Front Side 335 x 300 mm

300 mm

SOLONEX CO
TABLETS
PM00334202

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SOLONEX CO (film coated tablet)
Isoniazid 300 mg and Rifapentine 300 mg
Sugar free

Read all of this leaflet carefully before you start taking SOLONEX CO
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **SOLONEX CO** 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 **SOLONEX CO** is and what it is used for
2. What you need to know before you take **SOLONEX CO**
3. How to take **SOLONEX CO**
4. Possible side effects
5. How to store **SOLONEX CO**
6. Contents of the pack and other information

1. What SOLONEX CO is and what it is used for

SOLONEX CO contains isoniazid and rifapentine. It is used to prevent progression of inactive (latent) tuberculosis infection (LTBI) to active tuberculosis disease in adults.

2. What you need to know before you take SOLONEX CO

Do not take SOLONEX CO:
- If you are hypersensitive (allergic) to isoniazid or rifapentine or to any of the ingredients of **SOLONEX CO** listed in section 6.1.
- If you are hypersensitive to medicines which are chemically related to isoniazid such as ethionamide, pyrazinamide (used for TB) and niacin (Vitamin B3).
- If you are pregnant, breastfeeding or planning to become pregnant during treatment.
- If you have acute or chronic liver disease
- If you have a condition called porphyria (a group of disorders that can cause nerve or skin problems (blisters and itching) due to a problem with the production of haem (blood pigment) and red blood cells within the body).
- If you experience fits.
- If you are alcoholic.
- If you have severe kidney probems
- If you are currently on specific antiretroviral therapy belonging to the classes protease inhibitors (e.g. indinavir, atazanivir, lopinavir, ritonavir) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g. efavirenz, nevirapine)

Warnings and precautions
Talk to your doctor before taking SOLONEX CO if you
Have liver problems. Your doctor may do a blood test to check your liver function before and while you take **SOLONEX CO** (see section Do not take **SOLONEX CO** if).
Have active TB disease.
Take medicines to treat HIV infection or take oral contraceptives. Using these medicines with **SOLONEX CO** may make them less effective (see Other medicines and **SOLONEX CO**).
Use a medicine called digoxin (used to make the heart beat stronger and with a more regular rhythm). Your doctor will monitor your dose of digoxin as it could change due to **SOLONEX CO**. Even small changes need to be monitored to prevent serious side effects from occurring (also see Other medicines and **SOLONEX CO**).
Wear contact lenses or dentures. **SOLONEX CO** may change the normal colour of your skin, mouth and body fluids and cause your skin, teeth, tongue, urine, stools, saliva, sputum, tears, sweat, and breast milk to turn a red-orange colour. Contact lenses or dentures may become permanently stained.
If you experience any of the following after or while you are taking SOLONEX CO, tell your doctor or health care provider immediately:
If you experience symptoms of a hypersensitivity (allergic) reaction after taking **SOLONEX CO**, e.g. low blood pressure, hives, swelling of the face, lips, tongue or throat, difficulty breathing, red eyes or flu-like syndrome (weakness, extreme tiredness, muscle pain, nausea and vomiting, headache, fever, chills, aches, rash, itching, sweats, dizziness, shortness of breath, chest pain, cough, fainting, fast heartbeat). These may be symptoms of a serious allergic reaction and you must immediately stop taking **SOLONEX CO** and go to the casualty department at your nearest hospital (see Possible side effects).
SOLONEX CO may cause serious liver problems. Stop taking **SOLONEX CO** and call your doctor right away if you have any of the following signs and symptoms of liver problems: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine (see Possible side effects).
Severe skin problems such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have been reported with the use of **SOLONEX CO**.
SJS symptoms may include blistering, peeling or bleeding on any part of your skin with or without a rash. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.
DRESS symptoms and signs may include flu-like symptoms and a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia). If you develop any skin reaction, stop treatment immediately and contact your doctor or health care provider.
SOLONEX CO may cause a type of diarrhoea called Clostridium difficile-associated diarrhoea (CDAD) which may occur during or after taking **SOLONEX CO**. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis). Tell your doctor immediately if you have diarrhoea while you are taking or after you have stopped taking **SOLONEX CO** (see Possible side effects).

