en/of die ontwikkeling van selfmoordimpulse nie vasgestel is nie, behoort oorweging aan die verandering van die terapeutiese regimen, insluitende die moontlike onttrekking van **LENIO**, in diegene vir wie sulke simptome erg is, 'n vinnige aanvangs het en nie deel van die pasiënt se presenterende simptome was nie, geskenk te word.

Indien daar besluit word om met die behandeling te staak, behoort die dosis van **LENIO** geleidelik verminder te word (sien "**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**" en "**DOSIS EN GEBRUIKSAANWYSINGS**").

LENIO behoort met sorg gebruik te word in:
- Pasiënte met 'n geskiedenis van manie.
- Pasiënte wat reeds neuroleptika ontvang, aangesien simptome van Neuroleptiese Kwaadaardige Sindroom met hierdie kombinasie kan voorkom.
- Pasiënte wat gelyktydig met medisyne behandel word wat 'n toename in die risiko van bloeding veroorsaak, asook in pasiënte met 'n neiging tot bloeding of diegene met predisponerende kondisies. Behandeling met **LENIO** kan bloeding van die vel en slymvliese veroorsaak.

Die medetoediening saam met respiridoon kan tot 'n toename in die toksisiteit daarvan lei (sien "**INTERAKSIES**").

Die gelyktydige gebruik van **LENIO** en alkohol word nie aanbeveel nie.

Hartkondisie:
Die toediening van **LENIO** aan pasiënte met 'n ernstige kardiovaskulêre afwyking soos (onstabiele) angina pectoris, swak gemoniteerde hartdekompensasie, ventrikulêre ritme-afwyking en akute miokardiese infarksie is nie bestudeer nie en moet daarom vermy word. As antidepressant-medikasie nietemin vir sulke pasiënte aangedui word, behoort **LENIO** met sorg toegedien te word.

Epilepsie:
LENIO behoort met sorg in pasiënte met epilepsie gebruik te word.

Stuipaanvalle:
Stuipaanvalle kan in pasiënte wat met **LENIO** behandel word, voorkom.
LENIO behoort in enige pasiënt wat stuipaanvalle ontwikkel, onttrek te word.

Elektrokonvulsiewe terapie (EKT):
Daar is 'n tekort aan kliniese ondervinding met die gelyktydige toediening van **LENIO** en elektrokonvulsiewe terapie (EKT).

Hiponatremie:
Hiponatremie, wat gewoonlik omkeerbaar is met die onttrekking van **LENIO**, kan hoofsaaklik in bejaardes voorkom.

Gloukoom:
LENIO kan midriase veroorsaak en behoort met sorg in pasiënte met geslotehoek gloukoom gebruik te word.

Effek op die vermoë om te bestuur en met masjinerie te werk
Pasiënte behoort gewaarsku te word oor hul vermoë om te bestuur en met masjinerie te werk.

INTERAKSIES:
Simetidien, inhibeerder van medisynemetabolisme, kan die biobeskikbaarheid van **LENIO** verhoog, terwyl fenitoïen, 'n medisyne metabolismeïnduseerder, dit kan verlaag.

Wanneer **LENIO** saam met 'n bekende medisyne metaboliseringsensiem-inhibeerder toegedien word, behoort oorweging geskenk te word aan die gebruik van dosisse teen die laer vlak van die reikwydte. Geen aanvanklike dosisaanpassing van **LENIO** is nodig wanneer dit saam met bekende medisyne metaboliseringsensieminduseerder toegedien word nie. Enige daaropvolgende dosisaanpassing behoort deur die kliniese effekte (verdraagsaamheid en effektiwiteit) gelei.

LENIO inhibeer die spesifieke lewersitochroom P450 isoënsiem CYP2D6 wat vir die metabolisme van debrisokien en sparteïen verantwoordelik is. Dit kan tot verhoogde plasmavlakke van medetoegediende medisyne lei wat deur hierdie isoënsiem gemetaboliseer word. Medisyne wat deur hierdie isoënsiem gemetaboliseer word sluit sekere trisikliese antidepressante (bv. nortriptilien, amitriptilien, imipramien en desipramien), fenotiasienneuroleptika (bv. perfenasien en tioridasien), risperidoon, Tipe 1c anti-arritmiese middels (bv. propafenoon) en metoprolol in.

Die medetoediening saam met risperidoon kan tot 'n toename in die toksisiteit daarvan lei.

Interaksies tussen **LENIO** en MAOIs (sien "**KONTRA-INDIKASIES**"), asook tussen **LENIO** en triptofaanmedikasie kan voorkom, wat tot 'n "serotoniensidroom" kan lei.

Die gelyktydige toediening van **LENIO** en litium behoort met sorg onderneem te word. Litiumvlakke behoort gemonitor te word.

Die medetoediening van **LENIO** en fenitoïen word met 'n afname in plasmakonsentrasies van paroksetien en 'n toename in newe effekte (diaree, afsydigheid, wanbalans, senuweeagtigheid, ataksie en vertigo) geassosieer. Geen aanvanklike dosisaanpassing van paroksetien word as nodig beskou wanneer hierdie middels saam toegedien word nie. Enige daaropvolgende aanpassings behoort deur die kliniese effek gelei te word.

Die medetoediening van **LENIO** saam met teenstuipmiddels kan met 'n toename in die insidens van newe effekte geassosieer word.

Die daaglikse toediening van **LENIO** kan die plasmavlakke van prosiklidien aansienlik verhoog; ander anticholinergiese medisyne kan op 'n soortgelyke manier geaffekteer word. As anticholinergiese effekte waargeneem word, behoort die dosis van prosiklidien verminder te word.

LENIO behoort met groot sorg in pasiënte wat antistolmiddels ontvang, toegedien te word (sien **"WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**").

Die medetoediening van **LENIO** saam met warfarien kan tot 'n toename in bloeding in die teenwoordigheid van onveranderde protrombientye lei.

SWANGERSKAP EN LAKTASIE:
Die veiligheid van **LENIO** in swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Daar word aanbeveel dat **LENIO** soggens saam met 'n maaltyd geneem word.
LENIO behoort eerder gesluk as gekou te word.

Depressie: 20 mg per dag. Hierdie dosis kan geleidelik, afhangende van die pasiënt se respons en indien nodig, geleidelik met 10 mg inkremente na 'n maksimum van 50 mg per dag verhoog word.

Paniekafwyking: Die aanbevole dosis is 40 mg per dag. Die aanvanklike begindosis is 10 mg per dag wat met 10 mg inkremente na 'n maksimum van 60 mg per dag verhoog kan word.

Die lae aanvanklike dosis word aanbeveel om die potensiële agteruitgang van panieksimptome tot 'n minimum te beperk wanneer behandeling met **LENIO** geïnisieer word.

