PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

335 mm

320 mm

CO-AFARIS PAED
75/50/150
(Dispersible Tablet)
PM04339676

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CO-AFARIS PAED 75/50/150 (dispersible tablet)
Rifampicin 75 mg, isoniazid 50 mg and pyrazinamide 150 mg
Sugar free.
Contains 3,13 mg aspartame

Read all of this leaflet carefully before you start giving CO-AFARIS PAED 75/50/150
- 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.
- **CO-AFARIS PAED 75/50/150** has been prescribed for your child personally and you should not share your child's medicine with other people. It may harm them, even if their symptoms are the same as your child's.

What is in this leaflet

1. What **CO-AFARIS PAED 75/50/150** is and what it is used for
2. What you need to know before you take **CO-AFARIS PAED 75/50/150**
3. How to take **CO-AFARIS PAED 75/50/150**
4. Possible side effects
5. How to store **CO-AFARIS PAED 75/50/150**
6. Contents of the pack and other information

1. What CO-AFARIS PAED 75/50/150 is and what it is used for

CO-AFARIS PAED 75/50/150 is an antimicrobial medicine used in the treatment of pulmonary tuberculosis (TB infection in the lungs) in children.

2. What you need to know before you take CO-AFARIS PAED 75/50/150

Do not take CO-AFARIS PAED 75/50/150 if your child suffers from any of the conditions mentioned below:
- If your child is hypersensitive (allergic) to rifamycins including rifampicin, isoniazid or other chemically-related medicines such as ethionamide and niacin or to any of the ingredients contained in **CO-AFARIS PAED 75/50/150.** (listed in section 6).
- If your child has any kind of liver disease or jaundice (yellowing of the eyes and skin).
- **CO-AFARIS PAED 75/50/150** should not be taken with nevirapine (used in HIV treatment).
- If your child has any kidney disease.
- If your child has porphyria.
- If your child has a history of gout.
- If your child is diabetic
- If your child has epilepsy
- If your child develops thrombocytopenia and purpura while taking **CO-AFARIS PAED 75/50/150** (bruising, nosebleeds or bleeding in the mouth and gums, rash with pinpoint red spots).
- If your child is pregnant or breastfeeding her child.

If your child develops itching with swelling or skin rash or difficulty breathing, or if the skin and eyes turn yellow while taking **CO-AFARIS PAED 75/50/150,** do not give any more **CO-AFARIS PAED 75/50/150** and tell your doctor immediately.

Warnings and precautions
Take special care with **CO-AFARIS PAED 75/50/150**
- If your child developed thrombocytopenia and purpura while taking **CO-AFARIS PAED 75/50/150** (bruising, nosebleeds or bleeding in the mouth and gums, rash with pinpoint red spots).
- Before you give **CO-AFARIS PAED 75/50/150**, tell your doctor if your child has epilepsy.
- **CO-AFARIS PAED 75/50/150** should not be given to children whose liver is not functioning normally, however, in cases where there are no other treatment options your doctor will monitor your child's liver function before treatment and every two to four weeks during treatment with **CO-AFARIS PAED 75/50/150**.

Tell your doctor immediately and stop giving **CO-AFARIS PAED 75/50/150** if your child develops symptoms of hepatitis (inflammation of the liver, if left untreated, could lead to serious consequences) such as fatigue, weakness, feeling unwell, loss of appetite, nausea or vomiting.
- Your doctor will be monitoring your child's blood counts if your child has liver disease or is on long-term treatment with **CO-AFARIS PAED 75/50/150**. If your child develops low platelet counts (blood cells responsible for clotting) with symptoms of easy or excessive bruising, bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots usually on the lower legs, prolonged bleeding from cuts, spontaneous bleeding from the gums or nose and blood in urine or stools, then **CO-AFARIS PAED 75/50/150** should not be given and be permanently withdrawn (see Do not take).
- If other serious complications due to the medicine occur such as kidney failure, or blood diseases, **CO-AFARIS PAED 75/50/150 should be stopped and never restarted**.
- Urine, faeces, saliva, sputum, sweat and tears may be coloured red-orange by **CO-AFARIS PAED 75/50/150**.
- Soft contact lenses may be permanently stained.
- Your doctor may prescribe periodic eye examinations as **CO-AFARIS PAED 75/50/150** may cause blurred vision or loss of vision with or without eye pain and may also cause irritation of the eyes.
- Your doctor may prescribe Vitamin B_6 (pyridoxine) with **CO-AFARIS PAED 75/50/150** to minimise adverse reactions if your child is malnourished or has neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).
- Give **CO-AFARIS PAED 75/50/150** to your child as prescribed by your doctor on a continuous basis without interruption to avoid developing side effects such as a serious allergic reaction (swelling of the hands, feet, ankles, lips, mouth or throat, which may cause difficulty in breathing, rash and itching) or a "flu-like" syndrome (chills, dizziness, difficulty breathing, fever, headache, muscle pain, bone pain and shivering).
- Inform your doctor if your child has the following conditions:
  - Kidney disease
  - History of gout
  - Diabetes, as sugar levels may be difficult to control while taking **CO-AFARIS PAED 75/50/150**.

