PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

DUOPIC 150/75, 150 mg and 75 mg, film-coated tablets
Rifampicin/ Isoniazid
Sugar free

Read all of this leaflet carefully before you start taking DUOPIC 150/75

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- DUOPIC 150/75 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 DUOPIC 150/75 is and what it is used for
2. What you need to know before you take DUOPIC 150/75
3. How to take DUOPIC 150/75
4. Possible side effects
5. How to store DUOPIC 150/75
6. Contents of the pack and other information

1. What DUOPIC 150/75 is and what it is used for

DUOPIC 150/75 contains two different medicines called rifampicin and isoniazid. They both belong to a group of medicines called anti-tuberculous medicines. They work by killing the bacteria that cause tuberculosis. DUOPIC 150/75 tablets are used to treat tuberculosis (also known as TB).

2. What you need to know before you take DUOPIC 150/75

Do not take DUOPIC 150/75:

- if you are hypersensitive (allergic) to rifampicin, isoniazid or other chemically related medicines such as ethionamide, pyrazinamide, niacin or to any other ingredients of DUOPIC 150/75 (listed in section 6).
- if you have yellowing of the skin and eyes (jaundice).

- if you have acute porphyria (a disease in which the body cannot make certain substances in the blood and that presents with skin problems and/or affects the nervous system).
- if you have liver damage.
- if you have an active liver disease irrespective of the cause.
- if you have ever had liver problems caused by a medication.
- if you have liver problems, as rifampicin (one of the ingredients) is processed in the liver and can be harmful to it. The risk of liver inflammation (hepatitis) is higher if you drink alcohol every day or already have liver issues.
- if you are taking saquinavir, ritonavir or nevirapine for a Human Immunodeficiency virus (HIV) infection (see 'Other medicines and DUOPIC 150/75' section below).
- if you are taking lurasidone (medicine for schizophrenia and bipolar disorders), as rifampicin may reduce the blood levels of lurasidone.
- if you suffer from severe kidney dysfunction.
- if you have epilepsy or have ever had convulsions (fits).
- if you are pregnant or breastfeeding.
- If you suffer from thrombocytopenia (a decrease of platelets in the blood) or purpura (the appearance of red or purple discolorations of the skin).

Warnings and precautions

Take special care with DUOPIC 150/75:

Talk to your doctor or pharmacist before taking DUOPIC 150/75 tablets if:

- You have liver problems.
- You have any kidney problems and if you are taking more than 600 mg rifampicin per day.
- You inject yourself with drugs.
- You are a black or Hispanic woman.
- The person taking this medicine is a child.
- You are aged 65 years or older.
- You have a problem with bleeding or a tendency to bruise easily.
- You have diabetes. Your diabetes may become more difficult to control while taking this medicine.
- You have epilepsy.
- You have or have ever had mental health problems (such as depression or schizophrenia).
- You feel numb or weak in your arms and legs (peripheral neuropathy).
- You are infected with HIV.
- You are underweight or malnourished.
- You drink alcohol every day or you are an alcoholic.
- You have a rare blood problem called 'porphyria'.

- Your doctor has told you that your body takes a long time to get rid of some medicines (you have a slow acetylator status).
- You wear contact lenses. Taking DUOPIC 150/75 may permanently stain soft contact lenses.
- You develop a rash or have any signs of serious blood problems, like unexplained bruising, tiny red spots on your skin, or unusual tiredness, during your treatment, contact your doctor right away.
- You experience reappearance or worsening of symptoms of tuberculosis (paradoxical drug reaction). See section 4.
- You have a history of lung inflammation (interstitial lung disease/pneumonitis).
  Inform your doctor immediately while taking this medicine if you develop new or sudden worsening of shortness of breath, possibly with a dry cough or fever not responding to antibiotic treatment. These could be symptoms of lung inflammation (interstitial lung disease/pneumonitis) and can lead to serious breathing problems due to collection of fluid in the lungs and interfere with normal breathing which can lead to life threatening conditions.
- You have ever had issues with your brain's coordination, like problems with balance, difficulty moving smoothly, or issues with eye movement (such as uncontrollable eye shaking). These issues, known as cerebellar syndrome, can sometimes happen when taking isoniazid (contained in DUOPIC 150/75), especially in people with chronic kidney disease. This medication can affect how your brain controls your movements, so it's important to let your doctor know if you have had any of these symptoms or kidney problems.
- Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported with the use of DUOPIC 150/75.
    - SJS/TEN can appear initially as reddish target spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
    - DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell(eosinophilia) and enlarged lymph nodes.
    - AGEP appears at the initiation of treatment as a red, scaly widespread rash

with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk, and upper extremities.