Your doctor may prescribe Vitamin B_6 (pyridoxine) with **SOLONEX CO** to minimise adverse reactions if you are diabetic, alcoholic, HIV infected, malnourished or you have neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).

Other medicines and SOLONEX CO
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking any of the following medicines:
SOLONEX CO may make the following medicines work less well:
- medicines used to treat HIV infection: indinavir, darunavir, lopinavir, saquinavir, ritonavir, rilpivirine, efavirenz, zidovudine
- antifungal medicine (to treat fungal infections): itraconazole, ketoconazole, voriconazole
- pain killers (narcotic analgesics): methadone, alfentanil, buprenorphine
- medicines used for diabetes to lower blood sugar: repaglinide
- medicines to lower blood pressure, called calcium channel blockers: felodipine, diltiazem, verapamil, nifedipine
- medicines to lower blood pressure called alpha or beta adrenergic antagonists: alfuzosin, propranolol
- medicines to treat migraine, sometimes referred to as ergot alkaloid derivates: ergotamine
- medicines used to prevent the blood from clotting (anticoagulants): warfarin
- hormonal contraceptives for women. If you are using any form of contraception, such as contraceptive tablets, transdermal patches (patches used on the skin) or an implant while taking **SOLONEX CO** tablets, you should discuss the need to use an additional non-hormonal means of contraception or to change your contraceptive pill with your doctor or health care provider to make sure that your method of contraception is still effective.
- medicines used to lower your immune system: ciclosporin, tacrolimus, sirolimus
- medicines used as sedatives or to treat anxiety: midazolam.

Other medicines which could be affected by **SOLONEX CO**:
- Digoxin (used to make the heart beat stronger and with a more regular rhythm). Your doctor will monitor your dose of digoxin as it could change due to **SOLONEX CO**. Even small changes need to be monitored to prevent serious side effects from occurring (see Take special care with **SOLONEX CO**).
- Medicines used for inflammation (e.g. ibuprofen, diclofenac).
- Medicines used to lower blood sugar in diabetes: glipizide.
- **SOLONEX CO** may also interact with the laboratory tests to determine folate and vitamin B12 in your blood. Make sure that you inform your doctor or health care provider that you are using **SOLONEX CO** before such tests are performed.

SOLONEX CO with food and drink:
SOLONEX CO should be taken with food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **SOLONEX CO**.

Safety during pregnancy and breastfeeding has not been established.

Driving and using machines
SOLONEX CO may cause dizziness, impaired concentration, and/or drowsiness. If you feel dizzy or drowsy while taking **SOLONEX CO** do not drive and do not use any tools or machines.

3. How to take SOLONEX CO

Do not share medicines prescribed for you with any other person.

Always take **SOLONEX CO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

SOLONEX CO should be taken once-weekly, for 12 weeks as directly observed therapy (DOT). DOT is a way of helping people during their treatment, e.g. your treatment will be monitored weekly by visiting your local clinic, hospital or nurse and they will make sure you take your treatment correctly.
Your doctor will calculate the number of tablets you should take weekly based on your weight. This dose will therefore be calculated for you personally.
It is important to take all of your **SOLONEX CO**. Do not skip doses. Skipping doses may cause **SOLONEX CO** to not work as well and may increase the chance that your TB will not be treatable by **SOLONEX CO** or other medicines.
Take **SOLONEX CO** with food. This may help prevent nausea, vomiting or stomach upsets due to the medication.
It is preferable to take antacids at least 1 hour before or 2 hours after your dose of **SOLONEX CO** tablets.
If you cannot swallow **SOLONEX CO** tablets whole, they can be crushed and mixed with a small amount of semisolid food. Be sure to take all of the semisolid food with **SOLONEX CO** in it immediately.