Obsessiewe kompulsiewe afwyking: Die aanbevole dosis is 40 mg per dag. Die aanvanklike begindosis is 20 mg per dag wat met inkremente van 10 mg na 'n maksimum van 60 mg verhoog kan word.

Sosiale fobie: Die aanbevole dosis is 20 mg per dag. Die dosis kan geleidelik, wanneer nodig en gebaseer op die pasiënt se respons, met 10 mg inkremente na 'n maksimum van 60 verhoog word.

Kinders: Die veiligheid en effektiwiteit van **LENIO** in kinders jonger as 18 jaar oud is nie vasgestel nie. Vyandigheid, selfmoordidees en selfbesering kan met **LENIO** in kinders voorkom.

Bejaardes: Bejaarde indiwidue kan 'n toename in die plasmakonsentrasies met **LENIO** ondervind. Dosering behoort teen die volwasse begindosis te begin en kan dan geleidelik met 10 mg inkremente tot 40 mg per dag verhoog word.

Ingekorte lewer- en nierfunksie: 'n Toename in plasmakonsentrasies van **LENIO** kan in pasiënte met erg ingekorte nierfunksie (kreatieniensuiwering < 30 ml /min) of erg ingekorte lewerfunksie voorkom. Die dosis behoort daarom tot die onderste vlak van die dosisreikwydte beperk te word.

Pasiënte behoort vir 'n voldoende periode van tyd behandel te word om te verseker dat hulle simptoomvry is. Die kan etlike maande of langer duur.

Die skielike onttrekking van **LENIO** behoort vermy te word (sien" **NEWE EFFEKTE**").

NEWE EFFEKTE:
Definisie van frekwensies:
Selde (≥ 1/10 000, < 1/1 000)
Baie selde (< 1/10 000), insluitende geïsoleerde vermeldings
Baie dikwels (≥ 1/10)
Dikwels (≥ 1/100, < 1/10)
Soms (≥ 1/1 000, < 1/100)

Afwykings van die bloed- en limfsisteem:
Soms: Abnormale bloeding, hoofsaaklik van die vel en slymvliese (hoofsaaklik eggimose, maar ook in die maagdermkanaal, sentrale senuweestelsel en oog).

Endokriene afwykings:
Baie selde: Sindroom van ontoepaslike antidiuretiese hormoonsekresie (SODHS).

Psigiatriese afwykings:
Dikwels: Slaapsug, slaaploosheid
Soms: Verwardheid, hallusinasies.
Selde: Maniese reaksies.

Afwykings van die immuunstelsel:
Baie selde: Allergiese reaksies (insluitende urtikarie en angioëdeem).

Metaboliese en voedingsafwykings:
Dikwels: Verlies aan eetlus.
Selde: Hiponatremie.
(Hiponatremie wat hoofsaaklik in bejaarde pasiënte kan voorkom, is soms weens SODHS).

Afwykings van die senuweestelsel:
Dikwels: Duiseligheid, bewerasie.
Soms: Ekstrapiramidale afwykings.
Selde: Konvulsies.
Baie selde: Serotoniensindroom (simptome kan agitasie, verwardheid, diaforese, hallusinasies, hiperrefleksie, mioklonus, bewerasie, tagikardie en tremor insluit).
Ekstrapiramidale afwykings kan in pasiënte wat neuroleptiese medikasie gebruik, voorkom.

Algemene afwykings en kondisies by die plek van toediening:
Dikwels: Astenie.
Baie selde: Perifere edeem.

Oogafwykings:
Dikwels: Onduidelike gesig.
Baie selde: Akute gloukoom.

Respiratoriese, bors- en mediastinale afwykings:
Dikwels: Gaap.

Nier- en urienafwykings:
Soms: Urienretensie.

Reproduksiestelsel- en borsafwykings:
Baie dikwels: Seksuele disfunksie.
Selde: Hiperprolaktinemie / galaktoree.

Gastroïntestinale afwykings:
Baie dikwels: Naarheid.
Dikwels: Hardlywigheid, diaree, droë mond.

Hepatobileëre afwykings:
Selde: Verhogings van lewerensieme.
Baie selde: Lewerepisodes (soos hepatitis, soms geassosieer met geelsug en/of lewerversaking).
Verhoging van lewerensieme kan voorkom. Lewerepisodes, wat fataal kan wees (soos hepatitis, soms geassosieer met geelsug en/of lewerversaking) kan voorkom. Die onttrekking van **LENIO** behoort oorweeg te word as daar 'n verlengde verhoging van lewerfunksie toetsresultate is.

Afwyking van die vel en subkutane weefsel:
Dikwels: Sweet.
Soms: Veluitslag.
Baie selde: Fotosensitiwiteitsreaksies.

Simptome wat met onttrekking van LENIO behandeling waargeneem word:
Dikwels: Duiseligheid, sensoriese afwykings, slaapafwykings, angs, hoofpyn.
Soms: Agitasie, naarheid, bewerasie, verwardheid, sweet en diaree.
Die skielike staking van **LENIO** kan tot onttrekkingsimptome soos duiseligheid, sensoriese afwykings, (insluitende parestesie en elektriese skoksensasies), slaapafwykings, slaaploosheid, bewerasie, verwardheid, agitasie of angs, hoofpyn, senuweeagtigheide, vertigo, naarheid en sweet lei. Dit word daarom aanbeveel dat wanneer die behandeling met **LENIO** nie langer nodig is nie, die dosis geleidelik afgeskaal word (sien "**DOSIS EN GEBRUIKSAANWYSINGS**" en "**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**").

Kinders: Die veiligheid en effektiwiteit van **LENIO** in kinders jonger as 18 jaar is nie vasgestel nie. In kinders kan vyandigheid, selfmoordidees en selfbesering met **LENIO** voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
(Sien "**NEWE EFFEKTE**").

Simptome van oordosering:
Braking, pupille verwyd, koors, bloeddrukveranderinge, hoofpyn, onwillekeurige spiersametrekkings, agitasie, angs, tagikardie, koma en EKG-veranderinge.

Behandeling van oordosering:
Die behandeling is simptomaties en ondersteunend.
Daar is geen spesifieke teenmiddel nie. Om die absorpsie te verminder behoort die maag met maagspoeling of met induksie van emese, of beide geledig te word. Dit behoort gevolg te word met die toediening van 20 tot 30 g geaktiveerde koolstof elke 4 tot 6 ure gedurende die eerste 24 uur na inname. Gereelde monitering van lewenstekens en noukeurige waarneming word aanbeveel.

IDENTIFIKASIE:
LENIO 20 mg:
Wit tot byna-witgekleurde, filmbedekte gemodifiseerde kapsulevormige, bikonvekse tablette met '56' op die een kant gedruk en 'C' met 'n diep breeklyn aan die ander kant.

