Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

APPROVED
By Berenice Campbell at 12:58 pm, Mar 09, 2023

MEDPLOZ P1533064

MEDPLOZ P1533064

Professionele inligting oor medisyne vir menslike gebruik
SUID-AFRIKA S5
NAMIBIE (check PIL) NS3

EIENDOMSNAAM (en doseervorm):
MEDPLOZ 5 mg (tablet)
MEDPLOZ 10 mg (tablet)

SAMESTELLING:
MEDPLOZ 5 mg: Elke filmbedekte tablet bevat 5 mg zolpidemtartraat. Bevat suiker: 43,80 mg laktose.
MEDPLOZ 10 mg: Elke filmbedekte tablet bevat 10 mg zolpidemtartraat. Bevat suiker: 87,60 mg laktose.

Die ander bestanddele is laktose monohidraat, mikrokristallyne sellulose, natriumstyselglikolaat, magnesiumstearaat, hipromellose, macrogol 400 en titaandioksied (C.I. Nr. 77891).

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.2 Kalmeermiddels, slaapmiddels.

FARMAKOLOGIESE WERKING:
Zolpidem is 'n imidasopiridienverbinding met sederende/hipnotiese effekte. Hierdie effekte hou verband met 'n spesifieke agoniswerking by sentrale reseptors wat aan die GABA-omega bensodiasepien-1 en bensodiasepien-2 makromolekulêre reseptorkompleks behoort en moduleer die opening van die chloriedioonkanaal. Zolpidem werk hoofsaaklik op die omega-1 (bensodiasepien-1) reseptor subtipes. Die kliniese betekenis hiervan is nie bekend nie.

Farmakokinetika
Absorpsie:
Die biobeskikbaarheid van zolpidem is ongeveer 70 % na orale toediening. Piek plasmakonsentrasie word tussen 0,5 en 3 ure na dosering bereik.

Verspreiding:
Teen terapeutiese dosisvlakke is die farmakokinetika lineêr. Die graad van plasmaproteïenbinding is ongeveer 92 %. Die plasma eliminasiehalfleeftyd is ongeveer 2, 5 ure (1,4 – 3,8 ure).

Die volume van verspreiding in volwassenes is 0,54 ± 0,02 L/kg. In bejaardes (hoë ouderdom) verminder die volume van verspreiding na 0, 34 ± 0,05 L/kg.

Uitskeiding:
Zolpidem word in die vorm van onaktiewe metaboliete (lewermetabolisme), hoofsaaklik in die urien (56 %) en feses (37 %) uitgeskei.

Dit het geen induserende effekte op lewerensieme nie. Suiwering neem af in bejaarde pasiënte. Die piekkonsentrasie neem met ongeveer 50 % toe, terwyl die eliminasiehalfleeftyd met ongeveer 32 % toeneem. In pasiënte met ontoereikende nierfunksie, met of sonder dialise, is daar 'n matige afname in suiwering. Die ander farmakokinetiese parameters word nie beïnvloed nie.

Biobeskikbaarheid:
Die biobeskikbaarheid van zolpidem neem toe in pasiënte met ontoereikende lewerfunksie. Suiwering neem af en die eliminasiehalfleeftyd word verleng (ongeveer 10 ure).

INDIKASIES:
- **MEDPLOZ** word aangedui vir die behandeling van kort termyn slaaploosheid.
- **MEDPLOZ** word slegs aangedui wanneer die afwyking erg of ontwrigtend is, of wanneer dit die indiwidu onder erge spanning plaas.
- Hipersensitiwiteit vir die produk.
- Myasthenia gravis.
- Slaapapnee-sindroom.
- Akuut en erg ontoereikende longfunksie, aangesien respiratoriese insinking gepresipiteer kan word.
- Kinders jonger as 18 jaar.
- Erg ontoereikende lewerfunksie.
- Die gelyktydige toediening van MIV-proteaseïnhibeerders soos ritonavir, aangesien die plasmakonsentrasies kan toeneem en gevolglik ook die risiko van oormatige sedering en respiratoriese onderdrukking.

WAARSKUWINGS AND SPESIALE VOORSORGMAATREELS:
Die veiligheid en effektiwiteit in kinders jonger as 18 jaar is nie bepaal nie.

Afhanklikheid en misbruik:
Die gebruik van **MEDPLOZ** kan tot die ontwikkeling van fisiese en sielkundige afhanklikheid lei. Die risiko van afhanklikheid neem toe met die dosis en duurte van behandeling; dit is ook groter in pasiënte met 'n geskiedenis van alkohol- en dwelmmisbruik. Hierdie pasiënte moet onder sorgvuldige toesig gehou word wanneer hulle hipnotika gebruik. Staking van terapie kan tot onttrekking- en terugslagverskynsels lei. Hierdie simptome wissel van geringe disforie, hoofpyn of spierpyn, uitermatige angs en spanning, rusteloosheid, verwardheid en geïrriteerdheid en slaaploosheid tot 'n onttrekkingsindroom wat buik- en spierkrampe, braking, sweet, bewerasie en stuiptrekkings, derealisering, depersonalisering, hiperakuïteit, gevoelloosheid en prikkeling van die ledemate, hipersensitiwiteit vir lig, geraas en fisiese kontak, of hallusinasie.

Duurte van behandeling:
Die duurte van behandeling moet so kort as moontlik wees en moet nie 4 weke, insluitende die afskaalperiode, oorskry nie. Behandeling moet nie vir langer periodes sonder herevaluering van die situasie aan hou nie.

Dit kan handig wees om die pasiënt met aanvangs van die behandeling in te lig dat dit slegs vir 'n beperkte periode sal wees, asook om te verduidelik hoe die dosis geleidelik verminder sal word.

Toleransie:
Na herhaalde gebruik van **MEDPLOZ** vir 'n paar weke, kan 'n sekere mate van verlies aan die hipnotiese effekte ontwikkel.

Geheueverlies:
MEDPLOZ kan anterograde geheueverlies induseer. Hierdie kondisie kom meesal verskeie ure na inname van die produk voor en, om die risiko daarom te verminder, moet pasiënte verseker dat hulle vir 7 tot 8 ure daarna ononderbroke kan slaap (Sien **"NEWE EFFEKTE"**).

Terugslag slaaploosheid:
'n Verbygaande sindroom, waarin die simptome wat tot behandeling met sedeer-/hipnotiese middels gelei het, in 'n erger vorm terugkeer, kan met onttrekking van hipnosemiddels voorkom. Dit kan gepaard gaan met ander reaksies, insluitende gemoedsveranderinge, angs en rusteloosheid. Die sindroom sal meer waarskynlik ontwikkel as die gebruik van die produk skielik gestaak word. Gevolglik moet behandeling geleidelik afgeskaal word.