The highest risk for occurrence of serious skin reactions is within 2 days to 2 months after treatment initiation depending on the condition.

If you develop a serious rash or another of these skin symptoms, stop taking DUOPIC 150/75 tablets and contact your doctor or seek medical attention immediately.

Blood Tests

Your doctor will need to check your blood before you take this medicine. This will help your doctor know if any changes happen to your blood after taking this medicine. If you are aged 35 years or older, you will also need to have monthly blood tests to check how your liver is working.

Children and adolescents

DUOPIC 150/75 is not for use in children.

Other medicines and DUOPIC 150/75

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are pregnant and planning or required to undergo pregnancy termination using mifepristone.

When mifepristone is taken together with rifampicin (a strong antibiotic found in DUOPIC 150/75), the effectiveness of mifepristone may be reduced. Studies have shown that rifampicin can significantly lower the levels of mifepristone in the body, making it less effective.

In particular, do not take DUOPIC 150/75, and tell your doctor, if you are taking:

- Saquinavir, ritonavir or nevirapine used for HIV infection (see Do not take DUOPIC 150/75 section above).

  Rifampicin, which is contained in DUOPIC 150/75, speeds up the way your body breaks down certain HIV medications, such ritonavir, saquinavir, and nevirapine. This can make these HIV medications less effective because your body clears them too quickly. On the other hand, some of these HIV medications can slow down how your body processes

rifampicin, leading to higher levels of rifampicin in your blood and increasing the risk of side effects or toxicity.

- Lurasidone used for schizophrenia and bipolar disorders (see Do not take DUOPIC 150/75 section above).

  Rifampicin, which is in DUOPIC 150/75, can reduce the amount of lurasidone your body absorbs compared to when you take lurasidone on its own. This means that the medicine might not work as well when both are taken together.

The following medicines can make DUOPIC 150/75 tablets work less well:

- Antacids used for indigestion. Take DUOPIC 150/75 at least 1 hour before taking antacids
- Other medicines used for TB such as P-aminosalicyclic acid (PAS) and cycloserine. PAS and DUOPIC 150/75 should be taken at least 8 hours apart. Also, the risk of CNS toxicity is increased when isoniazid is given with cycloserine. Also, taking isoniazid, which is contained in DUOPIC 150/75, together with cycloserine can increase the risk of side effects affecting your brain and nervous system (CNS toxicity).

Tell your doctor if you are taking any of the following medicines, as your doctor may need to adjust the dosage of these medicines or DUOPIC 150/75:

Heart and blood medicines

- Medicines for high blood pressure such as enalapril and losartan
- Medicines for heart problems or to control your heartbeat such as procainamide, disopyramide, lorcainide, mexiletine, quinidine, propafenone, tocainide, digitoxin as well as digoxin
- Medicines used for heart problems or to control heartbeat and hypertension such as bisoprolol and propranolol
- Calcium channel blockers used to lower blood pressure (such as diltiazem, nifedipine, verapamil, nimodipine, isradipine, nicardipine and nisoldipine).
- Medicines used to thin the blood such as warfarin and clopidogrel
- Medicines used to lower cholesterol such as clofibrate and statins (e.g. simvastatin)
- Water tablets (diuretics) such as eplerenone

Mental health, epilepsy and motor neurone medicines:

- Medicines for thought disorders known as ‘antipsychotics’ such as haloperidol, chlorpromazine and aripiprazole
- Medicines used for epilepsy such as carbamazepine, ethosuximide, primidone and phenytoin
- Medicines to help you sleep (barbiturates)

- Medicines to calm or reduce anxiety (hypnotics and anxiolytics such as diazepam, triazolam, chlordiazepoxide, flurazepam, prazepam, zopiclone and zolpidem)
- Riluzole - used for motor neurone disease
- Some medicines used for depression such as amitriptyline and nortriptyline

