SOLIREST

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S3

SOLIREST 5 & 10 film-coated tablets
Solifenacin succinate
SOLIREST 5 contains 134,5 mg lactose monohydrate per film-coated tablet
SOLIREST 10 contains 129,5 mg lactose monohydrate per film-coated tablet

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

WHAT IS IN THIS LEAFLET

1. What SOLIREST is and what it is used for
SOLIREST contains the active ingredient solifenacin succinate which belongs to the group of anticholinergics. SOLIREST is used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.
SOLIREST is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. What you need to know before you take SOLIREST
Do not take SOLIREST if:
- you are hypersensitive to solifenacin succinate or any of the other ingredients of SOLIREST (listed in section 6).
- if you have an inability to pass urine or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- if you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- if you suffer from increased pressure in the eyes, with gradual loss of eyesight (glaucoma)
- if you are undergoing kidney dialysis
- if you have severe liver disease
- if you suffer from severe kidney disease or moderate liver disease and at the same time are being treated with medicines that may decrease the removal of SOLIREST from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Warnings and precautions
Take special care with SOLIREST:
- if you have trouble emptying your bladder (= bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- if you have some obstruction of the digestive system (constipation).
- if you are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.
- if you suffer from severe kidney disease.
- if you have moderate liver disease.
- if you have a stomach tear (hiatus hernia) or heartburn.
- if you have a nervous disorder (autonomic neuropathy).

Children and adolescents
SOLIREST is not to be used in children or adolescents under 18 years.

Other medicines and SOLIREST
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
- other anticholinergic medicines like scopolamine, orphenadrine and flavoxate, that prevents impulses responsible for muscle movement against someone's will. These medicines can increase the effects and side effects of the anticholinergic medicines and SOLIREST.
- cholinergics medicines such as botulinum toxin, nicotine and atropine that prevents or improve the contraction of smooth muscles, opens blood vessels and increase body secretions and slow the heart rate. They can reduce the effect of SOLIREST.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. SOLIREST can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which SOLIREST is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which SOLIREST is broken down by the body.

SOLIREST with food
SOLIREST can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking SOLIREST.
You should not take SOLIREST if you are pregnant or breastfeeding your baby.

Driving and using machines
SOLIREST may cause blurred vision and sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.
It is not always possible to predict to what extent SOLIREST may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which SOLIREST affects you.

3. How to take SOLIREST
Do not share medicines prescribed for you with any other person.
Always take SOLIREST exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is 5 mg per day, unless your doctor told you to take 10 mg per day.
Your doctor will tell you how long your treatment with SOLIREST will last. If you have the impression that the effect of SOLIREST is too strong or too weak, tell your doctor or pharmacist.
You should swallow the whole tablet with some liquid.
It can be taken with or without food, according to your preference. Do not crush the tablets.

If you take more SOLIREST than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Symptoms of overdose may include: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over- excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

If you forget to take SOLIREST
Do not take a double dose to make up for forgotten individual doses.

If you stop taking SOLIREST
Do not stop taking SOLIREST without speaking to your doctor.

4. Possible side effects
SOLIREST can have side effects.
Not all side-effects reported for SOLIREST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOLIREST, please consult your healthcare provider for advice.

If any of the following happens, stop taking SOLIREST and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SOLIREST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects
- blurred vision
- dry mouth
- constipation, nausea, indigestion with symptoms such as abdominal fullness and burping, stomach pain

Less frequent side effects
- urinary tract infection, bladder infection
- hallucinations, confusion
- sleepiness, impaired sense of taste (dysgeusia)
- dizziness, headache
- dry eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux), dry throat
- blockage in the colon or rectum that prevents food or gas from passing through
- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- vomiting
- dry skin
- localised skin eruption with minimal or no mucosal involvement
- hives
- difficulty in passing urine
- tiredness
- accumulation of fluid in the lower legs (oedema)

Unknown frequency of side effects
- decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- abrupt change in the brain that causes mental confusion and emotional disruption
- increased pressure in the eyes
- voice disorder
- a painful obstruction of the ileum or other part of the intestine
- liver disorder
- abnormal liver function tests
- widespread red and scaling of the skin
- muscle weakness
- renal disorder

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the *"6.04 Adverse Drug Reaction Reporting Form"*, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SOLIREST.

5. How to store SOLIREST
Store all medicine out of reach of children.
Store at or below 25 °C in the original package. Protect from moisture.
Do not remove foil strips from carton until required for use.
Do not use the tablets after the expiry date shown on the container.
Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information
What SOLIREST contains
The active ingredient is solifenacin succinate.
The other ingredients are: Lactose monohydrate, maize starch, magnesium stearate, hydroxypropyl methyl cellulose, hypromellose, polyethylene glycol 8 000, talc, titanium dioxide (E171) and iron oxide (E172) as tablet coating.

What SOLIREST looks like and contents of the pack
SOLIREST 5 tablets are light yellow round shaped, 7,5 mm, biconvex film-coated tablets, debossed with "SOL" on one side and "5" on other side.
SOLIREST 10 tablets are light pink round shaped, 7,5 mm, biconvex film-coated tablets, debossed with "SOL" on one side and "10" on other side.
SOLIREST film-coated tablets are packaged in PVC-Alu strips. 10 tablets per foil strip.
Pack sizes: 30 (3x10) film-coated tablets.