If you have the impression that the effect of **SOLONEX CO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more SOLONEX CO than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SOLONEX CO
Since your weekly dose of **SOLONEX CO** will be given to you via directly observed therapy (DOT) which includes a visit to, for example, your local clinic or hospital, it is unlikely that you will forget to take a dose. However, if you have missed the visit to your local clinic or hospital, visit them as soon as possible and do not skip the whole week until the next appointment.

If you stop taking SOLONEX CO
If **SOLONEX CO** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **SOLONEX CO** for as long as your doctor has prescribed.

4. Possible side effects

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

If any of the following happens, stop taking SOLONEX CO and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hypersensitivity (allergic) reaction: this may present as a sudden life-threatening allergic reaction and the signs may include low blood pressure, hives, swelling of the face, lips, tongue or throat, difficulty breathing, red eyes or flu-like syndrome (see below).
- Flu-like syndrome (weakness, extreme tiredness, muscle pain, nausea and vomiting, headache, fever, chills, aches, rash, itching, sweats, dizziness, shortness of breath, chest pain, cough, fainting, fast heartbeat) (see Take special care with **SOLONEX CO**).
- Hepatitis (inflammation of the liver) and liver problems (symptoms may include: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine) (see Take special care with **SOLONEX CO**).
- Diarrhoea called *Clostridium difficile-associated diarrhoea* (CDAD) which may occur during or after taking **SOLONEX CO**. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis (see Take special care with **SOLONEX CO**).
- Pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate).
- Pneumonia (infection of the lungs; symptoms may include fever and chills, cough, difficulty breathing, shortness of breath when you climb stairs).
- Seizures (have a "fit" or convulsion).

These are all very serious side effects. If you have them, you may have had a serious reaction to **SOLONEX CO**. 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:
Less frequent:
- influenza (flu)
- upper abdominal pain
- skin reaction
- pain in one or more muscles (myalgia)
- Chills
- Fever
- abnormal physical weakness or lack of energy (asthenia).
- Feeling anxious depressed or disorientated.
- Blurred vision or loss of vision, with or without eye pain (optic neuritis).

Frequency unknown:
- SJS including the following symptoms: blistering, peeling or bleeding on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles).
- DRESS including the following symptoms: flu-like symptoms, a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia).

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

Tell your doctor if you notice any of the following:
Frequent:
- Nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, enlarged salivary glands.

Less frequent:
- Headache
- Fatigue or extreme tiredness
- Irritation of the oesophagus (the tube that carries food from your throat down to your stomach).
- Joint pain, back pain, fever, eating disorder (anorexia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Should your general health worsen or if you experience any untoward effects while taking **SOLONEX CO**, please consult your healthcare provider for advice.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **SOLONEX CO.**

5. How to store SOLONEX CO

Store at or below 25 °C in a dry place protected from light.
KEEP OUT OF THE REACH OF CHILDREN.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / strip / label /carton bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What SOLONEX CO contains
The active ingredients are Isoniazid and Rifapentine.
Sugar free
Other ingredients are:
Tablet core contains
Calcium stearate, croscarmellose sodium, disodium EDTA, low-substituted hydroxypropyl cellulose, hypromellose, hydroxypropyl cellulose, iron oxide red, microcrystalline cellulose, povidone, pregelatinised starch, sodium ascorbate, sodium lauryl sulfate, sodium starch glycolate.
The tablet film-coating material contains
Hypromellose, macrogol, red iron oxide, titanium dioxide,talc

What SOLONEX CO looks like and contents of the pack
SOLONEX CO
Reddish brown coloured, capsule shaped, biconvex, film-coated tablets debossed with "J" and "21" on either side of breakline on one side and plain on the other side.
The tablet can be divided into equal halves.

Contents of the pack:
Blister pack
Tablets are packed in a blister containing aluminium foil as lidding material and cold form laminate OPA/ aluminium foil / PVC as the forming material.