Medicines for infections and the immune system:

- Medicines used for fungal infections such fluconazole, itraconazole, ketoconazole, voriconazole, caspofungin
- Some medicines used for an HIV infection such as stavudine and zalcitabine
- Some medicines used for viral infections such as ritonavir indinavir, delavirdine, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, daclatasvir, simeprevir, sofosbuvir and telaprevir. Rifampicin, which is found in DUOPIC 150/75, can lower the levels of maraviroc in your blood. This means that if you're taking both medications, rifampicin may make maraviroc less effective.
- Medicines used for bacterial infections (antibiotics) such as chloramphenicol, clarithromycin, dapsone, doxycycline, fluoroquinolones and telithromycin.
  Dapsone (an antibiotic) taken with rifampicin (contained in DUOPIC 150/75) may cause blood-related toxicity, including a decrease in bone marrow and blood cells, as well as methaemoglobinaemia (a condition where oxygen in your blood is reduced due to changes in red blood cells)
- Medicines used for lowering your immune system such as ciclosporin, sirolimus and tacrolimus
- Praziquantel - used for tapeworm infections
- Atovaquone - used for pneumonia

Hormone and cancer medicines:

- Some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene and gestrinone
- Some hormone medicines (estrogen, systemic hormones, progestogens) used for contraception or some types of cancer such as ethinyloestradiol, levonorgestrel or dydrogesterone
- Irinotecan - used for cancer
- Levothyroxine (thyroid hormone) used for thyroid problems
- Some medicines used for cancer (cytotoxics) such as imatinib

Pain and inflammation medicines:

- Non-steroidal anti-inflammatory drugs (NSAIDS) such as etoricoxib, aspirin and

indometacin
- Corticosteroids used for inflammation such as hydrocortisone, betamethasone and prednisolone
- Methadone - used for heroin withdrawal
- Medicines used for pain such as codeine, morphine, alfentanil, fentanyl or pethidine
- Paracetamol and DUOPIC 150/75 may increase the risk of liver damage

Other medicines:
- Other antibiotic medicines such as cefazolin
- Medicines used for diabetes such as chlorpropamide, tolbutamide, sulfonylureas, rosiglitazone, nateglinide and repaglinide
- Medicines used to relax muscles before surgery (anaesthetics) such as halothane and enflurane
- Medicines used to help men with erectile dysfunction (a condition where it is difficult to get or maintain an erection), such as tadalafil
- Some medicines used for feeling sick or being sick such as ondansetron and aprepitant
- Quinine - used for malaria
- Theophylline - used for wheezing or difficulty in breathing
- Clofazimine (used in the treatment of leprosy)
- Disulfiram (medicine used in the treatment of chronic alcoholism)
- Pyridoxine (Vitamin B6)
- Levodopa (a dopamine replacement therapy used to manage Parkinson's disease and parkinsonism symptoms)

Taking DUOPIC 150/75 with food, drink and alcohol

Isoniazid, which is contained in DUOPIC 150/75, may interact with foods containing histamine or tyramine (e.g. matured cheeses, cured meat, some fish like tuna, salmon and mackerel, wine and beer), causing symptoms including headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure). These foods should be avoided if you are receiving isoniazid (contained in DUOPIC 150/75). Your doctor will be able to advise further.

Do not drink alcohol while taking DUOPIC 150/75. This increases your risk for liver damage.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DUOPIC 150/75.

Safety and efficacy of DUOPIC 150/75 has not been established in pregnant or breastfeeding women.

Rifampicin, which is contained in DUOPIC 150/75, may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. You must use a reliable barrier method of contraception such as condoms or the “coil” while taking DUOPIC 150/75. If you have any questions or are unsure about this talk to your doctor or pharmacist.

DUOPIC 150/75 passes into mother’s milk and you should not breastfeed your baby while taking DUOPIC 150/75.

Driving and using machines

You may feel dizzy or faint, have problems with vision or have other side effects that could affect your ability to drive while taking DUOPIC 150/75.

It is not always possible to predict to what extent DUOPIC 150/75 may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which DUOPIC 150/75 affects you.