Holder of Certificate of Registration
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SOLIREST 10: 55/5.4/0029

The full Professional Information leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.

SOLIREST

PASIËNTE INLIGTINGSBLAD

SKEDULERINGSTATUS:
S3

SOLIREST 5 & 10 Film-bedekte tablette
Solifenasiensuksinaat
SOLIREST 5 bevat 134,5 mg laktosemonohidraat per film-bedekte tablet
SOLIREST 10 bevat 129,5 mg laktosemonohidraat per film-bedekte tablet

Lees hierdie hele blad noukeurig deur voordat u begin om SOLIREST te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- SOLIREST is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

WAT IN HIERDIE BLAD IS

1. Wat SOLIREST is en waarvoor dit gebruik word
SOLIREST bevat die aktiewe bestanddeel solifenasiensuksinaat wat deel uitmaak van die groep anticholinergika. SOLIREST word gebruik om die aktiwiteit van 'n ooraktiewe blaas te verminder. Dit stel u in staat om langer te wag voordat u na die badkamer hoef te gaan en verhoog die hoeveelheid urien wat deur u blaas gehou kan word.
SOLIREST word gebruik om die simptome van 'n ooraktiewe blaas te behandel. Hierdie simptome is onder meer 'n sterk, skielike drang om te urineer sonder vooraf waarskuwing, om gereeld te moet urineer of uself nat te maak omdat u nie betyds by die badkamer kon uitkom nie.

2. Wat u moet weet voordat u SOLIREST drink
Moenie SOLIREST drink nie as u:
- hipersensitief vir solifenasiensuksinaat of vir enige van die ander bestanddele (gelys in afdeling 6) is.
- nie in staat is om te urineer of u blaas heeltemal leeg te maak nie (urienretensie).
- 'n ernstige - of dermtoestand het (waaronder toksiese megakolon, 'n komplikasie wat verband hou met ulseratiewe kolitis)
- aan 'n spiersiekte, genaamd myasthenia gravis, ly wat erge swakheid van sekere spiere veroorsaak.
- aan hoë druk in die oë ly, met geleidelike verlies van visie (gloukoom)
- nierdialise ondergaan
- 'n ernstige lewersiekte het
- aan 'n erge niersiekte of matige lewersiekte ly en terselfdertyd behandel word met medisyne wat die verwydering van SOLIREST uit die liggaam kan verlaag (byvoorbeeld ketokonasool). U dokter of apteker sal vir u gesê het indien dit die geval is.

Waarskuwings en voorsorgmaatreëls
Wees besonder versigtig met SOLIREST as u:
- probleme ondervind om u blaas leeg te maak (blaasobstruksie) of probleme met urinering ondervind. Die risiko vir die ophoping van urien in die blaas (urienretensie) is baie hoër.
- 'n obstruksie in die spysverteringstelsel het (hardlywigheid).
- die risiko loop dat u spysverteringstelsel stadiger werk (maag- en stoelgang). U dokter of apteker sal vir u gesê het indien dit die geval is.
- u aan 'n erge niersiekte ly.
- 'n matige lewersiekte het.
- 'n maagbreuk (mantelvliesbreuk) of sooibrand het.
- 'n senustelselversteuring het (outonome neuropatie).

Kinders en adolessente
SOLIREST is nie geskik vir gebruik deur kinders of adolessente jonger as 18 jaar nie.

Ander medisyne en SOLIREST
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne (waaronder aanvullende of tradisionele medisyne) of die volgende gebruik:
- ander anticholinerge medisyne soos skopolamien, orfenadrien en flavoksaat, wat impulse wat verantwoor delik is vir spierbeweging teen iemand se wil voorkom, voorkom. Hierdie medisyne kan die effekte en newe-effekte van anticholinerge medisyne en SOLIREST verhoog.
- cholinerge medisyne soos botulinumtoksien, nikotien en atropien wat die sametrekking van gladde spiere voorkom of verbeter, bloedvate oopmaak en liggaamsekresies verhoog en die hartklop vertraag. Dit kan die effek van SOLIREST verlaag.
- medisyne, soos metoklopramied en sisapried, wat die spysverteringstelsel vinniger laat werk. SOLIREST kan die effek daarvan verlaag.
- medisyne, soos ketokonasool, ritonavir, nelfinavir, itrakonasool, verapamiel en diltiasem, wat die tempo verlaag waarteen SOLIREST deur die liggaam afgebreek word.
- medisyne, soos rifampisien, fenitoïen en karbaamasepien, omdat dit die tempo waarteen SOLIREST deur die liggaam afgebreek word kan verhoog.

SOLIREST saam met kos
SOLIREST kan met of sonder voedsel gedrink word.
Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u SOLIREST drink.
U moet SOLIREST nie drink as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjinerie
SOLIREST kan dowwe visie en slaperigheid of moegheid veroorsaak. As u enige van hierdie newe-effekte kry, moet u nie 'n voertuig bestuur of masjinerie hanteer nie.
Dit is nie altyd moontlik om te voorspel tot watter mate SOLIREST met u daaglikse aktiwiteite kan inmeng nie. U moet sorg dat u nie 'n voertuig bestuur of masjiene hanteer nie, totdat u weet hoe SOLIREST u beïnvloed.