Other medicines and CO-AFARIS PAED 75/50/150
Always tell your health care provider if your child is taking any other medicine. (This includes all complementary or traditional medicines).
CO-AFARIS PAED 75/50/150 may change the effect of other medicines and other medicines may change the effect of **CO-AFARIS PAED 75/50/150**.

Do not take CO-AFARIS PAED 75/50/150 and tell your doctor if you are taking the following medicines:
- Nevirapine, saquinavir and ritonavir (HIV medicines).

The following medicines can make **CO-AFARIS PAED 75/50/150** work less well.
- Alcohol, alfentanil, aminosalicylic acid (TB medicine), corticosteroids such as hydrocortisone, betamethasone and prednisolone (for treating inflammatory conditions), ketoconazole (for fungal infections), propranolol (for high blood pressure) and high doses of pyridoxine (vitamin B6).
- Antacids containing magnesium trisilicate, aluminium hydroxide or sodium bicarbonate and other aluminium containing antacids for indigestion. Take **CO-AFARIS PAED 75/50/150** at least 1 hour before the antacid.

When you are giving **CO-AFARIS PAED 75/50/150**, it is especially important to tell your doctor or healthcare professional if your child is taking any of the following medicines as your doctor may have to adjust the dose of the medicine:
- Medicines used to treat epilepsy such as ethosuximide, phenytoin and carbamazepine.
- Medicines such as itraconazole, fluconazole and ketoconazole used for treating fungal infections.
- HIV medicine such as zidovudine, delavirdine, efavirenz, HIV-protease inhibitors (lopinavir, duranavir, atazanavir, fosamprenavir, indinavir).
- Other medicines include certain anaesthetic medicines (to relax muscles prior to surgery), azathioprine, ciclosporin (immune suppressants), chloramphenicol, cycloserine, dapsone, doxycycline (medicines used for infections), cimetidine (used to treat ulcers), clofibrate (lowers cholesterol), corticosteroids such as hydrocortisone, betamethasone and prednisolone (for treating inflammatory conditions), warfarin (thins blood), diazepam, (for anxiety and depression), haloperidol (for mental illness), hexobarbitone (sedative), methadone (for heroin withdrawal), oral hypoglycaemic medicines used in diabetes treatment), sulphasalazine (used for rheumatoid arthritis and inflammatory bowel disease), Thyroid hormones (levothyroxine), theophylline (for wheezing or difficulty in breathing), quinine (used in malaria), medicines to control your heartbeat such as digoxin, disopyramide, lorcainide, mexiletine, propafenone, quinidine, tocainide, medicines to treat heart problems such as beta blockers (propranolol), verapamil and other calcium channel blocking medicines, medicines used for severe pain such as codeine, morphine, fentanyl or pethidine, medicines used for pain and fever such aspirin and medicines to help you sleep known as barbiturates (e.g. phenobarbitone).
- **CO-AFARIS PAED 75/50/150** may decrease the effectiveness of oral contraceptives. Use a reliable barrier method of contraception such as condoms while taking **CO-AFARIS PAED 75/50/150**.
- Allopurinol, colchicine, probenecid and sulfinpyrazone (used for the treatment of gout).

The following when taken with **CO-AFARIS PAED 75/50/150** may increase the incidence of side-effects:
- Medicines used to treat epilepsy such as ethosuximide, phenytoin, primidone and carbamazepine (your doctor will adjust the dose of the epilepsy medication accordingly)
- HIV medicine such as HIV-protease inhibitors (lopinavir, ritonavir, saquinavir, duranavir, atazanavir, fosamprenavir), stavudine and zalcitabine.
- Other medicine such as warfarin (thins blood), diazepam, triazolam (for anxiety and depression), cycloserine (TB medicine), disulfiram (treatment of alcohol dependence), theophylline (for wheezing or difficulty in breathing).
- Alcohol (daily consumption could lead to severe liver problems).

CO-AFARIS PAED 75/50/150 with food, drink and alcohol
- **CO-AFARIS PAED 75/50/150** may interact with tyramine-containing foods (cheese, red wine) and to foods containing histamine (e.g. skipjack, tuna, other tropical fish) resulting in headache, sweating, palpitations (heart beating too hard or too fast), flushing and low blood pressure. Avoid giving tyramine and histamine-containing foods to your child while on treatment with **CO-AFARIS PAED 75/50/150**.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Pregnancy:
Safety during pregnancy has not been established.
Breastfeeding:
Safety during breastfeeding has not been established.

Driving and using machines
CO-AFARIS PAED 75/50/150 may cause dizziness, impaired concentration, and/or drowsiness. If you experience these symptoms, avoid potentially hazardous tasks such as driving or operating machinery.

CO-AFARIS PAED 75/50/150 contains aspartame
CO-AFARIS PAED 75/50/150 contains 3,13 mg aspartame in each tablet.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take CO-AFARIS PAED 75/50/150

Do not share medicines prescribed for you with any other person.
Always give **CO-AFARIS PAED 75/50/150** exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are unsure.
If you have the impression that the effect of **CO-AFARIS PAED 75/50/150** is too strong or too weak, talk to your doctor or pharmacist.
CO-AFARIS PAED 75/50/150 is recommended in the intensive phase of the treatment of pulmonary tuberculosis. During this **phase CO-AFARIS PAED 75/50/150** should be given on a continuous daily basis.
Your doctor will prescribe the required number of tablets to be given on a daily basis based on your child's body weight.
The tablets can either be dispersed in as little as 5 ml of water, or chewed, and should preferably be taken on an empty stomach (30 minutes before or 2 hours after a meal) as a single dosage. **CO-AFARIS PAED 75/50/150** should be given at least 1 hour before aluminium containing antacids are taken.