LENIO 30 mg:
Blou, filmbedekte gemodifiseerde kapsulevormige, bikonvekse tablette met 'F' op die een kant en '12' die ander kant gedruk.

AANBIEDING:
LENIO 20 mg / 30 mg:
Tablette word in 250 µm wit, ondeursigtige PVC film, gelamineer met 25 µm PE, bedek met 90 g/m² PVdc en 25 µm gedrukte aluminiumfoelie verpak. Elke stolpstrokie bevat 10 tablette.
Pakgroote: 30s: 3 stolpstrokies met 10 tablette elk.

BERGINGSINSTRUKSIES:
Bewaar by of benede 25 °C. Beskerm teen lig en vogtigheid. Moenie uit die buitenste karton verwyder tot voor gebruik nie.

HOU BUITE BEREIK VAN KINDERS.

REGSITRASIENOMMER:
SUID-AFRIKA:
LENIO 20 mg: 42/1.2/0208
LENIO 30 mg: 42/1.2/0209

NAMIBIË:
LENIO 20 mg: 10/1.2/0263
LENIO 30 mg: 10/1.2/0264

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1,
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,1448,
Suid-Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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11 November 2022

DETACH BEFORE DISPENSING

SUID-AFRIKA: S5
NAMIBIË: NS3
LENIO 20 mg (tablet)
LENIO 30 mg (tablet)
Paroksetienhidrochloriedhemihidraat

Lees die hele brosjure sorgvuldig voordat u begin om LENIO te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **LENIO** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense deel nie. Dit mag hulle skade aandoen, ook al het hulle dieselfde simptome as u.

1. WAT LENIO BEVAT

Die aktiewe bestanddeel is paroksetien.

LENIO 20 mg:
Elke filmbedekte tablet bevat paroksetienhidrochloriedhemihidraat ekwivalent aan 20 mg paroksetien. Bevat suiker: 10 mg laktose.

LENIO 30 mg:
Elke filmbedekte tablet bevat paroksetienhidrochloriedhemihidraat ekwivalent aan 30 mg paroksetien. Bevat suiker: 15 mg laktose.

Die ander bestanddele van **LENIO** is anhidriese kalsiumhidrogeenfosfaat, kalsiumhidrogeenfosfaatdihidraat, magnesiumstearaat en natriumstyselglikolaat.

Die dekmateriaal van **LENIO 20 mg** bevat hipromellose, poliëtileenglikol 400, polisorbaat 80 en titaandioksied (C.I. Nr: 77891).

Die dekmateriaal van **LENIO 30 mg** bevat FD&C blou #2/indigokarmienaluminiumlakkleurstof (C.I. Nr.: 73015), hipromellose, poliëtileenglikol 400, polisorbaat 80 en titaandioksied (C.I. Nr: 77891).

2. WAARVOOR LENIO GEBRUIK WORD

LENIO behoort aan die klas medisyne wat selektiewe serotonienheropnameïnhibeerders (SSHIs) genoem word. Dit werk deur die hoeveelheid serotonien, 'n natuurlike substans in die brein wat help om geestelike balans te behou, te verhoog.

LENIO word gebruik om die volgende te behandel:
- Depressie.
- Obsessiewe kompulsiewe afwyking (kwellende gedagtes wat nie vermy kan nie en die behoefte om sekere aksies oor en oor uit te voer).
- Sosiale fobie (oormatige vrees vir interaksie met ander mense of van iets voor ander mense wat met die normale inmeng).
- Paniekafwyking (skielike, onverwagte aanvalle van oormatige vrees en kommer oor hierdie aanvalle).

3. VOORDAT U LENIO NEEM

Moenie LENIO neem:
- As u al ooit 'n allergiese reaksie teen paroksetien of enige van die ander bestanddele van **LENIO** getoon het.
- As u medisyne wat monoamienoksidaseïnhibeerders (MAOIs) genoem word, neem. U moet ten minste twee weke wag nadat u met MAOIs gestaak het voordat u kan begin om **LENIO** te neem.
  Nadat u **LENIO** gestaak het, moet u ten minste twee weke wag nadat u begin om 'n MAOI te neem.
- As u jonger as 18 jaar oud is.
- As u medisyne wat tioridasien genoem word, neem.

Neem spesiale sorg met LENIO:
- **LENIO** behoort nie in kinders en adolessente jonger as 18 jaar oud gebruik te word nie aangesien daar nie bewys is dat dit 'n effektiewe en veilige medisyne vir hierdie ouderdomsgroep is nie.
- U behoort te weet dat u geestesgesondheid op onverwagte maniere kan verander wanneer u **LENIO** of ander antidepressante neem. U kan gedagtes van selfmoord ontwikkel, veral aan die begin van u behandeling, as u enige van die volgende simptome ervaar. Dit kan tot verhoogde selfmoordgedagtes of -gedrag lei, veral as dit nuwe of erge simptome is. nuwe depressie of agteruitgang in u dokter onmiddellik kontak as u enige van die volgende simptome ervaar as dit nuwe of erge simptome is: nuwe depressie of agteruitgang in depressie, as u daaraan dink om uself skade aan te doen of aan selfmoord te doen of dink, of as u beplan of poog om selfmoord te pleeg. erge kommer, agitasie, paniekaanvalle, moeite om aan die slaap te raak, aggressiewe gedrag, geïrriteerdheid, vyandigheid, onbedagte aksies, erge rusteloosheid en opwinding (geestelike en/of fisiese hiperaktiwiteit).
- Wanneer u met die gebruik van **LENIO** staak, sal u dokter die dosis geleidelik verminder om die moontlikheid van onttrekkingsimptome te verminder.
- Die natriumvlakke in u bloed kan afneem, wat gewoonlik herstel wanneer die gebruik van **LENIO** gestaak word. Dit kom hoofsaaklik in bejaardes voor.
- As u medisyne wat risperidoon genoem word neem (sien "**Die neem van LENIO saam met ander medisyne saam met LENIO**").
- As u neuroleptiese of antipsigotiese medisyne neem (sien "**Die neem van ander medisyne saam met LENIO**").
- As u stuipaanvalle ontwikkel terwyl u **LENIO** neem, behoort die gebruik van **LENIO** gestaak te word.

Stel u dokter in kennis:
- As u tans of enige tyd in die verlede aan maniese episodes (ooraktiwiteit of gedagtes) ly of gely het.
- As u 'n geskiedenis van bloedingsafwykings het of as u medisyne neem wat u risiko vir bloeding kan verhoog.
- As u aan 'n hartsiekte ly.
- As u aan 'n lewer- of niersiekte ly.
- As u aan stuipaanvalle of epilepsie ly.
- As u elektrokonvulsiewe terapie (EKT) ontvang.
- As u aan gloukoom (verhoogde druk in die oog) ly.