Blister pack in plain laminated pouch
Tablets are packed in a blister containing aluminium foil as lidding material and cold form laminate OPA/ aluminium foil / PVC as the forming material. Blister is packed in plain laminated pouch.

Strip pack
Tablets are packed in a strip pack containing aluminium foil (soft tempered) laminated with 150 gauge polyethylene film as forming and lidding material.
Pack sizes include 12, 28, 36, 56, 84, 112 or 120 tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East), 1 Cussonia Drive,
Bassonia Rock, Ext 12, Alberton, South Africa.
Tel: +27 11 682 1169

This leaflet was last revised in
29 August 2023

Registration number
SOLONEX CO: 54/20.2.3/0160

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https:// www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 11 69

335 mm

Back Side 335 x 300 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS : S4

SOLONEX CO (filmbedekte tablet)
300 mg Isoniasied en 300 mg Rifapentien
Suikervry

Lees hierdie inligtingstuk sorgvuldig deur voordat jy SOLONEX CO begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **SOLONEX CO** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik wees vir hulle, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **SOLONEX CO** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **SOLONEX CO** neem
3. Hoe om **SOLONEX CO** te neem
4. Moontlike newe-effekte
5. Hoe om **SOLONEX CO** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat SOLONEX CO is en waarvoor dit gebruik word

SOLONEX CO bevat isoniasied en rifapentien. Dit word gebruik om vordering van onaktiewe (latente) tuberkulose infeksie (LTBI) na aktiewe tuberkulose siekte in volwassenes te verhoed.

2. Wat jy behoort te weet voordat jy SOLONEX CO neem

Moet nie SOLONEX CO neem nie:
- Indien jy hipersensitief (allergies) vir isoniasied of rifapentien of vir enige van die bestanddele van **SOLONEX CO** soos gelys in afdeling 6.1 is.
- Indien jy hipersensitief is vir medisyne wat chemies verwant is aan isoniasied soos etionamied, pirasinamied (wat vir TB gebruik word) en niasien (Vitamien B_3).
- Indien jy swanger is, borsvoed of beplan om swanger te raak tydens behandeling.
- Indien jy akute of chroniese lewersiekte het.
- Indien jy 'n toestand naamlik porfirie het ('n groep van versteurings wat senuwee- of velprobleme (blase en jeuk) kan veroorsaak as gevolg van 'n probleem met die produksie van heem (bloedpigment) en rooibloedselle in die liggaam).
- Indien jy aanvalle kry.
- Indien jy 'n alkoholis is.
- Indien jy ernstige nierprobleme het.
- Indien jy tans op spesifieke antiretrovirale behandeling is soos protease inhibeerders (bv. indinavir, atazinavir, lopinavir, ritonavir) en nie-nukleosied tru-transkriptase inhibeerders (NNTTI's) (bv. efavirenz, nevirapien)

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy SOLONEX CO neem indien jy
Lewerprobleme het. Jou dokter kan 'n bloedtoets doen om jou lewerfunksie te bepaal voor en terwyl jy **SOLONEX CO** neem (sien afdeling Moet nie **SOLONEX CO** neem nie indien).
Aktiewe TB siekte het.
Medisyne neem om MIV infeksie te behandel of orale voorbehoedmiddels gebruik. Die gebruik van hierdie medisyne saam met **SOLONEX CO** kan hulle minder doeltreffend maak (sien Ander medisyne en **SOLONEX CO**).
'n Medisyne naamlik digoksien gebruik (wat gebruik word om die hart sterker en met 'n meer reëlmatige ritme te laat klop). Jou dokter sal jou dosering van digoksien monitor, aangesien dit kan verander as gevolg van **SOLONEX CO**. Selfs klein veranderinge moet gemonitor word om te verhoed dat ernstige newe-effekte voorkom (sien ook Ander medisyne en **SOLONEX CO**).