If you take more CO-AFARIS PAED 75/50/150 than you should
In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.
Symptoms include nausea, vomiting, stomach pain, dizziness, high blood sugar levels, high levels of acid in the blood, hallucinations, difficulty in breathing and central nervous system depression with seizures and coma. Other signs of overdosage includes bright-red discolouration of the skin and mucous membranes, decreased mental alertness, swelling of the face and "puffy eyes" and generalised itching.
If any of the above symptoms occur, get medical help immediately by calling your nearest doctor or healthcare professional.

If you forget to give your child CO-AFARIS PAED 75/50/150
If your child has missed a dose of **CO-AFARIS PAED 75/50/150** give it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to your regular scheduling. Never double the dose.

If you stop giving your child CO-AFARIS PAED 75/50/150
If the full treatment prescribed by your doctor is not completed, some of the bacteria causing the TB infection may not be killed. These bacteria may continue to grow and multiply so the TB infection may not clear completely or it may return.

4. Possible side effects

CO-AFARIS PAED 75/50/150 can have side effects.
Not all side effects reported for **CO-AFARIS PAED 75/50/150** are included in this leaflet. Should your child's general health worsen, or if your child experiences any untoward effects while taking **CO-AFARIS PAED 75/50/150**, please consult your health care provider for advice.
If any of the following happens, stop taking **CO-AFARIS PAED 75/50/150** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious reaction to **CO-AFARIS PAED 75/50/150**. 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:
- Red and/or itchy skin, blisters or pimples.
- Skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (symptoms of Stevens Johnson Syndrome).
- Widespread scaling of the skin with itching, skin redness and hair loss (symptoms of exfoliative dermatitis).
- Shortness of breath and wheezing.
- Lung disease causing coughing, difficulty breathing and wheezing (symptoms of pneumonitis).
- Scarring and thickening in the lungs with shortness of breath (symptoms of pulmonary fibrosis).
- Blood in the urine or any other urination disturbances.
- Fever, chills, headache or dizziness.
- Bone pain.
- Bruising, nosebleeds or bleeding in the mouth and gums, rash with pinpoint red spots.
- Fatigue, weakness, malaise (feeling unwell), anorexia (loss of appetite), nausea or vomiting.
- Abdominal pain, blood in the stool, ongoing bouts of diarrhoea that do not respond to over-the-counter (OTC) medicines or an unexplained fever lasting more than a day or two (symptoms of ulcerative colitis).
- Bleeding from the stomach wall with vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- Inflammation of the pancreas with severe upper stomach pain, nausea and vomiting.

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

Tell your doctor immediately if your child has any of the following side effects, particularly if they occur several weeks after stopping treatment with CO-AFARIS PAED 75/50/150:
- Severe stomach cramps.
- Watery and severe diarrhoea, which may also be bloody.
- Fever, in combination with one or both of the above.

Your child may have a serious condition affecting the bowel, which may need urgent medical attention.
Do not give any diarrhoea medicine without first checking with your doctor.

Tell your doctor if you notice any of the following:

Frequently occurring side effects:
- Heartburn, anorexia, nausea, vomiting, wind, cramps or diarrhoea, constipation, dry mouth.
- Skin reactions with flushing and itching, with or without a rash.
- Aching muscles, muscle tenderness or weakness, not caused by exercise.
- Reddish-orange to reddish-brown discolouration of the urine, faeces, saliva, sputum, sweat and tears.
- Soft contact lenses may be permanently stained.
- Numbness or weakness of the arms and legs.
- Increase in liver enzymes.

Less frequent side effects:
- Increase in some white blood cells (eosinophilia).
- Lack of white blood cells resulting in frequent infections such as fever, severe chills, sore throat or mouth ulcers (leucopenia).
- Tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes (haemolytic anaemia).
- High blood glucose levels.
- High levels of acid in the blood.
- Mental illness with strange or disturbing thoughts or moods.
- Loss of memory.
- Headache, dizziness, drowsiness, fatigue, inability to concentrate or confusion.
- Poor coordination, pain in the fingers or toes, or numbness, unusually increased reflexes or twitching.
- Fits or increase in fits if you are an epileptic patient.
- Blurred vision or loss of vision with or without eye pain, eye irritation.
- Menstrual disturbances.
- Oral contraceptives may become less effective.
- Temporary hearing loss.
- Vertigo (feeling dizzy with a spinning sensation).
- Skin rash, itchy rash, acne, hair loss sensitivity to the sun, allergic reactions.
- Enlarged breasts.
- Oral thrush - white, furry, sore tongue and mouth.
- Swelling of hands, ankles or feet.
- Aggravation of stomach ulcers.
- Difficulty going to the toilet (urinating).
- Fever, aches and pains in muscles, pain and swelling of joints (especially big toe, ankle and knee with tense, hot skin over affected joints).
- Unusual tiredness or weakness.