3. How to take DUOPIC 150/75

Do not share medicines prescribed for you with any other person.
Always take DUOPIC 150/75 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Keep taking this medicine

You must take the tablets every day for the whole time the doctor has told you to take them.

The usual dose is:

Adults and the elderly weighing less than 38 kg

2 tablets each day

Adults and the elderly weighing less than 55 kg
3 tablets each day

Adults and the elderly weighing more than 55 kg
4 tablets each day

Adults and the elderly weighing more than 71 kg
5 tablets each day

If you are elderly, your doctor may monitor your treatment more closely.

Children
This medicine is not recommended for use in children.

Take this medicine by mouth
Swallow the tablets whole, with a drink of water
Take all your tablets together each day, as a single dose

Your doctor will tell you how long your treatment with DUOPIC 150/75 will last. Do not stop treatment early because your TB will not be treated properly. If you have the impression that the effect of DUOPIC 150/75 is too strong or too weak, tell your doctor or pharmacist.

If you take more DUOPIC 150/75 than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include:
Nausea (feel sick), vomiting (be sick), stomach pain, itching, headache, feel tired, sleepy, dizzy, light-headed, have blurred or strange visions (hallucinations), faint or feel faint, seizures, disorientation, slurring of speech, coma, hyperglycaemia, muscle aches, fatigue, frequent urination, thirst, dry mouth. Other signs of taking too much include fast heartbeat, uneven heartbeats, fits and heart attack.

If you forget to take DUOPIC 150/75
Do not take a double dose to make up for forgotten individual doses.

If you stop taking DUOPIC 150/75

Do not stop and start taking the tablets. This may increase the risk of side effects, and your TB will not be treated properly.

4. Possible side effects

DUOPIC 150/75 can have side effects.

Not all side effects reported for DUOPIC 150/75 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DUOPIC 150/75, please consult your health care provider for advice.

If any of the following happens, stop taking DUOPIC 150/75 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to DUOPIC 150/75. 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:

Frequent side effects

- you bruise more easily than usual. Or you may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem.

Less frequent side effects

- you get more infections more easily than normal. Signs include fever, sore throat or mouth ulcers. This could be because you have a low number of white blood cells.
- you have severe bleeding (haemorrhage).
- you have a sudden severe headache. This could be a sign of bleeding in the brain.

Unknown frequency

- pellagra: symptoms may include diarrhoea, skin rashes (especially in sun-exposed areas), mental confusion, and memory issues. In severe cases, untreated pellagra can be fatal.
- new or sudden worsening of shortness of breath and wheezing, possibly with a cough or fever. These could be symptoms of inflammation of the lungs (interstitial lung disease/pneumonitis).
- inflammation of the liver – yellowing of the skin and white part of eyes, increase in the blood level of liver enzymes.
- serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. See also section 2.
- widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.
- shortness of breath and wheezing.
- you get confused, sleepy, cold clammy skin, shallow or difficult breathing, a racing heartbeat or your skin is paler than normal. These could be signs of shock.
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). See also section 2.
- you have blood in your urine or an increase or decrease in amount of urine you produce. You may also get swelling, especially of the legs, ankles or feet. This may be caused by serious kidney problems.
- you have chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine. These could be signs of a serious type of anaemia.
- eosinophilia agranulocytosis: This is a rare condition where your body has too many certain types of white blood cells called eosinophils, which can cause inflammation and allergic reactions. It can also mean you have too few other types of white blood cells (called granulocytes), making you more vulnerable to infections.
- vitamin k dependent coagulation disorders: These are problems with your blood clotting system caused by a lack of vitamin K. Vitamin K is necessary for your body to produce certain proteins that help your blood clot properly. Without enough of it, you might have trouble stopping bleeding.
- you have bleeding from your nose, ear, gums, throat, skin or stomach. Signs may include a feeling of tenderness and swelling in your stomach, purple spots on your skin and black

or tar-like stools.