Kontaklense of kunsgebitte dra. **SOLONEX CO** kan die normale kleur van jou vel, mond en liggaamsvloeistowwe verander en veroorsaak dat jou vel, tande, tong, uriene, stoelgang, speeksel, sputum, trane, sweet en borsmelk 'n rooi-oranje kleur verkry. Kontaklense of kunsgebitte kan permanent gevlek word.
Indien jy enige van die volgende ervaar nadat, of terwyl jy SOLONEX CO neem, vertel onmiddellik jou dokter of gesondheidsorgverskaffer:
Indien jy simptome van 'n hipersensitiwiteit (allergiese) reaksie ervaar nadat jy **SOLONEX CO** geneem het, bv. lae bloeddruk, netelroos, swelling van die gesig, lippe, tong of keel, moeilike asemhaling, rooi oë of griepagtige sindroom (swakheid, uiterste moegheid, spierpyn, naarheid en braking, hoofpyn, koors, koue rillings, pyne, uitslag, jeuk, sweet, duiseligheid, kort van asem, borskaspyn, hoes, floute, vinnige hartklop). Hierdie kan simptome van 'n ernstige allergiese reaksie wees en jy moet onmiddellik ophou om **SOLONEX CO** te neem en na die ongevalle afdeling van jou naaste hospitaal gaan (sien Moontlike newe-effekte).
SOLONEX CO kan ernstige lewerprobleme veroorsaak. Hou op om **SOLONEX CO** te neem en skakel onmiddellik jou dokter indien jy enige van die volgende tekens en simptome van lewerprobleme het: naarheid, braking, maagpyn, verlies aan eetlus, moegheid, vergeling van die vel of wit van jou oë, donker uriene (sien Moontlike newe-effekte).
Ernstige velprobleme soos Stevens Johnson sindroom (SJS) en geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) sindroom is aangemeld met die gebruik van **SOLONEX CO**.
SJS simptome kan blase, afskilfering of bloeding op enige deel van jou vel insluit met of sonder 'n uitslag. Dit sluit jou lippe, oë, mond, neus, geslagsdele, hande of voete in. Jy kan ook terselfdertyd griepagtige simptome hê, soos koors, koue rillings of seer spiere.
GRESS simptome en tekens kan griepagtige simptome en 'n wydverspreide uitslag met 'n hoë liggaamstemperatuur en vergrote limfknope insluit. Abnormale bloedtoetsresultate kan verhoogde vlakke van lewerensieme en 'n verhoging in 'n tipe witbloedsel (eosinofilie) insluit.
Indien jy enige velreaksie ontwikkel, staak behandeling onmiddellik en kontak jou dokter of gesondheidsorgverskaffer.
SOLONEX CO kan 'n tipe van diaree naamlik *Clostridium difficile* geassosieerde diaree (CDAD) veroorsaak wat moontlik kan gebeur gedurende of na die gebruik van **SOLONEX CO**. Die erns van CDAD kan wissel van ligte diaree tot ernstige diaree wat dood kan veroorsaak (noodlottige kolitis). Vertel onmiddellik jou dokter indien jy diaree het terwyl jy **SOLONEX CO** neem of nadat jy opgehou het om dit te neem (sien Moontlike newe-effekte).

Jou dokter kan Vitamien B_6 (piridoksien) saam met **SOLONEX CO** voorskryf om ongewenste reaksies te verminder indien jy diabeties, alkoholies, MIV-besmet, ondervoed is, of indien jy neuropatie het (skade aan die senuwees wat lei tot swak koördinasie, spierswakheid, pyn in die vingers of tone of gevoelloosheid).