Die neem van LENIO saam met voedsel en vloeistof:
- Neem u tablette saam met voedsel.
- Moenie alkohol drink terwyl u **LENIO** neem nie. Alkohol kan u siekte of die newe effekte vererger.

Swangerskap en borsvoeding:
- Stel u dokter in kennis as u swanger is of beplan om swanger te raak of as u borsvoed.
- Die veiligheid van **LENIO** tydens swangerskap en borsvoeding is nie bevestig nie. Sommige studies het egter aangedui dat paroksetien hartdefekte in u ongebore baba kan veroorsaak.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of professionele gesondheidswerker vir advies nader voordat u **LENIO** neem.

Bestuur en die gebruik van masjinerie:
U behoort te weet dat **LENIO** u vermoë kan maak en u besluitneming en denke mag aantas. Moenie 'n motor bestuur of met masjinerie werk totdat u weet hoe hierdie medisyne u beïnvloed nie.

Die neem van ander medisyne saam met LENIO:
Sommige medisyne kan 'n interaksie met **LENIO** toon. Voordat u **LENIO** neem, moet u asseblief u dokter in kennis stel as u enige van die volgende medisyne neem:
- Simetidien, wat gebruik word in die behandeling van maagsere.
- Fenitoïen en ander antikonvulsiewe medisyne, wat vir stuipaanvalle en epilepsie gebruik word.
- Debrisokien.
- Sparteïen.
- Medisyne wat MAOIs genoem word, soos moklobemied.
- Ander antidepressante, insluitende triptofaan en trisikliese antidepressante soos nortriptilien, amitriptilien, imipramien en desipramien.
- 'n Neuroleptiese/anti-psigotiese middel wat tioridasien genoem word.
- **LENIO** neem as u risperidoon neem nie.
- Medisyne soos litiumsuksinaat, pethidien, tramadol, buprenorfien, nalbufien, pentasosien, dekstrometorfan (anti-psigotiese middels) wat gebruik word om pyn te behandel.
- Prosiklidien wat gebruik word om bewerasie, veral in Parkinson se siekte te verlig.
- Propafenoon en medisyne wat gebruik word om 'n ongereelde hartklop te behandel.
- Metoprolol, 'n betablokker wat gebruik word om hoë bloeddruk en hartprobleme te behandel.
- Warfarien of ander medisyne (antistolmiddels) wat gebruik word om bloedklonsels te verdun.

As u enige van hierdie middels gebruik, kan dit moontlik wees dat u nie **LENIO** kan gebruik nie of dat die dosis moontlik aangepas moet word, of u dokter kan besluit om u noukeurig vir nuwe effekte te monitor.

Stel altyd u dokter in kennis as u enige ander medisyne gebruik.
(Dit sluit komplementêre of tradisionele medisyne in).

4. HOE OM LENIO TE NEEM

Neem **LENIO** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **LENIO** te sterk of te swak is, moet u u dokter of apteker raadpleeg.
- Neem hierdie medisyne slegs soos deur u dokter voorgeskryf.
- Moenie meer of minder neem of meer gereeld neem as wat u dokter voorgeskryf het nie.
- Neem u tablette soggens saam met voedsel.
- Sluk hulle met 'n bietjie water in.
- Moenie kou nie.
- U dokter sal u aanraai watter dosis om te neem wanneer u begin om **LENIO** te neem. As u nie begin beter voel nie, kan u dokter besluit om die dosis geleidelik te verhoog, 10 mg op 'n keer, tot op 'n maksimum daaglikse dosis.

Die normale dosisse vir die verskillende kondisies is:
- Depressie:
  - Die begindosis is 20 mg/daagliks. Indien nodig, kan u dokter die dosis geleidelik verhoog tot 'n maksimum daaglikse dosis van 50 mg.
- Paniekafwyking (paniekaanvalle):
  Die begindosis is 10 mg/daagliks. Die aanbevole daaglikse dosis is 40 mg. Die maksimum daaglikse dosis is 60 mg.
- Obsessiewe Kompulsiewe Afwyking (obsessie en kompulsies):
  Die begindosis is 20 mg/daagliks. Die aanbevole daaglikse dosis is 40 mg. Die maksimum daaglikse dosis is 60 mg.
- Sosiale fobie (vrees vir of vermyding van sosiale situasies):
  Die aanbevole dosis is 20 mg/daagliks. Indien nodig kan u dokter die dosis geleidelik tot 'n maksimum van 60 mg/daagliks verhoog.

U dokter sal u raad gee oor die daaglikse dosis wat u moet neem.
Kinders – **LENIO** behoort nie in kinders jonger as 18 jaar oud gebruik te word nie. In kinders kan vyandigheid, selfmoordgedagtes en selfbesering met die gebruik van **LENIO** voorkom.
Ouer mense – Die maksimum daaglikse dosis in bejaardes is 40 mg.
Pasiënte met lewer- of niersiekte – As u aan 'n lewer- of niersiekte ly, kan u dokter besluit om u dosis na minder as normaal te verminder.
U dokter sal u in kennis stel oor die tydperk wat u die tablette moet neem. Dit kan vir etlike maande of langer wees.
Moenie die gebruik van **LENIO** staak sonder om u dokter te raadpleeg nie (sien **"Neem spesiale sorg met LENIO")**.

As u te veel LENIO geneem het:
- Kry onmiddellik mediese noodhulp as u dink dat u te veel van hierdie medisyne geneem het.
- Die simptome van oordosering kan braking, vergrootte pupille, koors, veranderinge in bloeddruk, hoofpyn, skielike onbeheerbare spierrukkings, agitasie, angs, toename in harttempo en koma insluit.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftheersentrum.

As u vergeet het om LENIO te neem:
Neem die oorgeslaande dosis sodra u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, moet u nie die oorgeslaande dosis neem nie en na die gereelde skedule terugkeer. Moenie die dosis verdubbel om vir die oorgeslaande dosis op te maak nie.

Die effekte wanneer behandeling met LENIO gestaak word:
U mag die volgende onttrekkingsimptome toon nadat u met die gebruik van **LENIO** gestaak het:
- Agitasie; spelte en naalde, elektriese skoksensasies; slaapafwykings; slaaploosheid, angs, verwardheid; naarheid; sweet; hoofpyn; diaree; bewerasie; senuweeagtigheid; fisiese onstabiliteit. Moenie die gebruik van hierdie medisyne skielik staak sonder om eers u dokter te raadpleeg nie.

Stel u dokter in kennis oor enige kommer wat u het terwyl u met die gebruik van **LENIO** ophou.

5. MOONTLIKE NEWE EFFEKTE

LENIO kan newe effekte hê.
Kry onmiddellik mediese noodhulp as u enige van hierdie tekens van 'n allergiese reaksie toon:
- Urtikarie (rooi en knopperige veluitslag).
- Moeilte met asemhaling.
- Swelling van u gesig, lippe, tong of keel.