Psigiatriese en "paradoksale" reaksies:
Depressie: **MEDPLOZ** behoort nie gebruik te word om depressiesindrome of angs met depressie te behandel nie, aangesien selfmoordneigings kan voorkom.

Psigotiese siekte: **MEDPLOZ** behoort nie as die primêre behandeling vir psigotiese siekte gebruik te word nie. (Sien **"NEWE EFFEKTE"**)

Spesifieke pasiënt groepe:
- Vir bejaardes: (sien **"DOSIS EN GEBRUIKSAANWYSINGS"**)
- Respiratoriese ontoereikenheid: Aangesien daar aangedui is dat hipnotika die respiratoriese dryfkrag belemmer, moet sorg aan die dag gelê te word wanneer **MEDPLOZ** aan pasiënte met chroniese respiratoriese ontoereikenheid voorgeskryf word.
- Erg ontoereikende lewerfunksie: Zolpidem word nie aangedui vir die behandeling van pasiënte met erg ontoereikende lewerfunksie nie, aangesien hipnotika enkefalopatie kan presipiteer.

Effekte op die vermoë om te bestuur of om met masjinerie te werk:
Sedering, lomerigheid, duiseligheid en vertigo kan die vermoë om te bestuur of om met masjinerie te werk in pasiënte wat **MEDPLOZ** gebruik, nadelig beïnvloed. Die waarskynlikheid van vertraagde skerpheid kan toekom wanneer die duurte van onvoldoende slaap verleng is.

INTERAKSIES:
- Gelyktydige inname van alkohol word nie aanbeveel nie. Die sederende effek word versterk wanneer hierdie produk in kombinasie met alkohol gebruik word. Dit beïnvloed die vermoë om te bestuur of om met masjinerie te werk.
- Kombinasie met Sentrale Senuweestelsel (SSS)- depressante: Versterking van die sentrale depressiewe effekte kan voorkom in gevalle van die meegaande gebruik van antipsigotika (neuroleptiese middels), hipnotika, angsiolitiese / sedeermiddels, antidepressiemiddels, narkotiese pynstillers, anti-epilepsiemiddels, narkosemiddels en sederende antihistamiene.

In die geval van narkotiese pynstillers kan versterking van die euforie ook voorkom, wat tot 'n toename in sielkundige afhanklikheid kan lei.

- Die aktiwiteit van **MEDPLOZ** kan versterk word deur verbindings wat sekere lewerensieme (veral sitochroom P450) inhibeer.

  Zolpidem word deur verskeie hepatiese sitochroom P450 ensieme gemetaboliseer: die belangrikste ensiem is CYP3A4, tesame met 'n bydrae van CYP1A2.

Die farmakodinamiese effek van **MEDPLOZ** neem af wanneer dit saam met rifampisien ('n CYP3A4 induseerder) toegedien word.

Wanneer zolpidem egter saam met itrakonasool ('n CYP3A4 inhibeerder) toegedien word, verander die farmakokinetika en farmakodinamika nie noemenswaardig nie. Die kliniese betekenis van hierdie resultate is onbekend.

- Geen noemenswaardige farmakokinetiese interaksies is waargeneem wanneer **MEDPLOZ** saam met warfarien, digoksien of ranitidien toegedien is nie.
- MIV-proteaseïnhibeerders soos ritonavir kan die plasmakonsentrasies van zolpidem verhoog, met 'n risiko van oormatige sedering en respiratoriese onderdrukking; die meegaande gebruik word nie aanbeveel nie.

SWANGERSKAP EN LAKTASIE:
Veiligheid in swangerskap is nie vasgestel nie.

As **MEDPLOZ** gedurende die laat fase van swangerskap of gedurende kraam toegedien word, kan effekte op die neonaat, soos hipotermie, hipotonie en matige respiratoriese onderdrukking, weens die farmakologiese werking van die produk verwag word.

Babas gebore van moeders wat **MEDPLOZ** chronies gedurende die laaste fase van swangerskap gebruik, kan fisiese afhanklikheid ontwikkel en 'n risiko loop om onttrekkingsimptome in die post-natale periode te ontwikkel.

Zolpidem behoort nie aan sogende moeders toegedien te word nie.

Klein hoeveelhede zolpidem kom in borsmelk voor.

DOSIS EN GEBRUIKSAANWYSINGS:
Veiligheid en effektiwiteit is nie in kinders jonger as 18 jaar bepaal nie. Behandeling behoort vir so kort as moontlik toegedien te word.

Oor die algemeen wissel die duurte van behandeling van 'n paar dae tot twee weke met 'n maksimum, insluitende die afskaalperiode, van vier weke.

In sekere gevalle kan langer periodes as die maksimum behandelingsperiode nodig wees. In sulke gevalle moet dit nie plaasvind sonder om die pasiënt se status te herevalueer nie.

MEDPLOZ moet onmiddellik voor slapenstyd, of in die bed geneem word.

Dosis
Die aanbevole daaglikse dosis vir volwassenes is 10 mg onmiddellik voor slapenstyd, of in die bed.

In bejaarde of gestremde pasiënte wat veral sensitief vir die effekte van zolpidem is, asook in pasiënte met ontoereikende lewerfunksie wat nie die middel so vinnig soos normale indiwidue suiwer nie, word 'n dosis van 5 mg aanbeveel. Hierdie dosis moet slegs onder die uiterste omstandighede oorskry word.

Die totale dosis **MEDPLOZ** moet nie 10 mg in enige pasiënt oorskry nie.

NEWE EFFEKTE:
Afwykings van die senuweestelsel:
Minder dikwels: Lomerigheid gedurende die dag, verwardheid, hoofpyn, duiseligheid, ataksie en stapafwykings.

Geheueverlies: Anterograde geheueverlies kan voorkom met die gebruik van terapeutiese dosisse **MEDPLOZ** – die risiko neem toe met hoër dosisse. Geheueverlies kan gepaard gaan met ontoepaslike gedrag.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Afname in skerpheid, moegheid.

Psigiatriese afwykings:
Minder dikwels: Depressie: Reeds bestaande depressie kan met die gebruik van **MEDPLOZ** ontmasker word.