Ander medisyne en SOLONEX CO
Vertel altyd vir jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne neem:
SOLONEX CO kan die volgende medisyne minder goed laat werk:
- medisyne wat gebruik word om MIV infeksie te behandel: indinavir, darunavir, lopinavir, sakwinavir, ritonavir, rilpivirien, efavirens, sidovudien
- swambestrydende medisyne (om swaminfeksies te behandel): itrakonasool, ketokonasool, vorikonasool
- pynstillers (narkotiese analgetikum): metadoon, alfentaniel, buprenorfien
- medisyne wat gebruik word vir diabetes om bloedsuiker te verlaag: repaglinied
- medisyne om bloeddruk te verlaag, naamlik kalsiumkanaalblokkeerders: felodipien, diltiasem, verapamil, nifedipien
- medisyne om bloeddruk te verlaag, naamlik alfa- of beta-adrenergiese antagoniste: alfusosien, propranolol
- medisyne om migraine te behandel, soms na verwys as ergot-alkaloïedderivate: ergotamien
- medisyne wat gebruik word om te verhoed dat die bloed stol (antikoagulante): warfarien
- hormonale voorbehoedmiddels vir vrouens. Indien jy enige vorm van kontrasepsie gebruik, soos kontraseptiewe tablette, transdermale plakkers (plakkers wat op die vel gebruik word) of 'n inplantaat terwyl jy **SOLONEX CO** tablette neem, moet jy die behoefte bespreek om 'n addisionele nie-hormonale middel van voorbehoeding te gebruik of om jou kontraseptiewe pil saam met jou dokter of gesondheidsorgverskaffer te verander, om seker te maak dat jou metode van voorbehoeding steeds doeltreffend is.
- medisyne wat gebruik word om jou immuunstelsel te onderdruk: siklosporien, takrolimus, sirolimus
- medisyne wat gebruik word as kalmeermiddels of om angs te behandel: midasolam.

Ander medisyne wat deur **SOLONEX CO** beïnvloed kan word:
- Digoksien (gebruik om die hart sterker en met 'n meer reëlmatige ritme te laat klop). Jou dokter sal jou dosering van digoksien monitor, aangesien dit kan verander as gevolg van **SOLONEX CO**. Selfs klein veranderinge moet gemonitor word om te verhoed dat ernstige newe-effekte kan voorkom (sien Wees veral versigtig met **SOLONEX CO**).
- Medisyne wat gebruik word vir inflammasie (bv. ibuprofen, diklofenak).
- Medisyne wat gebruik word om bloedsuiker in diabetes te verlaag: glipisied.
- **SOLONEX CO** kan ook interaksie hê met die laboratoriumtoetse om folaat en vitamien B_{12} in jou bloed te bepaal. Maak seker dat jy jou dokter of gesondheidsorgverskaffer inlig dat jy **SOLONEX CO** gebruik voordat sulke toetse uitgevoer word.

SOLONEX CO met voedsel en drank
SOLONEX CO moet saam met voedsel geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **SOLONEX CO** neem.

Veiligheid gedurende swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie
SOLONEX CO kan duiseligheid, ingekorte konsentrasie en/of lomerigheid veroorsaak. Indien jy duiselig of lomerig voel terwyl jy **SOLONEX CO** neem, moet nie bestuur nie en moet nie enige gereedskap of masjienerie gebruik nie.

3. Hoe om SOLONEX CO te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **SOLONEX CO** presies soos jou dokter jou beveel het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.

SOLONEX CO moet een keer per week geneem word, vir 12 weke as direk waargeneemde terapie (DWT). DWT is 'n manier om mense te help gedurende hul behandeling, bv. jou behandeling sal weekliks gemonitor word deur jou plaaslike kliniek, hospitaal of verpleegkundige te besoek, en hulle sal dan seker maak dat jy jou behandeling korrek neem.
Jou dokter sal die hoeveelheid tablette wat jy weekliks moet neem bereken op grond van jou gewig. Hierdie dosering sal dus vir jou persoonlik bereken word.
Dit is belangrik om al jou **SOLONEX CO** te neem. Moet nie dosisse oorslaan nie. Indien jy dosisse oorslaan, kan dit veroorsaak dat **SOLONEX CO** nie so goed werk nie en kan dit die kans verhoog dat jou TB nie deur **SOLONEX CO** of ander medisyne behandel kan word nie.
Neem **SOLONEX CO** saam met voedsel. Dit kan help om naarheid, braking of 'n omgekrapte maag as gevolg van die medikasie te verhoed.
Dit is verkieslik om teensuurmiddels ten minste 1 uur voor of 2 uur na jou dosis van **SOLONEX CO** tablette te neem.
Indien jy nie **SOLONEX CO** tablette heel kan sluk nie, kan dit fyngemaak en met 'n klein hoeveelheid semisoliede kos gemeng word. Maak seker dat jy al die semisoliede kos met **SOLONEX CO** in, onmiddellik neem.