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 **CO-AFARIS PAED 75/50/150**.

5. How to store CO-AFARIS PAED 75/50/150

Store all medicines out of reach of children.
Store at or below 25 °C.
Keep the aluminium sachet in the HDPE container until required for use.
Keep the blister in the carton until required for use.
Store this medicine away from light and moisture. Do not store in the bathroom cabinet.
Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

6. Contents of the pack and other information

What CO-AFARIS PAED 75/50/150 contains
CO-AFARIS PAED 75/50/150 contains the active substances rifampicin 75 mg, isoniazid 50 mg and pyrazinamide 150 mg.
The other ingredients are microcrystalline cellulose, crospovidone, povidone, bleached shellac, croscarmellose sodium, strawberry flavour, magnesium stearate.
Contains aspartame. Sugar free.

What CO-AFARIS PAED 75/50/150 looks like and contents of the pack
Brick red mottled, 11,0 mm circular, uncoated biconvex tablets having deep score on one side and plain surface on other side.
HDPE Container:
Tablets are packed in a transparent, self-sealing LDPE polybag and further packed in a silver coloured triple laminated aluminium sachet (LDP/PET/AL), kept in a white plastic container (HDPE), which is sealed at the mouth with an aluminium tagger and is closed with a white HDPE screw-on lid. Pack sizes include 100 tablets.
Alu-alu strip pack:
Tablets are packed in silver-metallic coloured aluminium foil (soft tempered) laminated with low density polyethylene film as the lidding and forming material. The strip is packed in a pre-printed carton. Pack sizes include 28, 56, 84, 100 and 112 tablets.

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

This leaflet was last revised in
02 July 2024

Registration number
52/20.2.3/0306

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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Back Page)

ARTWORK / PRINTPROOF APPROVAL FORM

335 mm

320 mm

PASIËNTINLIGTINGSTUK

SKEDULERING STATUS: S4

CO-AFARIS PAED 75/50/150 (oplosbare tablet)
Rifampisien 75 mg, isoniasied 50 mg and pirasinamied 150 mg
Suikervry.
Bevat 3,13 mg aspartaam

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om CO-AFARIS PAED 75/50/150 te gee
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **CO-AFARIS PAED 75/50/150** is vir jou kind persoonlik voorgeskryf, en jy moet nie jou kind se medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as jou kind s'n.

Wat is in hierdie inligtingstuk

1. Wat **CO-AFARIS PAED 75/50/150** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **CO-AFARIS PAED 75/50/150** neem
3. Hoe om **CO-AFARIS PAED 75/50/150** te neem
4. Moontlike newe-effekte
5. Hoe om **CO-AFARIS PAED 75/50/150** te bêre
6. Inhoud van die pak en ander inligting

1. Wat CO-AFARIS PAED 75/50/150 is en waarvoor dit gebruik word

CO-AFARIS PAED 75/50/150 is 'n antimikrobiese middel wat gebruik word in die behandeling van pulmonale tuberkulose (TB infeksie in die longe) in kinders.

2. Wat jy behoort te weet voordat jy CO-AFARIS PAED 75/50/150 gee

Moet nie CO-AFARIS PAED 75/50/150 gee indien jou kind aan enige van die toestande wat hieronder genoem word ly nie:
- Indien jou kind hipersensitief (allergies) is vir rifamisiene, insluitend rifampisien, isoniasied of ander chemies-verwante medisyne soos etionamied en niasien of vir enige van die bestanddele vervat in **CO-AFARIS PAED 75/50/150.** (gelys in afdeling 6).
- Indien jou kind enige vorm van lewersiekte of geelsug het (vergeling van die oë en vel).
- **CO-AFARIS PAED 75/50/150** moet nie saam met nevirapine (gebruik in MIV-behandeling) gegee word nie.
- Indien jou kind enige niersiekte het.
- Indien jou kind porfirie het.
- Indien jou kind 'n geskiedenis van jig het.
- Indien jou kind 'n diabeet is
- Indien jou kind epilepsie het.
- Indien jou kind trombositopenie en purpura ontwikkel terwyl **CO-AFARIS PAED 75/50/150** geneem word (kneusing, neusbloeding of bloeding in die mond en tandvleise, uitslag met bepaalde rooi kolletjies).
- Indien jou kind swanger is of haar kind borsvoed.