Raadpleeg onmiddellik u dokter as u enige van die volgende ernstige newe effekte ondervind:
- Stuipaanvalle (konvulsies).
- Abnormale kneusing of bloeding.
- Manie (geestelike en/of fisiese hiperaktiwiteit).
- As u rusteloos voel en u kan nie lank stil sit of staan nie.
- Spierstyfheid of –rukkings, onbeheerbare bewerasie van 'n deel van die liggaam.

Ander moontlike newe effekte is:
- Vloeistof- of vateretensie, slaapsug, onvermoë om te slaap, verwardheid, hallusinasies (vreemde visie of geluide), verlies aan eetlus, duiseligheid, swakheid, swelling van die hande en voete weens vloeistofretensie, onduidelike gesig, gaap, onvermoë om te urineer (urineretensie), verandering in seksdrang of seksuele funksionering, abnormale produksie van borsmelk, naarheid, hardlywigheid, diaree, droë mond, sweet, sensitiwiteit teen sonlig, veluitslag, lewereffekte wat in bloedtoetse vir lewerfunksie onthul word, lewerprobleme wat veroorsaak dat die vel of wit van die oë geel verkleur.

Stel u dokter so gou as moontlik in kennis as enige van die bogenoemde newe effekte erg of kwelend is, as hulle nie verdwyn nie of as u enige besorgdheid het terwyl u **LENIO** neem.

Nie al die newe effekte wat vir **LENIO** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **LENIO** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN LENIO

Berg alle medisyne buite bereik van kinders.
Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vogtigheid.
Moenie uit die buitenste karton verwyder tot voor gebruik nie.

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN LENIO

LENIO 20 mg/ 30 mg:
Tablette word in 250 µm wit, ondeursigtige PVC film, gelamineer met 25 µm PE bedek met 90 g/m² PVdc en 25 µm gedrukte aluminiumfoelie verpak. Elke stolpstrokie bevat 10 tablette.
Pakgrootte: 30s: 3 stolpstrokies met 10 tablette elk.

8. IDENTIFIKASIE VAN LENIO

LENIO 20 mg:
Wit tot byna wit filmbedekte gemodifiseerde, kapsulevormige, bikonvekse tablette met '56' op die een kant en 'C' met 'n diep breeklyn aan die ander kant gedruk.

LENIO 30 mg:
Blougekleurde filmbedekte gemodifiseerde, kapsulevormige, bikonvekse tablette met 'F' op die een kant en '12' aan die ander kant met 'C' daarop gedruk.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER

SUID-AFRIKA:
LENIO 20 mg: 42/1.2/0208
LENIO 30 mg: 42/1.2/0209

NAMIBIË:
LENIO 20 mg: 10/1.2/0263
LENIO 30 mg: 10/1.2/0264

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER

AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1,
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,1448,
Suid-Afrika

11. DATUM VAN PUBLIKASIE

Datum van registrasie:
2 Maart 2012

Datum van hersiening:
11 November 2022

■ Black

A/s: 360 x 460 mm Booklet Size: 40 x 60 mm

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		LENIO	Leaflet	P1532543	29.11.2022 & 05.00 pm
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		South Africa	02	Commercial	
Team Leader	Kiran Kumar	Dimensions (mm)	Colours		
Initiator	Bhogi	A/s 360 x 460 mm	No Of Colours: 01		
Artist	Sree Designers	Pharma Code: 32543	32543		
Additional Information: Supersedes: P1513203					

SCHEDULING STATUS

SOUTH AFRICA: S5

NAMIBIA: NS3

PROPRIETARY NAME (and dosage form):
LENIO 20 mg (tablet)
LENIO 30 mg (tablet)

COMPOSITION:
LENIO 20 mg:
Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 20 mg paroxetine. Contains sugar: 10 mg lactose.

LENIO 30 mg:
Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 30 mg paroxetine. Contains sugar: 15 mg lactose.

The other ingredients contained in **LENIO** are calcium hydrogen phosphate anhydrous, calcium hydrogen phosphate dihydrate, magnesium stearate and sodium starch glycolate.

The coating material for **LENIO 20 mg** contains hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891).

The coating material for **LENIO 30 mg** contains FD&C blue # 2/indigo carmine aluminium lake (C.I. No: 73015), hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891).

PHARMACOLOGICAL CLASSIFICATION:
A 1.2 Psychoanaleptics (Antidepressants)

PHARMACOLOGICAL ACTION:
Paroxetine is a selective serotonin re-uptake inhibitor (SSRI). The antidepressant effect of paroxetine is thought to be related to its effect on serotonergic neurotransmission.

Pharmacokinetics:
After oral administration, paroxetine is readily absorbed from the gastrointestinal tract. Absorption is not influenced by the presence of food, milk or antacids. Paroxetine is highly protein bound (95 %) and undergoes extensive first-pass metabolism in the liver where it is metabolised in part by cytochrome P450 2D6 (CYP2D6). The metabolites appear to be clinically inactive. The elimination half-life is about 24 hours, but there is wide intersubject variability. Steady-state is achieved in 7 to 14 days in most patients. Paroxetine is excreted renally (approximately 64 %) and in the faeces (approximately 36 %) mainly as inactive metabolites.

INDICATIONS:
- Depression.
- Obsessive Compulsive Disorder (OCD).
- Social phobia.
- Panic disorder.

CONTRA-INDICATIONS:
- Hypersensitivity to paroxetine or any of the ingredients of **LENIO**.
- Monoamine oxidase inhibitors (MAOIs): **LENIO** should not be used in combination with MAOIs or within 2 weeks of terminating treatment with MAOIs. MAOIs should not be introduced within 2 weeks of cessation of therapy with **LENIO**.
- Children under the age of 18 years (see **"WARNINGS AND SPECIAL PRECAUTIONS"** and **"SIDE EFFECTS"**).
- Co-administration with thioridazine.

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

Patients with major depressive disorder, both adults and children, 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 **LENIO** should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy, or at any time 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 and non-psychiatric disorders.

The following symptoms have been reported in patients being treated with antidepressants 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 **LENIO**, 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, the dose of **LENIO** should be tapered (see **"WARNINGS AND SPECIAL PRECAUTIONS"** and **"DOSAGE AND DIRECTIONS FOR USE"**).

LENIO should be used with caution in:
- Patients with a history of mania.
- Patients already receiving neuroleptics, since symptoms suggestive of Neuroleptic Malignant Syndrome may occur with this combination.
- Patients concomitantly treated with medicines that give an increased risk for bleeding, and in patients with a known tendency for bleeding or those with predisposing conditions. Treatment with **LENIO** may cause skin and mucous membrane bleedings.