Psigiatriese en teenstrydige reaksies: Dit is bekend dat reaksies soos rusteloosheid, agitasie, geïrriteerdheid, aggressie, delusies, woede-uitbarstings, nagmerries, hallusinasies, psigoses, ontoepaslike gedrag en ander nadelige gedragseffekte, met die gebruik van **MEDPLOZ** voorkom. Indien dit sou voorkom, behoort die gebruik van die middel onmiddellik gestaak te word. Dit is meer waarskynlik dat hierdie in kinders (sien **"KONTRA-INDIKASIES"**) en bejaardes voorkom.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Afgestompte emosies.

Muskuloskeletale, bindweefsel- en beenafwykings:
Minder dikwels: Spierswakheid.

Oogafwykings:
Minder dikwels: Dubbel sig.

Die verskynsels hierbo genoem kom hoofsaaklik aan die begin van terapie voor en meer dikwels in bejaarde pasiënte, maar kan met herhaalde toediening verdwyn.

Gastroïntestinale afwykings:
Minder dikwels: Gastroïntestinale afwykings soos naarheid, braking, diarree, droë mond, buik- of maagpyn.

Afwykings van die vel en subkutane weefsels:
Minder dikwels: Velreaksies.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Na oordosering met **MEDPLOZ** alleen, kan belemmering van die bewussyn wissel van slaapsug tot koma. Indiwidue het herstel van zolpidemdosisse van tot soveel as 400 mg. Oordosering waarby veelvuldige SSS-depressante (bv. alkohol) betrokke is, kan tot erger simptomatologie lei, insluitende fatale uitkomste.

Behandeling:
Algemene simptomatiese en ondersteunende maatstawwe moet toegepas word, saam met onmiddellike maagspoeling, waar nodig.

Intraveneuse vloeistowwe moet waar nodig toegedien word. Sederende medisyne behoort teruggehou te word, selfs as eksitasie voorkom. Die waarde van dialise in die behandeling van oordosering is nie bepaal nie, alhoewel studies met hemodialise in pasiënte met nierversaking en wat terapeutiese dosisse gebruik, aangetoon het dat zolpidem nie dialiseerbaar is nie. Waar ernstige simptome waargeneem word, kan die gebruik van bensodiasepienantagoniste (bv. flumaseniel) oorweeg word.

Die toediening van flumaseniel kan egter bydra tot die voorkoms van neurologiese simptome (stuiptrekkings).

In die bestuur van oordosering met enige medisinale produk, moet daar in gedagte gehou word dat meer as een middel moontlik geneem is.

IDENTIFIKASIE:
MEDPLOZ 5 mg: Wit tot byna wit, ronde, bikonvekse, filmbedekte tablette met "E" op die een kant en "78" op die ander kant gedruk.
MEDPLOZ 10 mg: Wit tot byna wit, ovaal, bikonvekse, filmbedekte tablette met "E" op die een kant en "80" op die ander kant gedruk.
Daar is 'n breeklyn tussen die 8" en die "0".

AANBIEDING:
MEDPLOZ 5 mg
1. Stolpverpakkings
Tablette word in stolpverpakkings verpak wat bestaan uit PVC/PVdc en gedrukte silwergekleurde aluminiumfoelie. Elke stolpverpakking bevat 10 tablette.

Pakgrootte: 30s – Elke karton bevat 3 stolpverpakkings van 10 tablette elk.

MEDPLOZ 10 mg
2. Stolpverpakkings
Tablette word in stolpverpakkings verpak wat bestaan uit PVC/PVdc en gedrukte silwergekleurde aluminiumfoelie. Elke stolpverpakking bevat 10 of 14 tablette onderskeidelik.

Pakgrootte: 30s – Elke karton bevat 3 stolpverpakkings van 10 tablette elk.

Pakgrootte: 14s – Elke karton bevat 1 stolpverpakkings van 14 tablette elk.

2. HDPE houer
Tablette word verpak in wit ondeursigtige HDPE houers met 'n wit ondeursigtige polipropileen dop met 'n induksie seëlprop. Die leë spasie in die houer word gevul met 'n rayon krul.

Pakgrootte: 30s- Een HDPE houer bevat 30 tablette.

BERGINGSINSTRUKSIES:
Berg in 'n droë plek by of benede 25 °C. Beskerm teen lig en vogtigheid. Hou die stolpverpakkings in die oorspronklike karton tot wanneer dit benodig word. Hou die HDPE houer dig toe.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

SUID-AFRIKA:
MEDPLOZ 5 mg: 43/2.2/0247
MEDPLOZ 10 mg: 43/2.2/0257

NAMIBIË:
MEDPLOZ 5 mg: 10/2.2/0593
MEDPLOZ 10 mg: 10/2.2/0594

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
AUROGEN
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:
Datum van registrasie:
4 Maart 2011
Datum van hersiening:
21 September 2021

DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSBLAD
SUID-AFRIKA: S5
NAMIBIË: NS3
MEDPLOZ 5 mg (tablet)
MEDPLOZ 10 mg (tablet)
Zolpidemtartraat

Lees die hele brosjure sorgvuldig voordat u begin om MEDPLOZ 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.
- **MEDPLOZ** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT MEDPLOZ BEVAT
Die aktiewe bestanddeel is zolpidemtartraat.

MEDPLOZ 5 mg: Elke filmbedekte tablet bevat 5 mg zolpidemtartraat. Bevat suiker: 43,80 mg laktose.
MEDPLOZ 10 mg: Elke filmbedekte tablet bevat 10 mg zolpidemtartraat. Bevat suiker: 87,60 mg laktose.

Die ander bestanddele is laktosemonohidraat, mikrokristallyne sellulose, natriumstyselglikolaat, magnesiumstearaat, hipromellose, makrogol 400 en titaandioksied (C.I. Nr. 77891)

2. WAARVOOR MEDPLOZ GEBRUIK WORD
Zolpidem word gebruik om slaaploosheid te behandel. Zolpidem word slegs gegee wanneer die afwyking erg is, die liggaam skade aandoen of uitermatig ontstellend vir die pasiënt is. Zolpidem behoort slegs vir 'n kort periode van tyd gebruik te word.

3. VOORDAT U MEDPLOZ NEEM
Moenie MEDPLOZ neem nie:
- As u ooit 'n ongewone of allergiese reaksie teen zolpidem of die produk gehad het.
- As u aan myasthenia gravis (spierafwyking wat swakheid veroorsaak) ly.
- As u aan slaapapnee ly (tydelike staking van asemhaling gedurende slaap).
- As u aan 'n longsiekte ly.
- As u aan 'n ernstige lewersiekte ly.
- As u jonger as 18 jaar oud is.
- As u borsvoed of swanger is. Die veiligheid van **MEDPLOZ** in swangerskap is nie vasgestel nie.