Indien jy onder die indruk is dat die effek van **SOLONEX CO** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer SOLONEX CO neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om SOLONEX CO te neem
Aangesien jou weeklikse dosis **SOLONEX CO** aan jou gegee sal word deur middel van direk waargeneemde terapie (DWT) wat 'n besoek aan byvoorbeeld jou plaaslike kliniek of hospitaal insluit, is dit onwaarskynlik dat jy sal vergeet om 'n dosis te neem. Indien jy egter die besoek aan jou plaaslike kliniek of hospitaal gemis het, besoek hulle so gou moontlik en moet nie die hele week oorslaan tot die volgende afspraak nie.

Indien jy ophou om SOLONEX CO te neem
Indien **SOLONEX CO** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **SOLONEX CO** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

SOLONEX CO kan newe-effekte hê.
Nie alle newe-effkte wat vir **SOLONEX CO** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige onaangename effekte ondervind terwyl jy **SOLONEX CO** neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om SOLONEX CO te neem en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Hipersensitiwiteit (allergiese) reaksie: dit kan presenteer as 'n skielike lewensbedreigende allergiese reaksie en die tekens kan lae bloeddruk, netelroos, swelling van die gesig, lippe, tong of keel, moeilike asemhaling, rooi oë of griepagtige sindroom insluit (sien onder).
- Griepagtige sindroom (swakheid, uiterste moegheid, spierpyn, naarheid en braking, hoofpyn, koors, koue rillings, pyne, uitslag, jeuk, sweet, duiseligheid, kort van asem, borskaspyn, hoes, floute, vinnige hartklop) (sien Wees veral versigtig met **SOLONEX CO**).
- Hepatitis (ontsteking van die lewer) en lewerprobleme (simptome kan insluit: naarheid, braking, maagpyn, verlies aan eetlus, moegheid, vergeling van die vel of wit van jou oë, donker uriene) (sien Wees veral versigtig met **SOLONEX CO**).
- Diaree naamlik *Clostridium difficile* geassosieerde diaree (CDAD) wat mag voorkom tydens of na die neem van **SOLONEX CO**. Die erns van CDAD kan wissel van ligte diaree tot ernstige diaree wat dood kan veroorsaak (dodelike kolitis (sien Wees veral versigtig met **SOLONEX CO**).
- Pankreatitis (ontsteking van die pankreas) (simptome kan boonste abdominale pyn insluit wat in die rug uitstraal; geswelde en teer buik; naarheid en braking, koors en verhoogde harttempo).
- Longontsteking (infeksie van die longe; simptome kan koors en koue rillings, hoes, moeilike asemhaling, kort van asem wanneer jy trappe klim, insluit).
- Stuipe (kry 'n "aanval" of konvulsie).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie teen **SOLONEX CO** gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
Minder gereeld
- Influensa (griep)
- Boonste abdominale pyn.
- Velreaksie.
- Pyn in een of meer spiere (mialgie).
- Koue rillings.
- Koors.
- Abnormale fisiese swakheid of gebrek aan energie (astenie).
- Voel angstig, depressief of gedisoriënteerd.
- Dowwe visie of verlies van visie, met of sonder oogpyn (optiese neuritis).