- severe watery diarrhoea that will not stop and you are feeling weak and have a fever. this may be something called ‘pseudomembranous colitis’.
- mental problems with unusual thoughts and strange visions (hallucinations).
- your fits get worse or you start to have fits.
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known).
- flu-like symptoms including chills, fever, headache, dizziness and bone pains.
- yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems or liver injury.
- blood clots in small blood vessels (thrombotic microangiopathy) – Symptoms may include increased bruising, bleeding, fever, extreme weakness, headache, dizziness or light-headedness. Your doctor may find changes in your blood and the function of your kidneys.
- symptoms related to cerebellar syndrome: poor coordination, poor balance, change in speech, involuntary eye movements.
- Paradoxical drug reactions (symptoms of tuberculosis may recur or new symptoms may appear after initial improvement during treatment).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- dizziness
- feeling sick or being sick
- fever, chills
- increased blood results such as bilirubin, liver enzymes

Less frequent side effects

- diarrhoea
- water retention (oedema) which may cause swollen face, stomach, arms or legs
- convulsions
- short-term memory loss, anxiety, being less alert or responsive
- temporary vision loss

Unknown frequency of side effects

- weight loss, night sweats and fever. These could be signs of a blood condition called eosinophilia
- decreased appetite
- inflammation of the blood vessels
- skin flushing or itching
- hives
- painful sores and blisters on your skin and in your mouth
- constipation, stomach discomfort or dry mouth
- muscle weakness or pain or loss of muscle reflexes
- heavy bleeding after the birth of your baby, entry of foetal blood into the maternal circulation before or during delivery
- irregular periods
- you have one of a group of disorders that can cause nerve or skin problems (porphyria)
- dizziness, feel lightheaded and faint especially when you stand or sit up quickly (due to low blood pressure)
- balance problems with dizziness (vertigo)
- unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia)
- acne
- nausea, vomiting, indigestion
- breast enlargement in men
- increased thirst, going to the toilet more often and feeling tired, your blood sugar may be high
- autoantibodies can damage your joints, skin, muscles, and other parts of your body
- fever
- hair loss

You notice a discoloration (yellow, brown, orange or red colour) in your teeth, urine, sweat, phlegm (sputum), saliva or tears. This is quite common and you need not worry. However, the colour may permanently stain soft contact lenses. The colour in tears may last for some time after you have stopped taking DUOPIC 150/75.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org), found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DUOPIC 150/75.

You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

5. How to store DUOPIC 150/75

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PVC/PVDC blister pack: Store at or below 25 °C. Store in the original container to protect from light and moisture.

Aluminium foil blister pack: Store at or below 30 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DUOPIC 150/75 contains

The active substances are rifampicin 150 mg and isoniazid 75 mg.

The other ingredients are:

Tablet core – ascorbic acid, colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

Coating materials – hypromellose, iron oxide red, polyethylene glycol 4000, simethicone emulsion, talc and titanium dioxide.

What DUOPIC 150/75 looks like and contents of the pack

DUOPIC 150/75 tablets are brick red coloured capsule-shaped biconvex film coated tablets, break line on one side and plain on other side.

DUOPIC 150/75 tablets are packed in Alu/Alu blister packs or PVC/PVDC blister packs. The blisters strips are packed in an outer cardboard carton with a package leaflet.
Pack sizes: 56, 84, 90 or 672 tablets.

Not all pack sizes and pack types may be marketed.

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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S4**

DUOPIC 150/75, 150 mg en 75 mg, filmbedekte tablette
Rifampisien/ Isoniasied
Suiker-vry

Lees hierdie biljet noukeurig deur voordat u DUOPIC 150/75 begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- DUOPIC 150/75 is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat DUOPIC 150/75 is en waarvoor dit gebruik word
2. Wat u moet weet voordat u DUOPIC 150/75 neem
3. Hoe om DUOPIC 150/75 te neem
4. Moontlike newe-effekte
5. Hoe om DUOPIC 150/75 te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat DUOPIC 150/75 is en waarvoor dit gebruik word

DUOPIC 150/75 bevat twee verskillende medisyne genaamd rifampisien en isoniasied. Hulle behoort albei tot 'n groep medisyne wat anti-tuberkulose medisyne genoem word. Hulle werk deur die bakterieë wat tuberkulose veroorsaak, dood te maak. DUOPIC 150/75 tablette word gebruik om tuberkulose (ook bekend as TB) te behandel.