Neem spesiale sorg met MEDPLOZ:
- **MEDPLOZ** behoort vir 'n kort periode van tyd gebruik te word, en veral nie langer as 4 weke nie. U dokter mag die hoeveelheid wat u gebruik geleidelik verminder voordat u heeltemal met die gebruik daarvan staak.
- Na herhaalde gebruik van **MEDPLOZ** vir 'n paar weke, kan 'n sekere mate van verlies van die slaapeffek ontwikkel.
- **MEDPLOZ** kan 'n sekere tipe geheueverlies of "amnesie" veroorsaak. Wanneer dit voorkom, kan 'n persoon nie onthou wat gedurende die verskeie ure tussen die gebruik van die medisyne en die tyd wanneer die effek daarvan afneem, gebeur het nie.
- Nadat **MEDPLOZ** vir slaaploosheid geneem is, mag u vir die eerste paar nagte nadat u met die gebruik daarvan gestaak het, moeite ondervind om aan die slaap te raak (terugslagslaaploosheid). Buiveranderinge, angs en rusteloosheid kan ook voorkom.

  Terugslagslaaploosheid sal meer waarskynlik voorkom as die gebruik van **MEDPLOZ** skielik gestaak word. Daarom behoort die hoeveelheid wat u gebruik geleidelik verminder te word.
- Moenie meer van die medisyne gebruik, moenie dit meer dikwels gebruik en moet die medisyne nie vir langer gebruik as wat u dokter voorgeskryf het nie. As te veel daarvan geneem word, kan dit gewoontevormend raak (veroorsaak geestelike of liggaamlike afhanklikheid). As u 'n geskiedenis van alkohol- of medisyne-misbruik het, neem die risiko van afhanklikheid toe. Wanneer fisiese afhanklikheid ontwikkel het, sal die skielike staking van behandeling gepaardgaan met onttrekkingsimptome. Dit mag hoofpyn, spierpyn, uitermatige angs en spanning, rusteloosheid, verwardheid en geïrriteerdheid insluit. In uitermatige gevalle kan die volgende simptome voorkom: Derealisering (veranderde ondervinding van die eksterne omgewing sodat dit onwerklik voel), depersonalisering (subjektiewe gevoel van onwerklikheid in 'n persoon in hom-/ haarself), ongevoeligheid en prikkeling in die ledemate, hipersensitiwiteit teen lig, geraas en fisiese kontak, hallusinasies (sien, hoor of voel dinge wat nie daar is nie) of epileptiese stuipaanvalle.
- In ouer pasiënte is die dosis van **MEDPLOZ** kleiner.
- Maak seker dat u u dokter in kennis stel as u moeite met asemhaling ondervind. Sorg behoort in hierdie pasiënte aan die dag gelê te word aangesien daar aangetoon is dat slaaptablette die asemhalingsdrang onderdruk.
- Maak seker dat u u dokter in kennis stel as u aan depressie, psigotiese siekte ly of selfmoordidees het.
- Maak seker dat u u dokter in kennis stel as u 'n geskiedenis van alkohol- en medisynemisbruik het, aangesien **MEDPLOZ** nie in daardie geval aan u toegedien behoort te word nie.
- Maak seker dat u u dokter in kennis stel as u aan 'n erge lewersiekte ly, aangesien **MEDPLOZ** nie in pasiënte wat aan 'n erge lewersiekte ly, gebruik behoort te word nie.

Swangerskap en borsvoeding:
- As **MEDPLOZ** gedurende die laatfase van swangerskap toegedien word, kan die pasgebore baba aan abnormale lae liggaamstemperatuur, hipotonie (abnormaal lae spiertonus) en respiratoriese onderdrukking (abnormaal stadige en/of vlak asemhaling) ly. Babas wat uit moeders gebore word wat **MEDPLOZ** gedurende swangerskap gebruik het, kan fisiese afhanklikheid en 'n sekere mate van risiko vir onttrekkingsimptome ontwikkel.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidsbeampte om advies raadpleeg voordat u **MEDPLOZ** drink.

Bestuur en die gebruik van masjinerie:
MEDPLOZ kan lomerigheid, duiseligheid en verlies aan skerpheid veroorsaak. Maak seker dat u weet hoe u op **MEDPLOZ** reageer voordat u bestuur, masjinerie gebruik of enigiets anders doen wat gevaarlik kan wees as u duiselig of nie op en wakker is nie.

Die neem van ander medisyne saam met MEDPLOZ:
- **MEDPLOZ** sal bydra tot die effekte van alkohol en ander Sentrale Senuweestelsel (SSS)-depressante (medisyne wat die senuweestelsel vertraag, moontlik lomerigheid veroorsaak). Sommige voorbeelde van SSS-depressante is antihistamiene of medisyne vir hooikoors, ander allergieë, sedeermiddels, kalmeermiddels of slaapmedisyne; pynmedikasie of narkotika op voorskrif, medisyne vir stuipaanvalle en narkosemiddels. Raadpleeg u dokter voordat u enige van die bogenoemde neem terwyl u **MEDPLOZ** gebruik.
- Stel u dokter in kennis as u rifampisien neem – Die werking van **MEDPLOZ** neem af wanneer dit saam met rifampisien geneem word.
- Stel u dokter in kennis as u 'n MIV-proteaseïnhibeerder soos ritonavir neem – Die bloedvlakke van zolpidem mag toeneem met 'n risiko van uitermatige sedering en respiratoriese onderdrukking (abnormaal stadige en/of vlak asemhaling).

Stel altyd u gesondheidsbeampte in kennis as u ander medisyne neem. (Dit sluit komplementêre en tradisionele medisyne in)

4. HOE OM MEDPLOZ TE NEEM
- Neem **MEDPLOZ** slegs soos deur u dokter voorgeskryf. Moet dit nie langer gebruik as wat u dokter voorgeskryf het nie. Die lengte van behandeling wissel vanaf 'n paar dae tot twee weke met 'n maksimum van vier weke.
- **MEDPLOZ** behoort onmiddellik voor slapenstyd of wanneer u reeds in die bed is, geneem te word.
- **Dosis:**

  Volwassenes - 10 mg onmiddellik voor slapenstyd of wanneer u reeds in die bed is.

  Bejaarde of gestremde pasiënte en in pasiënte met lewersiekte - 5 mg onmiddellik voor slapenstyd of wanneer u reeds in die bed is.