Indien jou kind 'n gejeuk met swelling of veluitslag of probleme om asem te haal ontwikkel, of as die vel en oë geel word terwyl **CO-AFARIS PAED 75/50/150** geneem word, moet **CO-AFARIS PAED 75/50/150** nie langer gegee word nie en jou dokter moet onmiddellik ingelig word.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **CO-AFARIS PAED 75/50/150**
- Indien jou kind trombositopenie en purpura ontwikkel terwyl **CO-AFARIS PAED 75/50/150** geneem word (kneusing, neusbloeding of bloeding in die mond en tandvleise, uitslag met bepaalde rooi kolletjies).
- Voordat jy **CO-AFARIS PAED 75/50/150** gee, sê vir jou dokter indien jou kind epilepsie het.
- **CO-AFARIS PAED 75/50/150** moet nie gegee word aan kinders wie se lewer nie normaal funksioneer nie, in gevalle waar daar egter geen ander behandelings opsies is nie, sal jou dokter jou kind se lewerfunksie monitor voor behandeling en elke twee tot vier weke gedurende behandeling met **CO-AFARIS PAED 75/50/150**.
  Vertel onmiddellik jou dokter en hou op om **CO-AFARIS PAED 75/50/150** te gee indien jou kind simptome van hepatitis ontwikkel (ontsteking van die lewer wat, indien dit nie behandel word nie, tot ernstige gevolge kan lei) soos moegheid, swakheid, voel nie lekker nie, verlies aan eetlus, naarheid of braking.
- Jou dokter sal jou kind se bloedtellings monitor indien jou kind 'n lewersiekte het of op langtermynbehandeling met **CO-AFARIS PAED 75/50/150** is. Indien jou kind lae bloedplaatjie-tellings ontwikkel (bloedselle wat verantwoordelik is vir stolling) met simptome van maklike of oormatige kneusing, bloeding in die vel wat voorkom as 'n uitslag met punt grootte rooi-pers kolletjies, gewoonlik op die onderste deel van die bene, langdurige bloeding vanuit snye, spontane bloeding van die tandvleise of neus en bloed in uriene of stoelgang, dan moet **CO-AFARIS PAED 75/50/150** nie gegee word nie en permanent gestaak word (sien Moet nie neem nie).
- Indien ander ernstige komplikasies as gevolg van die medisyne voorkom, soos nierversaking of bloedsiektes, **moet CO-AFARIS PAED 75/50/150 gestaak word en nooit weer begin word nie.**
- Uriene, ontlasting, speeksel, sputum, sweet en trane kan rooi-oranje gekleurd wees deur **CO-AFARIS PAED 75/50/150**.
- Sagte kontaklense kan permanent gevlek word.
- Jou dokter kan periodieke oogondersoeke voorskryf, aangesien **CO-AFARIS PAED 75/50/150** dowwe visie of verlies aan sig, met of sonder oogpyn kan veroorsaak en kan ook irritasie van die oë veroorsaak.
- Jou dokter kan vitamien B_6 (piridoksien) voorskryf saam met **CO-AFARIS PAED 75/50/150** om ongunstige reaksies te verminder indien jou kind ondervoed is of neuropatie het (skade aan die senuwees wat tot swak koördinasie lei, spierswakheid, pyn in die vingers of tone, of gevoelloosheid).
- Gee **CO-AFARIS PAED 75/50/150** op 'n deurlopende basis sonder onderbreking aan jou kind, soos deur jou dokter voorgeskryf, om te vehoed dat newe-effekte ontwikkel, soos 'n ernstige allergiese reaksie (swelling van die hande, voete, enkels, lippe, mond of keel, wat probleme met asemhaling, uitslag en gejeuk kan veroorsaak) of 'n "griepagtige" sindroom (koue rillings, duiseligheid, probleme met asemhaling, koors, hoofpyn, spierpyn, beenpyn en bewing).
- **Stel jou dokter in kennis indien jou kind die volgende toestande het:**
  - **Niersiekte**
  - **Geskiedenis van jig**
  - Diabetes, aangesien suikervlakke moeilik kan wees om te beheer terwyl **CO-AFARIS PAED 75/50/150** geneem word.

Ander medisyne en CO-AFARIS PAED 75/50/150
Vertel altyd jou gesondheidsorgverskaffer indien jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
CO-AFARIS PAED 75/50/150 kan die effek van ander medisyne verander en ander medisyne kan die effek van **CO-AFARIS PAED 75/50/150** verander.
Moet nie CO-AFARIS PAED 75/50/150 gee nie en vertel jou dokter as jy die volgende medisyne neem:
- Nevirapien, sakwinavir en ritonavir (MIV-medisyne).

Die volgende medisyne kan **CO-AFARIS PAED 75/50/150** minder goed laat werk:
- Alkohol, alfentaniel, amino-salisielsuur (TB-medisyne), kortikosteroïede soos hidrokortisoon, betametasoon en prednisoloon (vir die behandeling van inflammatoriese toestande), ketokonasool (vir swambesmettings), propranolol (vir hoë bloeddruk) en hoë dosisse van piridoksien (vitamien B_6).
- Teensuurmiddels wat magnesiumtrisilikaat, aluminiumhidroksied of natriumbikarbonaat bevat en ander aluminiumbevattende teensuurmiddels vir swak spysvertering. Gee **CO-AFARIS PAED 75/50/150** ten minste 1 uur voor die teensuurmiddel.

