

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

SOLONEX CO 300 mg/300 mg (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 and children 2 years of age and older.

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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 problems
- If you are currently on antiretroviral therapy

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,

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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 B₆ (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 derivatives: 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.

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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.

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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.

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If you stop taking SOLONEX CO

If **SOLONEX CO** is stopped earlier than your doctor has prescribed, your symptoms 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

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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:

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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 / label / carton bottle.

Return all unused medicine to your pharmacist.

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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.

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.

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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, 56, 84, 112 or 120 tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

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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 1169

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