  Die totale dosis **MEDPLOZ** behoort nie 10 mg te oorskry nie.

Neem altyd **MEDPLOZ** 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 **MEDPLOZ** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

As u te veel MEDPLOZ geneem het:
Oordosering met zolpidem alleen kan tot bewusteloosheid lei, wat kan wissel van slaperigheid tot ligte koma. Gevalle van oordosering waarby alkohol of ander SSS- depressante saam met zolpidem betrokke is, het tot meer ernstige simptome gelei, insluitende fatale uitkomste.

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

As u vergeet het om MEDPLOZ te neem:
As u 'n dosis **MEDPLOZ** oorgeslaan het, vergeet daarvan en keer terug na u gereelde dosisskedulering. Moenie die dosis verdubbel nie.

5. MOONTLIKE NEWE EFFEKTE
MEDPLOZ kan newe effekte hê.

Lomerigheid gedurende die dag, verwardheid, hoofpyn, duiseligheid, verlies aan spierkoördinasie, lompheid of onstabiliteit, afname in skerpheid, moegheid, afgestompte emosies, spierswakheid, dubbelvisie.

Die newe effekte hierbo genoem kom hoofsaaklik aan die begin van terapie voor en dan meer dikwels in bejaarde pasiënte, maar kan met behandeling verdwyn namate u liggaam aan die medisyne gewoond raak.

Ander newe effekte sluit die volgende in: Buik- of maagpyn, diaree, veluitslag, geheueprobleme, geestelike depressie, rusteloosheid, agitasie, geïrriteerdheid, aggressie, delusies, woede, nagmerries, hallusinasies, (sien, hoor of voel dinge wat nie daar is nie), psigoses, ontoepaslike gedrag

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

6. OPBERGING EN WEGDOEN VAN MEDPLOZ
Bewaar teen of benede 25 °C in 'n droë plek.
Bewaar weg van lig en vogtigheid. Hou die stolpstrokies in die oorspronklike karton tot voor gebruik. Hou die HDPE houer dig toe.
Moenie in die badkamer, naby die kombuiswasbak of in ander vogtige omgewings hou nie. Vogtigheid kan veroorsaak dat die medisyne afbreek.

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

7. AANBIEDING VAN MEDPLOZ
MEDPLOZ 5 mg
1. Stolpverpakking:
Tablette word in stolpverpakkings wat uit PVC/PVdc en gedrukte silwerkleurige aluminiumfoelie bestaan, verpak. Elke stolpverpakking bevat 10 tablette.

Pakgrootte: 30 s – Elke karton bevat 3 stolpstrokies van 10 tablette elk.

MEDPLOZ 10 mg
2. Stolpverpakkings
Tablette word in stolpverpakkings verpak wat bestaan uit PVC/PVdc en gedrukte silwergekleurde aluminiumfoelie. Elke stolpverpakking bevat 10 of 14 tablette onderskeidelik.

Pakgrootte: 30 s – Elke karton bevat 3 stolpstrokies van 10 tablette elk.

Pakgrootte: 14s – Elke karton bevat 1 stolpverpakkings van 14 tablette elk.

2. HDPE houer:
Tablette word in wit, ondeursigtige HDPE houers met 'n wit, ondeursigtige deksel met induksie seëlprop verpak. Die oop spasie in die houer word met 'n Rayon krul gevul.

Pakgrootte: 30 s – Een HDPE houer bevat 30 tablette.

8. IDENTIFIKASIE VAN MEDPLOZ
MEDPLOZ 5 mg: Wit tot byna-wit, ronde, bikonvekse, filmbedekte tablette met "E" op die een kant en "78" op die ander kant gedruk.
MEDPLOZ 10 mg: Wit tot byna-wit, ovaalvormige, bikonvekse, filmbedekte tablette met "E" op die een kant en op die ander kant' "80" met die "8" aan die een kant van die breeklyn en "0" aan ander kant gedruk.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER

SUID-AFRIKA:
MEDPLOZ 5 mg: 43/2.2/0247
MEDPLOZ 10 mg: 43/2.2/0257

NAMIBIË:
MEDPLOZ 5 mg: 10/2.2/0593
MEDPLOZ 10 mg: 10/2.2/0594

10.NAAM EN ADRES VAN DIE REGISTRASIEHOUER
AUROGEN SOUTH AFRICA (EDMS.) BPK.
Woodhill Kantoorpark, Gebou 1
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12, 1448
Johannesburg
Suid-Afrika

11.DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Datum van registrasie:
4 Maart 2011
Datum van hersiening:
21 September 2021

A/s: 350 x 480 mm ■ Black

AUROBINDO Packaging Development	**Product Name**	**Component**	**Item Code**	**Date & Time**
	Medploz	Leaflet	P1533064	08.03.2023 & 11.20 am
	Customer / Country	**Version No.**	**Reason of Issue**	**No. of Colours :**
	Aurogen - South Africa U3	03	Revision	
Team Leader: Kiran	**Dimensions**			
Initiator: Bhogi	350 x 480 mm	33064		
Design Agency One Creative Designers	**Pharma Code**			
	33064			

Additional Information:
Supersede Code: P1512731

Professional Information for Medicines for Human Use
SCHEDULING STATUS
SOUTH AFRICA: S5
NAMIBIA: NS3
PROPRIETARY NAME (and dosage form):
MEDPLOZ 5 mg (tablet)
MEDPLOZ 10 mg (tablet)

COMPOSITION:
MEDPLOZ 5 mg: Each film-coated tablet contains 5 mg zolpidem tartrate. Contains sugar: 43,80 mg lactose.
MEDPLOZ 10 mg: Each film-coated tablet contains 10 mg zolpidem tartrate. Contains sugar: 87,60 mg lactose.

The other ingredients are microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (C.I. No: 77891).

PHARMACOLOGICAL CLASSIFICATION:
A2.2 Sedatives, hypnotics.

PHARMACOLOGICAL ACTION:
Zolpidem is an imidazopyridine compound with sedative/hypnotic effects. These effects are related to a specific agonist action at central receptors belonging to GABA-omega benzodiazepine-1 and benzodiazepine-2 macromolecular receptor complex, modulating the opening of the chloride ion channel. Zolpidem acts primarily upon the omega-1 (benzodiazepine-1) receptor subtypes. The clinical relevance of this is not known.

Pharmacokinetics

Absorption:
The bioavailability of zolpidem is about 70 % after oral administration. Peak plasma concentration is reached between 0,5 and 3 hours after dosing.