Wanneer jy **CO-AFARIS PAED 75/50/150** gee, is dit veral belangrik om jou dokter of professionele gesondheidsorgwerker te vertel indien jou kind enige van die volgende medisyne neem, aangesien jou dokter moontlik die dosis van die medisyne sal moet aanpas:
- Medisyne wat gebruik word om epilepsie te behandel soos etosuksimied, fenitoïen en karbamasepien.
- Medisyne soos itrakonasool, flukonasool en ketokonasool wat gebruik word vir die behandeling van swambesmettings.
- MIV-medisyne soos sidovudien, delavirdien, efavirens, MIV-protease inhibeerders (lopinavir, duranavir, atasanavir, fosamprenavir, indinavir).
- Ander medisyne sluit sekere narkose middels in (om spiere te laat ontspan voor chirurgie), asatioprien, siklosporien (immuunonderdrukkers), chlooramfenikol, sikloserien, dapsoon, doksisiklien (medisyne wat gebruik word vir infeksies), simetidien (gebruik om ulkusse te behandel), klofibraat (verlaag cholesterol), kortikosteroïede soos hidrokortisoon, betametasoon en prednisoloon (vir behandeling van inflammatoriese toestande), warfarien (verdun bloed), diasepam, (vir angs en depressie), haloperidol (vir geestesongesteldheid), heksobarbitoon (kalmeermiddel), metadoon (vir heroïen onttrekking), orale hipoglukemiese medisyne wat gebruik word in behandeling van diabetes), sulfasalasien (gebruik vir rumatoïede artritis en inflammatoriese dermsiekte), Skildklierhormone (levotiroksien), teofillien (vir asemgefluit of probleme met asemhaling), kinien (gebruik in malaria), medisyne om jou hartklop te beheer soos digoksien, disopiramied, lorkaïnied, meksiletien, propafenoon, kinidien, tokaïnied, medisyne om hartprobleme te behandel soos betablokkers (propranolol), verapamil en ander kalsiumkanaal blokkerende middels, medisyne wat gebruik word vir erge pyn soos kodeïen, morfien, fentaniel of petidien, medisyne wat gebruik word vir pyn en koors soos aspirien en medisyne wat jou help om te slaap, bekend as barbiturate (bv. fenobarbitoon).
- **CO-AFARIS PAED 75/50/150** kan die effektiwiteit van orale voorbehoedmiddels verminder. Gebruik 'n betroubare versperringsmetode van voorbehoeding, soos kondome, terwyl jy **CO-AFARIS PAED 75/50/150** neem.
- Allopurinol, kolgisien, probenesied en sulfienpirasoon (gebruik vir die behandeling van jig).

Die volgende kan, wanneer dit saam met **CO-AFARIS PAED 75/50/150** geneem word, die voorkoms van newe-effekte verhoog:
- Medisyne wat gebruik word om epilepsie te behandel, soos etosuksimied, fenitoïen, primidoon en karbamasepien (jou dokter sal die dosis van die epilepsie-medikasie dienooreenkomstig aanpas)
- MIV-medisyne soos MIV-protease inhibeerders (lopinavir, ritonavir, sakwinavir, duranavir, atasanavir, fosamprenavir), stavudien en salsitabien.
- Ander medisyne soos warfarien (verdun bloed), diasepam, triasolam (vir angs en depressie), sikloserien (TB-medisyne), disulfiram (behandeling van alkohol afhanklikheid), teofillien (vir asemgefluit of probleme met asemhaling).
- Alkohol (daaglikse verbruik kan lei tot ernstige lewerprobleme).

CO-AFARIS PAED 75/50/150 met voedsel, vloeistowwe en alkohol
- **CO-AFARIS PAED 75/50/150** kan in wisselwerking tree met tiramienbevattende voedsel (kaas, rooiwyn) en met voedsel wat histamien bevat (bv. skipjak, tuna, ander tropiese visse) wat kan lei tot hoofpyn, sweet, hartkloppings (hart wat te hard of te vinnig klop), gloede en lae bloeddruk. Vermy om tiramien- en histamienbevattende voedsel aan jou kind te gee tydens behandeling met **CO-AFARIS PAED 75/50/150**.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, vermoed dat jy moontlik swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
Swangerskap:
Veiligheid gedurende swangerskap is nie vasgestel nie.
Borsvoeding:
Veiligheid gedurende borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie
CO-AFARIS PAED 75/50/150 kan duiseligheid, verswakte konsentrasie en/of lomerigheid veroorsaak. Wanneer jy hierdie simptome ervaar, vermy potensieel gevaarlike take soos bestuur of hantering van masjinerie.

CO-AFARIS PAED 75/50/150 bevat aspartaam
CO-AFARIS PAED 75/50/150 bevat 3,13 mg aspartaam in elke tablet.
Aspartaam is 'n bron van fenielalanien. Dit kan skadelik wees indien jy fenielketonurie het (PKU), 'n seldsame genetiese afwyking waarin fenielalanien opbou omdat die liggaam dit nie behoorlik kan verwyder nie.

3. Hoe om CO-AFARIS PAED 75/50/150 te gee

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Gee altyd **CO-AFARIS PAED 75/50/150** presies soos wat jou dokter of apteker vir jou gesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie.
Indien jy die indruk kry dat die effek van **CO-AFARIS PAED 75/50/150** te sterk of te swak is, praat met jou dokter of apteker.
CO-AFARIS PAED 75/50/150 word aanbeveel in die intensiewe fase van die behandeling van pulmonale tuberkulose. **Gedurende hierdie fase moet CO-AFARIS PAED 75/50/150 op 'n deurlopende daaglikse basis gegee word.**
Jou dokter sal die vereiste aantal tablette voorskryf wat op 'n daagliks basis gegee moet word op grond van jou kind se liggaamsgewig.
Die tablette kan óf in so min as 5 ml water opgelos word, óf gekou word, en moet verkieslik as 'n enkele dosis op 'n leë maag (30 minute voor, of 2 ure na 'n maaltyd) geneem word. **CO-AFARIS PAED 75/50/150** moet gegee word, ten minste 1 uur voordat aluminiumbevattende teensuurmiddels geneem word.