Frekwensie onbekend
- SJS insluitend die volgende simptome: blase, afskilfering of bloeding op enige deel van jou vel met of sonder 'n uitslag (insluitend jou lippe, oë, mond, neus, geslagsdele, hande of voete), griepagtige simptome (koors, koue rillings of seer spiere).
- GRESS insluitend die volgende simptome: griepagtige simptome, 'n wydverspreide uitslag met 'n hoë liggaamstemperatuur en vergrote limfknope. Abnormale bloedtoetsresultate kan verhoogde vlakke van lewerensieme en 'n toename in 'n tipe witbloedsel (eosinofilie) insluit.

Hierdie is alles ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- Naarheid, braking, hardlywigheid, droë mond, diaree, maagpyn, vergrote speekselkliere.

Minder gereeld
- Hoofpyn
- Vermoeidheid of uiterste moegheid
- Irritasie van die esofagus (die buis wat kos van jou keel af na jou maag vervoer).
- Gewrigspyn, rugpyn, koors, eetversteuring (anoreksie).

Stel asseblief jou dokter of apteker in kennis indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.
Indien jou algemene gesondheid versleg of indien jy enige nadelige effekte ervaar terwyl jy **SOLONEX CO** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **SOLONEX CO**.

5. Hoe om SOLONEX CO te bewaar

Bewaar by of benede 25 °C in 'n droë plek en teen lig beskerm.
HOU BUITE DIE BEREIK VAN KINDERS.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook/ strook/etiket/karton/bottel gebruik nie
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat SOLONEX CO bevat
Die aktiewe bestanddele is Isoniasied en Rifapentien.
Suikervry
Ander bestanddele is:
Tabletkern bevat
Kalsiumstearaat, natriumkroskarmellose, dinatrium EDTA, lae-gesubstitueerde hidroksipropielsellulose, hipromellose, hidroksipropielsellulose, rooi ysteroksied, mikrokristallyne sellulose, povidoon, voorafgegelatiniseerde stysel, natriumaskorbaat, natriumlaurielsulfaat, natriumstyselglikolaat.
Die tablet filmbedekkingsmateriaal bevat
Hipromellose, makrogol, rooi ysteroksied, titaandioksied, talk.

Hoe SOLONEX CO lyk en inhoud van die pak
SOLONEX CO
Rooierige bruin gekleurde, kapsuulvormige, bikonvekse, filmbedekte tablette bedruk met "J" en "21" aan weerskante van breeklyn op die een kant en glad aan die ander kant.

Inhoud van die pak:
Stulpverpakking
Tablette word in 'n stulpverpakking verpak wat aluminiumfoelie as dekmateriaal en kouevorm gelamineerde OPA/aluminiumfoelie/PVC as die vormingsmateriaal bevat.

Stulpverpakking in gewone gelamineerde sakkie
Tablette word in 'n stulpverpakking verpak wat aluminiumfoelie as dekmateriaal en kouevorm gelamineerde OPA/aluminiumfoelie/PVC as die vormingsmateriaal bevat. Stulpstrook word in gewone gelamineerde sakkie verpak.

Strookpak
Tablette word verpak in 'n strookpak wat aluminiumfoelie (sag gehard) bevat, gelamineer met 150 maat poliëtileenfilm as vormings- en dekmateriaal.
Verpakkingsgroottes sluit 12, 28, 56, 84, 112 of 120 tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos), Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12, Alberton, Suid-Afrika.
Tel: +27 11 682 1169

Hierdie inligtingstuk was laas hersien in
29 Augustus 2023

Registrasienommer
SOLONEX CO: 54/20.2.3/0160

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https:// www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

300 mm

335 mm

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude professional information and dimension change.

1. Product: SOLONEX CO (Isoniazid 300 mg and Rifapentine 300 mg tablets)	
2. Country: South Africa	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 300 (W) mm**
9. Design / Style: Booklets	**10. Item code No.: PM00334202**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40397 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: PM00334201**
15. Revision No: 01	**16. A/W File name: Z:\South Africa\SOLONEX CO\01\SOLONEX CO- PIL - PM00334202.cdr**
Approved By:	**17. Location: OXALIS**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	25/08/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM00334201	23/02/23	11/04/23
2) Exclude professional information and dimension change.	PM00334202		