Distribution:
The pharmacokinetics are linear at therapeutic dose levels. The degree of plasma protein binding is about 92 %. The plasma elimination half-life is about 2,5 hours (1,4 – 3,8 hours).

The distribution volume in adults is 0,54 ± 0,02 L/kg. The distribution volume decreases to 0,34 ± 0,05 L/kg in the very elderly.

Excretion:
Zolpidem is excreted in the form of inactive metabolites (hepatic metabolism), mainly in the urine (56 %) and faeces (37 %). It has no inducing effects on hepatic enzymes. Clearance is reduced in elderly subjects. The peak concentration is increased by about 50 % and elimination half-life by 32 %. In patients with renal insufficiency, whether dialysed or not, there is a moderate reduction in clearance. The other pharmacokinetic parameters are unaffected.

Bioavailability:
In patients with hepatic insufficiency, the bioavailability of zolpidem is increased. Clearance is reduced and the elimination half-life prolonged (about 10 hours).

INDICATIONS:
- **MEDPLOZ** is indicated for the short term treatment of insomnia.
- **MEDPLOZ**, is only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

CONTRA-INDICATIONS:
- Hypersensitivity to the product.
- Myasthenia gravis.
- Sleep apnoea syndrome.
- Acute and severe pulmonary insufficiency, as respiratory failure may be precipitated.
- Severe hepatic insufficiency.
- Children under the age of 18.
- Concomitant administration with HIV protease inhibitors such as ritonavir as plasma concentrations may be increased and thus the risk of extreme sedation and respiratory depression.

WARNINGS AND SPECIAL PRECAUTIONS:
Safety and efficacy in children under the age of 18 years have not been established.

Dependence and Abuse:
Use of **MEDPLOZ** may lead to the development of physical and psychological dependence. The risk of dependence increases with the dose and duration of treatment; it is also greater in patients with a history of alcohol or medicine abuse. These patients should be under careful surveillance when receiving hypnotics. Discontinuation of therapy may result in withdrawal or rebound phenomena. These symptoms range from mild dysphoria, headaches or muscle pain, extreme anxiety and tension, restlessness, confusion and irritability and insomnia to a withdrawal syndrome that may include abdominal and muscle cramps, vomiting, sweating, tremors and convulsions, derealisation, depersonalisation, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, or hallucinations.

Duration of treatment:
The duration of treatment should be as short as possible and should not exceed 4 weeks, including the tapering off process. Extensions beyond these periods should not take place without re-evaluation of the situation.

It may be useful to inform the patient when treatment is started that it will be of limited duration, and to explain precisely how the dosage will be progressively decreased.

Tolerance:
After repeated use of **MEDPLOZ** for a few weeks, some loss of efficacy of the hypnotic effects may develop.

Amnesia:
MEDPLOZ may induce anterograde amnesia. The condition occurs most often several hours after ingesting the product and therefore, to reduce this risk, patients should ensure that they will be able to have an uninterrupted sleep of 7 to 8 hours (see **"SIDE EFFECTS"**).

Rebound Insomnia:
A transient syndrome, whereby the symptoms that led to treatment with sedative/hypnotic agents recur in an enhanced form, may occur on withdrawal of hypnotic treatment. It may be accompanied by other reactions including mood changes, anxiety and restlessness. The syndrome is more likely to develop if the product is discontinued abruptly, and therefore treatment should be withdrawn gradually.

Psychiatric and "Paradoxical" Reactions:
Depression: **MEDPLOZ** should not be used to treat depressive syndromes, or anxiety with depression as suicidal tendencies may be present.

Psychotic illness: **MEDPLOZ** should not be used as the primary treatment of psychotic illness.
(see **"SIDE EFFECTS"**)

Specific patient groups:
- For the elderly: (See " **DOSAGE AND DIRECTIONS FOR USE**")
- Respiratory insufficiency: Since hypnotics have been shown to impair respiratory drive, caution should be observed when prescribing **MEDPLOZ** to patients with chronic respiratory insufficiency.
- Severe hepatic insufficiency: Zolpidem is not indicated to treat patients with severe hepatic insufficiency as hypnotics may precipitate encephalopathy.

Effects on ability to drive or to use machines:
Sedation, drowsiness, dizziness and vertigo may adversely affect the ability to drive or to use machines in patients taking **MEDPLOZ**.
The likelihood of impaired alertness may increase if insufficient sleep duration occurs.

INTERACTIONS:
- Concomitant intake with alcohol is not recommended. The sedative effect may be enhanced when the product is used in combination with alcohol. This affects the ability to use machines or drive.
- Combination with Central Nervous System (CNS)- depressants: Enhancement of the central depressive effects may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant agents, narcotic analgesics, antiepileptic medicines, anaesthetics and sedative antihistamines.

In the case of narcotic analgesics enhancement of the euphoria may also occur leading to an increase in psychological dependence.
• The activity of **MEDPLOZ** may be enhanced by compounds which inhibit certain hepatic enzymes (particularly cytochrome P450).
Zolpidem is metabolised via several hepatic cytochrome P450 enzymes: the main enzyme being CYP3A4 with the contribution of CYP1A2.

The pharmacodynamic effect of **MEDPLOZ** is decreased when it is administered with rifampicin (a CYP3A4 inducer).

However when zolpidem was administered with itraconazole (a CYP3A4 inhibitor) its pharmacokinetics and pharmacodynamics were not significantly modified. The clinical relevance of these results in unknown.

- No significant pharmacokinetic interactions were observed when **MEDPLOZ** was administered with warfarin, digoxin or ranitidine.
- HIV-protease inhibitors such as ritonavir may increase plasma concentrations of zolpidem with a risk of profound sedation and respiratory depression; use together is not recommended.

PREGNANCY AND LACTATION:
Safety in pregnancy has not been established.
If **MEDPLOZ** is administered during the late phase of pregnancy, or during labour, effects on the neonate such as hypothermia, hypotonia and moderate respiratory depression, can be expected due to the pharmacological action of the product.
Infants born to mothers who take **MEDPLOZ** chronically during the latter stages of pregnancy may develop physical dependence and may be at some risk of developing withdrawal symptoms in the postnatal period.
Zolpidem should not be administered to breastfeeding mothers.
Small quantities of zolpidem appear in breast milk.