Co-administration with risperidone may lead to increased toxicity thereof (see **"INTERACTIONS"**). The concomitant use of **LENIO** and alcohol is not advised.

Cardiac Condition:
Administration of **LENIO** to patients with a serious cardiovascular disorder such as (unstable) angina pectoris, poorly monitored cardiac decompensation, ventricular rhythm disorder and acute myocardial infarction, has not been studied and must therefore be avoided. If antidepressant medication is nevertheless indicated for such patients, **LENIO** should be administered with caution.

Epilepsy:
LENIO should be used with caution in patients with epilepsy.

Seizures:
Seizures may occur in patients treated with **LENIO**.
LENIO should be discontinued in any patient who develops seizures.

Electroconvulsive Therapy (ECT):
Clinical experience of the concurrent administration of **LENIO** and electroconvulsive therapy is lacking.

Hyponatraemia:
Hyponatraemia, which is generally reversible on discontinuation of **LENIO**, may occur predominantly in the elderly.

Glaucoma:
LENIO may cause mydriasis and should be used with caution in patients with narrow angle glaucoma.

Effects on ability to drive and use machines
Patients should be cautioned about their ability to drive a car and operate machinery.

INTERACTIONS:
Cimetidine, a medicine metabolising inhibitor, can increase the bioavailability of **LENIO**, whereas the medicine metabolising inducer phenytoin can decrease it.

When **LENIO** is to be co-administered with a known medicine metabolising enzyme inhibitor, consideration should be given to using doses at the lower end of the range. No initial dosage adjustment of **LENIO** is considered necessary when the medicine is to be co-administered with known medicine metabolising enzyme inducers. Any subsequent dosage adjustment should be guided by clinical effects (tolerability and efficacy).

LENIO inhibits the specific hepatic cytochrome P450 isozyme CYP2D6 responsible for the metabolism of debrisoquine and sparteine. This may lead to enhanced plasma levels of those co-administered medicines which are metabolised by this isozyme. Medicines metabolised by this isozyme include certain tricyclic antidepressants (e.g. nortriptyline, amitriptyline, imipramine and desipramine), phenothiazine neuroleptics (e.g. perphenazine and thioridazine), risperidone, Type 1c antiarrhythmics (e.g. propafenone) and metoprolol.

Co-administration with risperidone may lead to increased toxicity thereof.

Interaction between **LENIO** and MAOIs (see **"CONTRA-INDICATIONS"**), and also between **LENIO** and tryptophan medication may occur, resulting in a "serotonin syndrome".

Concurrent administration of **LENIO** and lithium should be undertaken with caution. Lithium levels should be monitored.

Co-administration of **LENIO** and phenytoin is associated with decreased plasma concentrations of paroxetine and increased adverse experiences (diarrhoea, indifference, imbalance, nervousness, ataxia and vertigo). No initial dosage adjustment of paroxetine is considered necessary when these agents are co-administered. Any subsequent adjustments should be guided by clinical effect.

Co-administration of **LENIO** with anti-convulsants may be associated with an increased incidence of adverse events.

Daily administration of **LENIO** may significantly increase the plasma levels of procyclidine; other anti-cholinergic medicines may be similarly affected. If anti-cholinergic effects are seen, the dose of procyclidine should be reduced.

LENIO should be administered with great caution to patients receiving oral anticoagulants (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

Co-administration of **LENIO** with warfarin may result in increased bleeding in the presence of unaltered prothrombin times.

PREGNANCY AND LACTATION:
The safety of **LENIO** in pregnancy or lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
It is recommended that **LENIO** is administered in the morning with food.
LENIO should be swallowed rather than chewed.

Depression: 20 mg daily. This dose can be increased gradually if needed by 10 mg increments to a maximum of 50 mg daily according to the patient's response.

Panic Disorder: The recommended dose is 40 mg daily. The initial starting dose is 10 mg daily, which may be increased by 10 mg increments. The maximum dose is 60 mg daily.

The low initial starting dose is recommended to minimise the potential worsening of panic symptoms when initiating treatment with **LENIO**.

Obsessive Compulsive Disorder: The recommended dose is 40 mg daily. The initial starting dose is 20 mg daily, which may be increased by 10 mg increments to a maximum of 60 mg daily.

Social Phobia: The recommended daily dose is 20 mg. This dose may be increased gradually if needed by 10 mg increments to a maximum of 60 mg according to the patient's response.

Children: The safety and efficacy of **LENIO** in children under the age of 18 years have not been established. In children hostility, suicide ideation and self-harm may occur with **LENIO**.

Elderly: Elderly subjects may experience increased plasma concentrations with **LENIO**. Dosing should commence at the adult starting dose and may be increased gradually by 10 mg increments up to 40 mg daily.

Hepatic and renal impairment: Increased plasma concentrations of **LENIO** may occur in patients with severe renal impairment (creatinine clearance < 30 ml/min) or severe hepatic impairment. The dosage should therefore be restricted to the lower end of the dosage range.

Patients should be treated for a sufficient period to ensure that they remain free from symptoms. This may be several months or longer.

Abrupt discontinuation of **LENIO** should be avoided (see **"SIDE EFFECTS"**).

SIDE EFFECTS:
Definition of frequencies:
Rare (≥ 1/10 000, < 1/1 000)
Very rare (< 1/10 000), including isolated reports
Very common (≥ 1/10)
Common (≥ 1/100, < 1/10)
Uncommon (≥ 1/1 000, < 1/100)

Blood and lymphatic system disorders:
Uncommon: Abnormal bleeding, predominantly of the skin and mucous membranes (mostly ecchymosis, but also in the gastrointestinal tract, central nervous system and eye).

Endocrine disorders:
Very rare: Syndrome of inappropriate anti-diuretic hormone secretion (SIADH).

Psychiatric disorders:
Common: Somnolence, insomnia.
Uncommon: Confusion, hallucinations.
Rare: Manic reactions.

Immune system disorders:
Very rare: Allergic reactions (including urticaria and angioedema).

Metabolism and nutrition disorders:
Common: Decreased appetite.
Rare: Hyponatraemia.
(Hyponatraemia, which may occur predominantly in elderly patients, is sometimes due to SIADH).

Nervous system disorders:
Common: Dizziness, tremor.
Uncommon: Extrapyramidal disorders.
Rare: Convulsions.
Very rare: Serotonin syndrome (symptoms may include agitation, confusion, diaphoresis, hallucinations, hyperreflexia, myoclonus, shivering, tachycardia and tremor).
Extrapyramidal disorders may occur in patients using neuroleptic medication.

General disorders and administration site conditions:
Common: Asthenia.
Very rare: Peripheral oedema.

Eye disorders:
Common: Blurred vision.
Very rare: Acute glaucoma.

Respiratory, thoracic and mediastinal disorders:
Common: Yawning.