2. Wat u moet weet voordat u DUOPIC 150/75 neem

Moenie DUOPIC 150/75 neem nie:

- indien u hipersensitief (allergies) is vir rifampisien, isoniasied of ander chemies verwante medisyne soos etionamied, pirazinamied, niasien of vir enige ander bestanddele van DUOPIC 150/75 (gelys in afdeling 6).
- indien u vergeling van die vel en oë het (geelsug).
- indien u akute porfirie het ('n siekte waarin die liggaam nie sekere stowwe in die bloed kan maak nie en wat as velprobleme voordoen en/of die senuweestelsel beïnvloed).

- indien u lewerskade het.
- indien u 'n aktiewe lewersiekte het, ongeag die oorsaak.
- indien u al ooit lewerprobleme gehad het wat veroorsaak word deur 'n medikasie.
- indien u lewerprobleme het, aangesien rifampisien (een van die bestanddele) in die lewer verwerk word en skadelik daarvoor kan wees. Die risiko van lewerinflammasie (hepatitis) is hoër as u elke dag alkohol drink of reeds lewerprobleme het.
- indien u sakinavir, ritonavir of nevirapien neem vir Menslike Immuniteitsgebrekvirus (MIV) infeksie (sien 'Ander medisyne en DUOPIC 150/75' afdeling hieronder).
- indien u lurasidoon (medisyne vir skisofrenie en bipolêre versteurings) neem, aangesien rifampisien die bloedvlakke van lurasidoon kan verlaag.
- indien u aan ernstige nierdisfunksie ly.
- indien u epilepsie het of al ooit stuiptrekkings (stuipaanvalle) gehad het.
- indien u swanger is of borsvoed.
- indien u ly aan trombositopenie ('n afname van bloedplaatjies in die bloed) of purpura (die voorkoms van rooi of pers verkleurings van die vel).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met DUOPIC 150/75:

Raadpleeg u dokter of apteker voordat u DUOPIC 150/75 tablette neem indien:

- U lewerprobleme het.
- U enige nierprobleme het en indien u meer as 600 mg rifampisien per dag neem.
- U uself met dwelms inspuit.
- U 'n swart of Spaanse vrou is.
- Die persoon wat hierdie medisyne gebruik, 'n kind is.
- U ouer as 65 jaar is.
- U 'n probleem met bloeding of 'n neiging om maklik te kneus het.
- U diabetes het. U diabetes kan moeiliker word om te beheer terwyl u hierdie medisyne neem.
- U epilepsie het.
- U tans, of al voorheen ooit geestesgesondheidsprobleme gehad het (soos depressie of skisofrenie).
- U gevoelloos voel of swak in u arms en bene (perifere neuropatie).
- U besmet is met MIV.
- U ondergewig of ondervoed is.
- U elke dag alkohol drink of u 'n alkoholis is.
- U 'n seldsame bloedprobleem genaamd 'porfirie' het.
- U dokter u ingelig het dat u liggaam lank neem om van sommige medisyne ontslae te raak

(u het 'n stadige asetilator-status).