DOSAGE AND DIRECTIONS FOR USE:
Safety and efficacy in children under the age of 18 years have not been established.
Treatment should be as short as possible. Generally, the duration of treatment varies from a few days to two weeks with a maximum, including the tapering off process, of four weeks.
In certain cases, extension beyond the maximum treatment period may be necessary. If so, it should not take place without reevaluation of the patient's status.
MEDPLOZ should be taken immediately before going to bed, or in bed.

Dose:
The recommended daily dose for adults is 10 mg immediately before bedtime, or in bed.
In elderly or debilitated patients who may be especially sensitive to the effects of zolpidem, and in patients with hepatic insufficiency who do not clear the agent as rapidly as normal individuals, a dose of 5 mg is recommended, which should be exceeded only under exceptional circumstances.

The total dose of **MEDPLOZ** should not exceed 10 mg in any patient.

SIDE EFFECTS:
Nervous system disorders:
Less frequent: Drowsiness during the day, confusion, headache, dizziness, ataxia and gait disturbances.
Amnesia: Anterograde amnesia may occur using therapeutic dosages of **MEDPLOZ**, the risk increasing at higher dosages. Amnesic effects may be associated with inappropriate behaviour.
The following side effects have been reported and frequencies are unknown: Reduced alertness, fatigue.

Psychiatric disorders:
Less frequent: Depression: Pre-existing depression may be unmasked during the use of **MEDPLOZ.**
Psychiatric and "Paradoxical" reactions: Reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects are known to occur when using **MEDPLOZ**. Should this occur, use of the product should be discontinued. These reactions are more likely to occur in children (see **"CONTRA-INDICATIONS"**) and in the elderly.
The following side effect has been reported and frequency is unknown: Numbed emotions.

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Muscle weakness.

Eye disorders:
Less frequent: Double vision.
These phenomena mentioned above occur predominantly at the start of therapy and most frequently in elderly patients, but may disappear with repeated administration.

Gastrointestinal disorders:
Less frequent: Gastrointestinal disturbances, such as nausea, vomiting, diarrhoea, dry mouth, abdominal or gastric pain.

Skin and subcutaneous tissue disorders:
Less frequent: Skin reactions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Following an overdose with **MEDPLOZ** alone, impairment of consciousness may range from somnolence to light coma. Individuals have fully recovered from zolpidem doses of up to 400 mg. Overdose involving multiple CNS-depressant agents (e.g. alcohol), may result in more severe symptomatology, including fatal outcomes.

Treatment:
General symptomatic and supportive measures should be used, along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Sedative medicines should be withheld even if excitation occurs. The value of dialysis in the treatment of overdose has not been determined, although haemodialysis studies in patients with renal failure receiving therapeutic doses have demonstrated that zolpidem is not dialysable. Where serious symptoms are observed, the use of benzodiazepine – antagonists (e.g. flumazenil) may be considered.

However, flumazenil administration may contribute to the appearance of neurological symptoms (convulsions).

In the management of overdose with any medicinal product, it should be borne in mind that multiple agents may have been taken.

IDENTIFICATION:
MEDPLOZ 5 mg: White to off – white, circular, biconvex, film – coated tablets, debossed with "E" on one side and "78" on the other side.

MEDPLOZ 10 mg: White to off – white, oval shaped, biconvex film – coated tablets, debossed with "E" on one side and debossed with "80" with a score line between "8" and "0" on the other side.

PRESENTATION:
MEDPLOZ 5 mg

1. Blister Packs:
Tablets are packed in blister packs composed of clear PVC/PVdc and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30 s – Each carton contains 3 blisters of 10 tablets each.

MEDPLOZ 10 mg:

2. Blister Packs:
Tablets are packed in blister packs composed of clear PVC/PVdc and printed silver-coloured aluminium foil. Each blister contains 10 or 14 tablets respectively.

Pack size: 30 s – Each carton contains 3 blisters of 10 tablets each.

Pack size: 14 s – Each carton contains 1 blisters of 14 tablets each.

2. HDPE Container Pack:
Tablets are packed in white opaque HDPE containers with white opaque polypropylene closure with induction sealing wad. The void space in the container is filled by Rayon coil.

Pack size: 30 s: One HDPE container of 30 tablets.

STORAGE INSTRUCTIONS:
Store in a dry place at or below 25 °C. Protect from light and moisture. Keep blisters in the original carton until required for use. Keep the HDPE container well closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

SOUTH AFRICA:
MEDPLOZ 5 mg: 43/2.2/0247
MEDPLOZ 10 mg: 43/2.2/0257

NAMIBIA:
MEDPLOZ 5 mg: 10/2.2/0593
MEDPLOZ 10 mg: 10/2.2/0594

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 Avenue,
Meyersdal, Ext. 12, Johannesburg,
South Africa, 1448

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date or registration:
4 March 2011
Date of revision:
21 September 2021

P1533064

DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET
SOUTH AFRICA: S5
NAMIBIA: NS3
MEDPLOZ 5 mg (tablet)
MEDPLOZ 10 mg (tablet)
Zolpidem tartrate

Read all of this leaflet carefully before you start taking MEDPLOZ.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MEDPLOZ** 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 MEDPLOZ CONTAINS
The active substance is zolpidem tartrate.
MEDPLOZ 5 mg: Each film-coated tablet contains 5 mg zolpidem tartrate. Contains sugar: 43,80 mg lactose.
MEDPLOZ 10 mg: Each film-coated tablet contains 10 mg zolpidem tartrate. Contains sugar: 87,60 mg lactose.
The other ingredients are microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (C.I. No: 77891).

2. WHAT MEDPLOZ IS USED FOR
Zolpidem is used to treat insomnia (trouble in sleeping). Zolpidem is only given when the disorder is severe, disabling or extremely distressing to the patient. Zolpidem should be used only for short periods of time.

3. BEFORE YOU TAKE MEDPLOZ
Do not take MEDPLOZ:
- If you have ever had an unusual or allergic reaction to zolpidem or the product.
- If you suffer from myasthenia gravis (muscle disorder causing weakness).
- If you suffer from sleep apnoea (temporary stopping of breathing during sleep).
- If you suffer from lung disease.
- If you have severe liver disease.
- If you are under the age of 18 years.
- If you are breastfeeding or pregnant. The safety of **MEDPLOZ** in pregnancy has not been established.