Indien jy meer CO-AFARIS PAED 75/50/150 gee as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Simptome sluit naarheid, braking, maagpyn, duiseligheid, hoë bloedsuikervlakke, hoë vlakke van suur in die bloed, hallusinasies, probleme met asemhaling en sentrale senuweestelsel onderdrukking met aanvalle en koma in. Ander tekens van oordosering sluit helderrooi verkleuring van die vel en slymvliese, verminderde geestelike waaksaamheid, swelling van die gesig en "pofferige oë" en algemene gejeuk in.
Indien enige van die bogenoemde simptome voorkom, kry onmiddellik mediese hulp deur jou naaste dokter of professionele gesondheidsorgwerker te kontak.

Indien jy vergeet om jou kind CO-AFARIS PAED 75/50/150 te gee
Indien jou kind 'n dosis van **CO-AFARIS PAED 75/50/150** oorgeslaan het, gee dit sodra jy daarvan onthou. Indien dit egter amper tyd is vir die volgende dosis, slaan die vergete dosis oor en gaan terug na jou gewone skedulering. Moet nooit die dosis verdubbel nie.

Indien jy ophou om jou kind CO-AFARIS PAED 75/50/150 te gee
Indien die volledige behandeling wat deur jou dokter voorgeskryf is nie voltooi word nie, kan sommige van die bakterieë wat die TB infeksie veroorsaak nie doodgemaak word nie. Hierdie bakterieë kan voortgaan om te groei en te vermeerder, sodat die TB infeksie moontlik nie heeltemal opklaar nie of dit kan terugkeer.

4. Moontlike newe-effekte

CO-AFARIS PAED 75/50/150 kan newe-effekte hê.
Nie alle newe-effekte wat vir **CO-AFARIS PAED 75/50/150** aamgemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou kind se algemene gesondheid versleg, of indien jou kind enige ongunstige effekte ervaar terwyl **CO-AFARIS PAED 75/50/150** geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om **CO-AFARIS PAED 75/50/150** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak
- uitslag of gejeuk
- floute
- vergeling van die vel en oë, ook geelsug genoem

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **CO-AFARIS PAED 75/50/150** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Rooi, en/of jeukerige vel, blase of puisies.
- Veltoestand met erge blase en bloeding in die lippe, oë, mond, neus en geslagsdele (simptome van Stevens Johnson-sindroom).
- Wydverspreide skubvorming van die vel met gejeuk, velrooiheid en haarverlies (simptome van afskilferende dermatitis).
- Kort van asem en asemgefluit.
- Longsiekte wat hoes, probleme met asemhaling en asemgefluit veroorsaak (simptome van longontsteking).
- Littekens en verdikking in die longe met kort van asem (simptome van pulmonale fibrose).
- Bloed in die uriene of enige ander urinering versteurings.
- Koors, koue rillings, hoofpyn of duiseligheid.
- Beenpyn.
- Kneusing, neusbloeding of bloeding in die mond en tandvleise, uitslag met punt grootte rooi kolletjies.
- Moegheid, swakheid, malaise (voel nie lekker nie), anoreksie (verlies aan eetlus), naarheid of braking.
- Abdominale pyn, bloed in die stoelgang, voortdurende aanvalle van diarree wat nie reageer op oor die toonbank (OTC) medisyne nie, of 'n onverklaarbare koors wat langer as 'n dag of twee aanhou (simptome van ulseratiewe kolitis).
- Bloeding vanuit die maagwand met braking van bloed of materiaal wat lyk soos gemaalde koffie, bloeding vanuit die agterste opening, swart klewerige dermbewegings (stoelgang) of bloedige diarree.
- Ontsteking van die pankreas met erge boonste maagpyn, naarheid en braking.

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese hulp.

Vertel jou dokter onmiddellik indien jou kind enige van die volgende newe-effekte het, veral as dit 'n paar weke nadat die behandeling met CO-AFARIS PAED 75/50/150 gestaak is, voorkom:
- Erge maagkrampe.
- Waterige en erge diarree, wat ook bloederig kan wees.
- Koors, in kombinasie met een of albei van die bogenoemde.

Jou kind kan dalk 'n ernstige toestand hê wat die derm affekteer, wat moontlik dringende mediese aandag benodig. Moet nie enige medisyne vir diarree gee, sonder om eers met jou dokter te praat nie.