- U kontaklense dra. Die neem van DUOPIC 150/75 kan sagte kontaklense permanent vlek.
- U 'n uitslag ontwikkel of enige tekens het van ernstige bloedprobleme, soos onverklaarbare kneusplekke, klein rooi kolletjies op u vel, of ongewone moegheid tydens u behandeling, kontak u dokter dadelik.
- U herverskyning of verergering van simptome van tuberkulose ervaar (paradoksale geneesmiddelreaksie). Sien afdeling 4.
- U 'n geskiedenis van longontsteking het (interstisiële longsiekte/longontsteking).
  Stel u dokter onmiddellik in kennis terwyl u hierdie medisyne neem indien u nuwe of skielike verergering van kortasem ontwikkel, moontlik met 'n droë hoes of koors wat nie reageer op antibiotiese behandeling nie. Dit kan simptome van longontsteking wees (interstisiële longsiekte/longontsteking) en kan lei tot ernstige asemhalingsprobleme as gevolg van die versameling van vloeistof in die longe en inmeng met normale asemhaling wat tot lewensgevaarlike toestande kan lei.
- U het al ooit probleme met u brein se koördinasie gehad, soos probleme met balans, probleme om glad te beweeg of probleme met oogbeweging (soos onbeheerbare oogskudding). Hierdie probleme, bekend as serebellêre sindroom, kan soms voorkom wanneer isoniasied (vervat in DUOPIC 150/75) geneem word, veral by mense met chroniese niersiekte. Hierdie medikasie kan beïnvloed hoe u brein u bewegings beheer, daarom is dit belangrik om u dokter in te lig dat u enige van hierdie simptome of nierprobleme gehad het.
- Ernstige velreaksies, insluitend Stevens-Johnson se sindroom (SJS), toksiese epidermale nekrolise (TEN), geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) en akute algemene eksantemateuse pustulose (AAEP) is aangemeld met die gebruik van DUOPIC 150/75.
- SJS/TEN kan aanvanklik verskyn as rooierige teikenkolle of sirkelvormige areas, dikwels met sentrale blase op die lyf. Ulkusse van die mond, keel, neus, geslagsdele en oë (rooi en geswelde oë) kan ook voorkom. Hierdie ernstige veluitslag word dikwels voorafgegaan met koors en/of griepagtige simptome. Die uitslag kan vorder tot wydverspreide afskilfering van die vel en lewensgevaarlike komplikasies of kan dodelik wees.
- GRESS verskyn aanvanklik as griepagtige simptome en 'n uitslag op die gesig, dan 'n wydverspreide uitslag met 'n hoë liggaamstemperatuur, verhoogde vlakke van lewerensieme wat in bloedtoetse gesien word, en 'n toename in 'n tipe witbloedsel (eosinofilie) en vergrote limfknope.
- AAEP verskyn by die aanvang van die behandeling as 'n rooi, skubberige wydverspreide uitslag met knoppe onder die vel en blase, wat gepaard gaan met koors. Die mees algemene ligging: hoofsaaklik gelokaliseer op die velvoue, romp en boonste ledemate.

Die grootste risiko vir die voorkoms van ernstige velreaksies is binne 2 dae tot 2 maande na die aanvang van die behandeling, afhangende van die toestand.

Indien u 'n ernstige uitslag of ander van hierdie velsimptome ontwikkel, staak DUOPIC 150/75 tablette en kontak u dokter of soek onmiddellik mediese hulp.

Bloedtoetse

U dokter sal u bloed moet toets voordat u hierdie medisyne neem. Dit sal u dokter help om te weet of enige veranderinge aan u bloed plaasvind nadat u hierdie medisyne geneem het. Indien u 35 jaar of ouer is, sal u ook maandelikse bloedtoetse moet ondergaan om te kyk hoe u lewer werk.

Kinders en adolessente

DUOPIC 150/75 is nie vir gebruik by kinders nie.

Ander medisyne en DUOPIC 150/75

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig u dokter of apteker in indien u swanger is en beplan, of vereis word, om swangerskapbeëindiging te ondergaan met behulp van mifepristoon.
Wanneer mifepristoon saam met rifampisien ('n sterk antibiotikum wat in DUOPIC 150/75 voorkom), geneem word, kan die doeltreffendheid van mifepristoon verminder word. Studies het getoon dat rifampisien die vlakke van mifepristoon in die liggaam aansienlik kan verlaag, wat dit minder effektief maak.

In besonder, moenie DUOPIC 150/75 neem nie, en lig u dokter in, indien u die volgende neem:

- Sakinavir, ritonavir of nevirapien wat gebruik word vir MIV-infeksie (sien ‘Moenie DUOPIC 150/75 neem nie indien’ afdeling hierbo)
  Rifampisien, wat in DUOPIC 150/75 vervat is, versnel die manier waarop u liggaam sekere MIV-medikasie, soos ritonavir, sakinavir en nevirapien, afbreek. Dit kan hierdie MIV-medikasie minder effektief maak omdat u liggaam dit te vinnig uitskei. Aan die ander kant kan sommige van hierdie MIV-medikasie vertraag hoe u liggaam rifampisien verwerk, wat lei tot hoër vlakke van rifampisien in u bloed en die risiko van newe-effekte of toksisiteit verhoog.

- Lurasidoon, wat gebruik word vir skisofrenie en bipolêre versteurings (sien 'Moenie DUOPIC 150/75 neem nie indien' afdeling hierbo)
  Rifampisien, wat in DUOPIC 150/75 is, kan die hoeveelheid lurasidoon wat u liggaam absorbeer verminder, in vergelyking met wanneer u lurasidoon op sy eie neem. Dit beteken dat die medisyne dalk nie so goed werk wanneer albei saam geneem word nie.