Take special care with MEDPLOZ:
- **MEDPLOZ** should be used for a short period of time, and generally for not longer than 4 weeks. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.
- After repeated use of **MEDPLOZ** for a few weeks, some loss of the sleeping effect may develop.
- **MEDPLOZ** may cause a special type of memory loss or "amnesia". When this occurs, a person does not remember what has happened during the several hours between use of the medicine and the time when its effects wear off.
- After taking **MEDPLOZ** for insomnia, you may have difficulty sleeping (rebound insomnia) for the first few nights after you stop taking it. Mood changes, anxiety and restlessness may also occur. Rebound insomnia is more likely to occur if **MEDPLOZ** is stopped suddenly, and therefore the amount you are taking should be reduced gradually.
- Do not take more of this medicine, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much is taken, it may become habit-forming (causing mental or physical dependence). If you have a history of alcohol or medicine abuse, the risk of dependence increases. Once physical dependence has developed, sudden stopping of treatment will be accompanied by withdrawal symptoms. These may include headaches, muscle pain, extreme anxiety and tension, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: derealisation (altered experience of the external world so that it seems unreal), depersonalisation (subjective experience of unreality in one's sense of self), numbness and tingling of the limbs, hypersensitivity to light, noise and physical contact, hallucinations (seeing, hearing, or feeling things that are not there) or epileptic seizures.
- In older adults, the dose of **MEDPLOZ** is reduced.
- Make sure you tell your doctor if you have breathing difficulties. Caution should be observed in these patients, since sleeping tablets have been shown to impair respiratory drive.
- Make sure you tell your doctor if you suffer from depression, psychotic illness, or suicidal thoughts.
- Make sure you tell your doctor if you have a history of alcohol and medicine abuse, since **MEDPLOZ** should then not be given to you.
- Make sure you tell your doctor if you have severe liver disease, since **MEDPLOZ** should not be used to treat patients with severe liver disease.

Pregnancy and Breastfeeding:
- If **MEDPLOZ** is given during the late phase of pregnancy, or during labour, the newborn may suffer from abnormally low body temperature, hypotonia (abnormally low muscle tone) and respiratory depression (abnormally slow and/or shallow breathing). Infants born to mothers who have taken **MEDPLOZ** during pregnancy may develop physical dependence and may be at some risk of developing withdrawal symptoms.

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

Driving and using machinery:
MEDPLOZ may cause drowsiness, dizziness and loss of alertness. Make sure you know how you react to **MEDPLOZ** before you drive, use machines, or do anything else that could be dangerous if you are dizzy, or are not alert.

Taking other medicines with MEDPLOZ:
- **MEDPLOZ** will add to the effects of alcohol and other Central Nervous System (CNS)- depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS - depressants are antihistamines or medicines for hay fever, other allergies; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; medicines for seizures and anaesthetics.

  Check with your doctor before taking any of the above while you are using **MEDPLOZ**.

  MEDPLOZ should not be taken together with alcohol.
- Tell your doctor if you are taking rifampicin – The action of **MEDPLOZ** is decreased when it is taken together with rifampicin.
- Tell your doctor if you are taking an HIV-protease inhibitor such as ritonavir – The blood level of zolpidem may be increased with a risk of extreme sedation and respiratory depression (abnormally slow and/or shallow breathing).

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

4. HOW TO TAKE MEDPLOZ
- Take **MEDPLOZ** only as directed by your doctor. Do not take it for a longer time than your doctor has ordered. The length of treatment varies from a few days to two weeks, with a maximum of four weeks.
- **MEDPLOZ** should be taken immediately before going to bed, or in bed.
- **Dose:**

  Adults – 10 mg immediately before bedtime, or in bed.

  Elderly or debilitated patients and in patients with liver disease – 5 mg immediately before bedtime, or in bed.

  The total dose of **MEDPLOZ** should not exceed 10 mg.

Always take **MEDPLOZ** 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 **MEDPLOZ** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MEDPLOZ than you should:
Taking an overdose of zolpidem alone may lead to unconsciousness, ranging from sleepiness to light coma. Overdose cases involving taking alcohol or other CNS depressants with zolpidem have resulted in more severe symptoms, including fatal outcomes.

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

If you forget to take MEDPLOZ:
If you miss a dose of **MEDPLOZ**, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

5. POSSIBLE SIDE EFFECTS
MEDPLOZ can have side effects.
Daytime drowsiness, confusion, headache, dizziness, loss of muscle co-ordination, clumsiness or unsteadiness, reduced alertness, fatigue, numbed emotions, muscle weakness, double vision.
These side effects mentioned above occur mainly at the start of therapy and most frequently in elderly patients, but may go away during treatment as your body adjusts to the medicine.
Other side effects include: abdominal or stomach pain, diarrhoea, skin rashes, memory problems, mental depression, restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations (seeing, hearing, or feeling things that are not there), psychoses, inappropriate behaviour.

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

6. STORING AND DISPOSING OF MEDPLOZ
Store at or below 25 °C in a dry place.
Store away from light and moisture. Keep blisters in the original carton until required for use. Keep the HDPE container well closed.
Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Store all medicines out of the reach and sight of children.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MEDPLOZ
MEDPLOZ 5 mg
1. Blister Packs:
Tablets are packed in blister packs composed of clear PVC/PVdc and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30 s – Each carton contains 3 blisters of 10 tablets each.

MEDPLOZ 10 mg:

2. Blister Packs:
Tablets are packed in blister packs composed of clear PVC/PVdc and printed silver-coloured aluminium foil. Each blister contains 10 or 14 tablets respectively.

Pack size: 30 s – Each carton contains 3 blisters of 10 tablets each.

Pack size: 14 s – Each carton contains 1 blisters of 14 tablets each.

2. HDPE Container Pack:
Tablets are packed in white opaque HDPE containers with white opaque polypropylene closure with induction sealing wad. The void space in the container is filled by Rayon coil.

Pack size: 30 s: One HDPE container of 30 tablets.

8. IDENTIFICATION OF MEDPLOZ
MEDPLOZ 5 mg: White to off – white, circular, biconvex, film – coated tablets, debossed with "E" on one side and "78" on the other side.
MEDPLOZ 10 mg: White to off – white, oval shaped, biconvex film – coated tablets, debossed with "E" on one side and debossed with "80" with a score line between "8" and "0" on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER
SOUTH AFRICA:
MEDPLOZ 5 mg: 43/2.2/0247
MEDPLOZ 10 mg: 43/2.2/0257
NAMIBIA:
MEDPLOZ 5 mg: 10/2.2/0593
MEDPLOZ 10 mg: 10/2.2/0594

10. NAME AND ADDRESS OF REGISTRATION HOLDER
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, Johannesburg,
South Africa, 1448

11. DATE OF PUBLICATION
Date or registration:
4 March 2011
Date of revision:
21 September 2021