Renal and urinary disorders:
Uncommon: Urinary retention.

Reproductive system and breast disorders:
Very common: Sexual dysfunction.
Rare: Hyperprolactinaemia / galactorrhoea.

Gastrointestinal disorders:
Very common: Nausea.
Common: Constipation, diarrhoea, dry mouth.

Hepato-biliary disorders:
Rare: Elevation of hepatic enzymes.
Very rare: Hepatic events (such as hepatitis, sometimes associated with jaundice and/or liver failure).
Elevation of hepatic enzymes may occur. Hepatic events, which may be fatal (such as hepatitis, sometimes associated with jaundice, and/or liver failure) may occur. Discontinuation of **LENIO** should be considered if there is prolonged elevation of liver function test results.

Skin and subcutaneous tissue disorders:
Common: Sweating.
Uncommon: Skin rashes.
Very rare: Photosensitivity reactions.

Symptoms seen on discontinuation of LENIO treatment:
Common: Dizziness, sensory disturbances, sleep disturbances, anxiety, headache.
Uncommon: Agitation, nausea, tremor, confusion, sweating, diarrhoea.
Abrupt discontinuation of **LENIO** may lead to withdrawal symptoms such as dizziness, sensory disturbances, (including paraesthesia and electric shock sensations), sleep disturbances, insomnia, tremor, confusion, agitation or anxiety, headache, nervousness, vertigo, nausea and sweating. It is therefore advised that when **LENIO** treatment is no longer required, gradual discontinuation by dose tapering be carried out (see **"DOSAGE AND DIRECTIONS FOR USE"** and **"WARNINGS AND SPECIAL PRECAUTIONS"**).

Children: The safety and efficacy of **LENIO** in children under the age of 18 years have not been established. In children hostility, suicide ideation and self-harm may occur with **LENIO**.

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

Symptoms of overdose:
Vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety, tachycardia, coma, and ECG changes.

Treatment of overdose:
Treatment is symptomatic and supportive.
There is no specific antidote. To decrease absorption, the stomach should be emptied by gastric lavage or induction of emesis or both. This should be followed by administration of 20 to 30 g of activated charcoal every 4 to 6 hours during the first 24 hours after ingestion. Frequent monitoring of vital signs and careful observation is recommended.

IDENTIFICATION:
LENIO 20 mg:
White to off-white coloured film-coated modified capsule shaped, biconvex tablets debossed with '56' on one side and 'C' with a deep breakline on the other side.

LENIO 30 mg:
Blue coloured film-coated modified capsule shaped, biconvex tablets debossed with 'F' on one side and '12' on the other side.

PRESENTATION:
LENIO 20 mg/ 30 mg:
Tablets are packed in 250 µm white opaque PVC film laminated with 25 µm PE coated with 90 g/m^2 PVdc and 25 µm printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30s: 3 blisters of 10 tablets each.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light and moisture. Do not remove from the outer carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
LENIO 20 mg: 42/1.2/0208
LENIO 30 mg: 42/1.2/0209

NAMIBIA:
LENIO 20 mg: 10/1.2/0263
LENIO 30 mg: 10/1.2/0264

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1,
First Floor 53 Phillip Engelbrecht AvenueMeyersdal Ext 12,
1448 Johannesburg, South Africa

DATE OF PUBLICATION OF PACKAGE INSERT:
Date of registration:
2 March 2012

Date of revision:
11 November 2022

P1532543

DETACH BEFORE DISPENSING

- Take this medication only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- Take your tablets in the morning with food.
- Swallow them with a drink of water.
- Do not chew.
- Your doctor will advise you what dose to take when you first start taking **LENIO**.
- If you don't start to feel better, your doctor may decide to increase the dose gradually, 10 mg at a time, up to a maximum daily dose.
- The usual doses for the different conditions are:
  - Depression:
    The starting dose is 20 mg daily. If required, your doctor can gradually increase your dose to a maximum of 50 mg daily.
  - Panic disorder (panic attacks):
    The starting dose is 10 mg daily. The recommended daily dose is 40 mg. The maximum daily dose is 60 mg.
  - Obsessive compulsive Disorder (obsessions and compulsions):
    The starting dose is 20 mg daily. The recommended daily dose is 40 mg. The maximum daily dose is 60 mg.
  - Social phobia (fear or avoidance of social situations):
    The recommended dose is 20 mg daily. If required, your doctor can gradually increase your dose to a maximum of 60 mg daily.
- Your doctor will advise you on the daily dose you should take.
- Children - **LENIO** should not be used for children under 18 years. In children, hostility, suicidal thoughts and harming themselves may occur with **LENIO**.
- Older people – The maximum dose for elderly patients is 40 mg per day.
- Patients with liver or kidney disease – If you have liver or kidney disease, your doctor may decide that you should have a lower dose of **LENIO** than usual.
- Your doctor will tell you how long you need to keep taking your tablets. This may be for many months or even longer.
- Do not stop taking **LENIO** without talking to your doctor (see **"Take special care with LENIO"**).

If you take more LENIO than you should:
- Seek emergency medical attention if you think you have used too much of this medicine.
- Symptoms of overdose may include: vomiting, widened pupils, fever, changes in blood pressure, headache, sudden muscle twitching or jerking that you cannot control, feeling agitated, feeling anxious, increased rate of heartbeat and coma.

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

If you forget to take LENIO:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Effects when treatment with LENIO is stopped:
You may have the following withdrawal symptoms after you stop taking **LENIO**:
- Feeling agitated; feelings like pins and needles; electric shock sensations; sleep disturbances; inability to sleep; feeling anxious; confusion; feeling sick (nausea); sweating; headache; diarrhoea; tremor (shakiness); feeling nervous; feeling dizzy, unsteady or off-balance. Do not stop taking this medicine suddenly without first speaking to your doctor.

Tell your doctor about any concerns you have while stopping **LENIO**.

5. POSSIBLE SIDE EFFECTS

LENIO can have side effects.
Get emergency medical help at once if you have any of these signs of an allergic reaction:
- Hives (red and lumpy skin rash).
- Difficulty breathing.
- Swelling of your face, lips, tongue, or throat.

Call your doctor immediately if you have any of these serious side effects:
- Seizure (convulsions).
- Abnormal bruising or bleeding.
- Mania (mental and/or physical hyperactivity).
- If you feel restless and feel like you can't sit or stand still.
- Muscle stiffness or twitching, uncontrollable shaking of a part of the body.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles this may be because your blood is low in sodium.
- If you have some or all of the following symptoms you may have something called serotonin syndrome: feeling confused, feeling agitated, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat.
- Acute glaucoma: If your eyes become painful and you develop blurred vision.