Vertel vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat gereeld voorkom:
- Sooibrand, anoreksie, naarheid, braking, winde, krampe of diarree, hardlywigheid, droë mond.
- Velreaksies met gloede en gejeuk, met of sonder 'n uitslag.
- Seer spiere, spier teerheid of swakheid, nie veroorsaak deur oefening nie.
- Rooi-oranje tot rooibruin verkleuring van die uriene, ontlasting, speeksel, sputum, sweet en trane.
- Sagte kontaklense kan permanent gevlek word.
- Gevoelloosheid of swakheid van die arms en bene.
- Toename in lewerensieme.

Minder gereelde newe-effekte:
- Toename in sommige witbloedselle (eosinofilie).
- Gebrek aan witbloedselle wat gereelde infeksies soos koors, erge koue rillings, seer keel of mondsere (leukopenie) tot gevolg het.
- Moegheid, hoofpyne, kort van asem wees tydens oefening, duiseligheid, bleek lyk en vergeling van die vel en/of oë (hemolitiese anemie).
- Hoë bloedglukosevlakke.
- Hoë vlakke van suur in die bloed.
- Geestesongesteldheid met vreemde of ontstellende gedagtes of buie.
- Verlies aan geheue.
- Hoofpyn, duiseligheid, lomerigheid, moegheid, onvermoë om te konsentreer of verwarring.
- Swak koördinasie, pyn in die vingers of tone, of gevoelloosheid, ongewone verhoogde reflekse of rukkings.
- Aanvalle of toename in aanvalle as jy 'n epileptiese pasiënt is.
- Dowwe visie of verlies van sig met of sonder oogpyn, oogirritasie.
- Menstruele versteurings.
- Orale voorbehoedmiddels kan minder effektief word.
- Tydelike gehoorverlies.
- Vertigo (voel duiselig met 'n draai sensasie).
- Veluitslag, jeukerige uitslag, aknee, haarverlies, sensitiwiteit vir die son, allergiese reaksies.
- Vergrote borste.
- Mondsproei - wit, wollerige, seer tong en mond.
- Swelling van hande, enkels of voete.
- Verergering van maag ulkusse.
- Probleme om toilet toe te gaan (urineer).
- Koors, pyne en pyne in spiere, pyn en swelling van gewrigte (veral groottoon, enkel en knie met stywe, warm vel oor aangetaste gewrigte).
- Ongewone moegheid of swakheid

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van 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 **CO-AFARIS PAED 75/50/150.**

5. Hoe om CO-AFARIS PAED 75/50/150 te bêre

Hou alle medisyne buite bereik van kinders.
Bewaar by of benede 25 °C.
Hou die aluminiumsakkie in die HDPE houer totdat dit benodig word vir gebruik.
Hou die stulpstrook in die karton totdat dit benodig word vir gebruik.
Stoor hierdie medisyne weg van lig en vog. Moet nie in die badkamer se kas bêre nie.
Enige vervalde of verouderde medisyne en ongebruikte medisyne kan na jou naaste apteek teruggeneem word.

6. Inhoud van die pak en ander inligting

Wat CO-AFARIS PAED 75/50/150 bevat
CO-AFARIS PAED 75/50/150 bevat die aktiewe bestanddele rifampisien 75 mg, isoniasied 50 mg en pirasinamied 150 mg.
Die ander bestanddele is mikrokristallyne sellulose, krospovidoon, povidoon, gebleikte skulp, natriumkroskarmellose, aarbei geur, magnesiumstearaat.
Bevat aspartaam. Suiker vry.

Hoe CO-AFARIS PAED 75/50/150 lyk en inhoud van die pak
Baksteenrooi gevlekte, 11,0 mm sirkelvormige, onbedekte bikonvekse tablette met 'n diep keep aan die een kant en glad aan die ander kant.
HDPE houer:
Tablette word verpak in 'n deursigtige, selfverseëlende LDPE polisak en verder verpak in 'n silwerkleurige drievoudige gelamineerde aluminiumsakkie (LDP/PET/AL), gehou in 'n wit plastiekhouer (HDPE), wat met 'n aluminiummerker by die opening verseël is en met 'n wit HDPE aanskroefdeksel toegemaak word. Verpakkingsgroottes sluit 100 tablette in
Alu-alu pak:
Tablette word verpak in silwer-metaalkleurige aluminiumfoelie (sag getemper) gelamineer met lae digtheid poliëtileen film as die dek- en vormingsmateriaal. Die strook is verpak in 'n vooraf gedrukte karton.Verpakkingsgroottes sluit 28, 56, 84, 100 en 112 tablette in.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1 Bassonia Estate Kantoorpark (Oos)
1 Cussonia-rylaan Bassonia Rock, Uitbr. 12
Alberton
Gauteng

Hierdie inligtingstuk is laas hersien in
02 Julie 2024

Registrasienommer
52/20.2.3/0306

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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product : RIFAMPICIN, PYRAZINAMIDE, ISONIAZID (CO-AFARIS PAED 75/50/150)	
2. Country: South Africa (Tender)	**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 320 (W) mm**
9. Design / Style: Booklets	**10. Item code No.: PM04339676**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40383 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. File Name : Z:\South Africa\Rifa 75, Iso 50 & Pyra 150\Tender 2024\01\Rifampicin 75 mg, Isoniazid 50 mg & Pyra 150 PIL - PM04339676.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA Date: 2025.08.21 09:42:17 +02'00'				

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.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04339676		