3. Hoe om SOLIREST te drink
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Drink SOLIREST altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
Die gewone dosis is 5 mg per dag, tensy u dokter vir u gesê het om 10 mg per dag te drink.
U dokter sal vir u sê hoe lank u behandeling met SOLIREST sal duur. Sê vir u dokter of apteker as u die indruk het dat die effek van SOLIREST te sterk of te swak is.
U moet die tablet heel met water afsluk. Dit kan met of sonder voedsel gedrink word, net soos u verkies. Moenie die tablette breek nie.

As u meer SOLIREST gedrink het as wat u moes
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Simptome van oordosering is onder meer hoofpyn, droë mond, duiseligheid, slaperigheid en dowwe visie, waarneem van dinge wat nie daar is nie (hallusinasies), oormatige opgewondenheid, toevalle (stuiptrekkings), probleme met asemhaling, vinniger hartklop (tagikardie), ophoping van urien in die blaas (urienretensie) en gedilateerde pupille (midriase).

As u vergeet om SOLIREST te drink
Moenie 'n dubbele dosis gebruik om vir vergete individuele dosisse op te maak nie.
As u ophou om SOLIREST te drink
Moenie ophou om SOLIREST te drink sonder om eers met u dokter te praat nie.

4. Moontlike newe-effekte
SOLIREST kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir SOLIREST aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u SOLIREST drink, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.
Indien enige van die volgende voorkom, moet u ophou om

SOLIREST te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige reaksie op SOLIREST het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
- veranderinge in die elektriese aktiwiteit van die hart (EKG), onreëlmatige hartklop, dreunende hartklop, vinniger hartklop

Dit is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Algemene newe-effekte
- dowwe visie
- droë mond
- hardlywigheid, naarheid, slegte spysvertering met simptome soos volheid in die buik en winde opbreek, maagpyn

Minder algemene newe-effekte
- urienweginfeksie, blaasinfeksie
- hallusinasies, verwardheid
- slaperigheid, verswakte smaaksin (disgeusie)
- duiseligheid, hoofpyn
- droë oë
- droë neusgange
- reflukssiekte (gastro-esofageale terugvloei), droë keel
- verstopping in die dikderm of rektum wat voorkom dat voedsel of gas deurgaan
- vassit van 'n groot hoeveelheid harde stoelgang in die dikderm (fekale impaksie)
- braking
- droë vel
- gelokaliseerde veluitbarstings met minimale of geen mukosale betrokkenheid nie
- galbulte
- moeilike urinering
- moegheid
- ophoop van vloeistof in die onderbene (edeem)

Newe-effekte van onbekende frekwensie
- swak eetlus, hoë vlakke van kalium in die bloed wat abnormale hartritme kan veroorsaak
- skielike verandering in die brein wat geestelike verwardheid en emosionele ontwrigting veroorsaak
- hoë druk in die oë
- stemversteuring
- 'n pynlike obstruksie in die ileum of ander dele van die dunderm
- lewerversteuring
- abnormale uitslae van lewerfunksietoetse
- wydverspreide rooi en afskilfering van die vel
- spierswakheid
- niervversteurings

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SAHPRA aanmeld met die toepaslike vorm, naamlik *"6.04 Adverse Drug Reaction Reporting Form"* wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van SOLIREST te gee.

5. Hoe om SOLIREST te bêre
Hou alle medisyne buite bereik van kinders.
Bewaar teen of onder 25 °C in die oorspronklike pakkie.
Beskerm teen vog.
Moenie die foeliestroke voor gebruik uit die karton verwyder nie.
Moenie die tablette na die vervaldatum op die karton gebruik nie.
Gee die vervalde medisyne vir veilige wegdoening terug aan u apteker.

6. Inhoud van die pak en ander inligting
Wat SOLIREST bevat
Die aktiewe bestanddeel is solifenasiensuksinaat.
Die ander bestanddele is laktosemonohidraat, mieliestysel, magnesiumstearaat, hidroksipropielmetielsellulose, hipromellose, poliëtileenglikol 8 000, talk, titaandioksied (E171) en ysteroksied (E172) as tabletbedekking.

Hoe SOLIREST lyk en die inhoud van die pakkie
SOLIREST 5 tablette is liggeel, ronde, bikonvekse film-bedekte tablette van 7,5 mm, met "SOL" op die een kant en "5" op die ander kant gedruk.
SOLIREST 10 tablette is ligpienk, ronde, bikonvekse film-bedekte tablette van 7,5 mm, met "SOL" op die een kant en "10" op die ander kant gedruk.
SOLIREST film-bedekte tablette is in PVC-Alu-stroke verpak. 10 tablette per foeliestrook.
Pakgroottes: 30 (3x10) film-bedekte tablette.

Houer van die registrasiesertifikaat
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Hierdie blad is laas hersien op
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Registrasienommer
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