Other possible side effects are:
- Fluid or water retention; sleepiness;, inability to sleep; confusion; having hallucinations (strange visions or sounds); decreased appetite; dizziness; feeling weak; swelling of hands and feet due to retained fluid; blurred vision; yawning; an inability to urinate (urinary retention); change in sex drive or sexual function; abnormal production of breast milk; nausea (feeling sick); constipation; diarrhoea; dry mouth; sweating; sensitivity to sunlight; skin rashes; effects on the liver showing up in blood tests of your liver function; liver problems that make the skin or whites of the eyes go yellow.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **LENIO**.

Not all side effects reported for **LENIO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LENIO**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF LENIO

Store all medicines out of the reach of children.
Store at or below 25 °C (room temperature). Protect from light and moisture. Do not remove from the outer carton until required for use.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF LENIO

LENIO 20 mg/ 30 mg:
Tablets are packed in 250 µm white opaque PVC film laminated with 25 µm PE coated with 90 g/m^2 PVdc and 25 µm printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30s: 3 blisters of 10 tablets each.

8. IDENTIFICATION OF LENIO

LENIO 20 mg:
White to off-white coloured film-coated modified capsule shaped, biconvex tablets debossed with '56' on one side and 'C' with a deep breakline on the other side.

LENIO 30 mg:
Blue coloured film-coated modified capsule shaped, biconvex tablets debossed with 'F' on one side and '12' on the other side.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

SOUTH AFRICA:
LENIO 20 mg: 42/1.2/0208
LENIO 30 mg: 42/1.2/0209

NAMIBIA:
LENIO 20 mg: 10/1.2/0263
LENIO 30 mg: 10/1.2/0264

10. NAME AND ADDRESS OF REGISTRATION HOLDER

AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1,
First Floor53 Phillip Engelbrecht Avenue
Meyersdal Ext 12, 1448Johannesburg,
South Africa

11. DATE OF PUBLICATION

Date of registration:
2 March 2012

Date of revision:
11 November 2022

SOUTH AFRICA: S5

NAMIBIA: NS3

LENIO 20 mg (tablet)
LENIO 30 mg (tablet)
Paroxetine hydrochloride hemihydrate

Read all of this leaflet carefully before you start taking LENIO.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LENIO** 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.

1. WHAT LENIO CONTAINS

The active substance is paroxetine.

LENIO 20 mg:
Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 20 mg paroxetine. Contains sugar: 10 mg lactose.

LENIO 30 mg:
Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 30 mg paroxetine. Contains sugar: 15 mg lactose.

The other ingredients contained in **LENIO** are calcium hydrogen phosphate anhydrous, calcium hydrogen phosphate dihydrate, magnesium stearate and sodium starch glycolate.

The coating material for **LENIO 20 mg** contains hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891).

The coating material for **LENIO 30 mg** contains FD&C blue #2/indigo carmine aluminium lake (C.I. No: 73015), hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891).

2. WHAT LENIO IS USED FOR

LENIO belongs to a class of medications called selective serotonin reuptake inhibitors (SSRIs). It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

LENIO is used to treat:
- Depression.
- Obsessive compulsive disorder (bothersome thoughts that won't go away and the need to perform certain actions over and over).
- Social phobia (extreme fear of interacting with others or performing in front of others that interferes with normal life).
- Panic disorder (sudden, unexpected attacks of extreme fear and worry about these attacks).

3. BEFORE YOU TAKE LENIO

Do not take LENIO:
- If you have ever had an allergic reaction to paroxetine or any of the other ingredients found in **LENIO**.
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs). You must wait at least 2 weeks after stopping a MAOI before you can take **LENIO**. After you stop taking **LENIO**, you must wait at least 2 weeks before you start taking a MAOI.
- If you are under the age of 18 years.
- If you are taking a medicine called thioridazine.

Take special care with LENIO:
- **LENIO** should not be used for children and adolescents under 18 years because it has not been proven to be an effective and safe medicine for this age group.
- You should know that your mental health may change in unexpected ways when you take **LENIO** or other antidepressants. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms, especially if they are new and severe: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep; aggressive behaviour; irritability, hostility; acting without thinking; severe restlessness; and mania (mental and/or physical hyperactivity).
- When stopping **LENIO**, your doctor will gradually reduce your dose to help reduce the chance of withdrawal effects.
- A low level of sodium in the blood may occur, which is usually reversible when **LENIO** is stopped. This occurs mainly in the elderly.
- If you are taking a medicine called risperidone (see **"Taking other medicines with LENIO"**).
- If you are taking neuroleptic or antipsychotic medicines (see **"Taking other medicines with LENIO"**).
- If you develop seizures while taking **LENIO**, **LENIO** should be discontinued.

Tell your doctor:
- If you have or have ever had episodes of mania (overactive behaviour or thoughts).
- If you have a history of bleeding disorders or are taking medicines that may increase your risk of bleeding.
- If you have heart disease.
- If you have liver or kidney disease.
- If you have seizures or epilepsy.
- If you are having electroconvulsive therapy (ECT).
- If you have glaucoma (raised pressure in the eye).

Taking LENIO with food and drink:
- Take your tablets with food.
- Do not drink alcohol while you are taking **LENIO**. Alcohol may make your symptoms or side effects worse.

Pregnancy and Breastfeeding:
- Tell your doctor if you are pregnant or plan to become pregnant, or are breastfeeding.
- The safety of **LENIO** in pregnancy and breastfeeding has not been confirmed. However, some studies have shown that paroxetine may cause heart defects in your unborn baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LENIO**.

Driving and using machinery:
You should know that **LENIO** may make you drowsy and affect your judgement and thinking. Do not drive a car or operate machinery until you know how this medication affects you.

Taking other medicines with LENIO:
Some medicines may interact with paroxetine. Before taking **LENIO**, tell your doctor if you are using any of the following medicines:
- Cimetidine, used to treat ulcers.
- Phenytoin, and other anti-convulsant medicines, used to treat fits or epilepsy.
- Debrisoquine
- Sparteine
- Medicines called MAOIs such as moclobemide.
- Other antidepressants including tryptophan and tricyclic antidepressants such as nortriptyline, amitriptyline, imipramine and desipramine.
- A neuroleptic/anti-psychotic medicine called thioridazine – Do not take **LENIO** if you are taking thioridazine.
- Medicines such as lithium, risperidone, perphenazine (called anti-psychotics) used to treat some psychiatric conditions.
- Procyclidine, used to relieve tremor, especially in Parkinson's disease.
- Propatenone and medicines used to treat an irregular heartbeat.
- Metoprolol, a beta-blocker used to treat high blood pressure and heart problems.
- Warfarin or other medicines (called anticoagulants) used to thin the blood.

If you are using any of these medicines, you may not be able to take **LENIO**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. HOW TO TAKE LENIO

Always take **LENIO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **LENIO** is too strong or too weak, talk to your doctor or pharmacist.