Die volgende medisyne kan DUOPIC 150/75 tablette minder goed laat werk:

- Teensuurmiddels wat gebruik word vir slegte spysvertering. Neem DUOPIC 150/75 ten minste 1 uur voor die neem van teensuurmiddels
- Ander medisyne wat vir TB gebruik word, soos P-aminosalisikliese suur (PAS) en sikloserien. PAS en DUOPIC 150/75 moet ten minste 8 ure uitmekaar geneem word. Die risiko van SSS-toksisiteit word ook verhoog wanneer isoniasied saam met sikloserien gegee word. Die neem van isoniasied, wat in DUOPIC 150/75 vervat is, saam met sikloserien kan ook die risiko verhoog dat newe-effekte u brein en senuweestelsel beïnvloed (SSS-toksisiteit).

Lig u dokter in indien u enige van die volgende medisyne neem, aangesien u dokter dalk die dosis van hierdie medisyne of DUOPIC 150/75 moet aanpas:

Hart- en bloedmedisyne

- Medisyne vir hoë bloeddruk soos enalapriel en losartaan
- Medisyne vir hartprobleme of om u hartklop te beheer, soos prokaïnamied disopiramied, lorkaïnied, meksiletien, kinidien, propafenoon, tokaïnied, digitoksien sowel as digoksien
- Medisyne wat gebruik word vir hartprobleme of om hartklop en hipertensie te beheer, soos bisoprolol, propranolol
- Kalsiumkanaalblokkers wat gebruik word om bloeddruk te verlaag (soos diltiasem, nifedipien, verapamiel, nimodipien, isradipien, nikardipien en nisoldipien).
- Medisyne wat gebruik word om die bloed te verdun, soos warfarien en klopidogrel
- Medisyne wat gebruik word om cholesterol te verlaag soos klofibraat en statiene (bv. simvastatien)
- Watertablette (diuretika) soos eplerenoon

Geestesgesondheid, epilepsie en motorneuroon-medisyne:

- Medisyne vir denkversteurings bekend as 'antipsigotika' soos haloperidol, chloorpromasien en aripiprasool
- Medisyne wat vir epilepsie gebruik word, soos karbamasepien, etosuksimied, primidoon en fenitoïen
- Medisyne om u te help slaap (barbiturate)

- Medisyne om angs te kalmeer of te verminder (hipnotika en angswerende middels soos diasepaam, triasolaam, chloordiasepoksied, flurasepaam, prasepaam, zopikloon en zolpidiem)
- Riluzool - gebruik vir motorneuronsiekte
- Sommige medisyne wat vir depressie gebruik word, soos amitriptilien en nortriptilien

Medisyne vir infeksies en die immuunstelsel:

- Medisyne wat gebruik word vir swaminfeksies soos flukonasool, itrakonasool, ketokonasool, vorikonasool, kaspofungin
- Sommige medisyne wat vir 'n MIV-infeksie gebruik word, soos stavudien en zalsitabien
- Sommige medisyne wat vir virusinfeksies gebruik word, soos ritonavir, indinavir, delavirdien, efavirens, amprenavir, nelfinavir, atazanavir, lopinavir, daklatasvir, simeprevir, sofosbuvir en telaprevir. Rifampisien, wat in DUOPIC 150/75 voorkom, kan die vlakke van maraviroc in u bloed verlaag. Dit beteken dat indien u albei medikasie neem, rifampisien maraviroc minder effektief kan maak.
- Medisyne wat gebruik word vir bakteriële infeksies (antibiotika) soos chlooramfenikol, klaritromisien, dapsoon, doksisiklien, fluoorkinolone, telitromisien
  Dapsoon ('n antibiotikum) wat saam met rifampisien geneem word (vervat in DUOPIC 150/75) kan bloedverwante toksisiteit veroorsaak, insluitend 'n afname in beenmurg en bloedselle, sowel as methemoglobinemie ('n toestand waar suurstof in u bloed verminder word as gevolg van veranderinge in rooibloedselle)
- Medisyne wat gebruik word om u immuunstelsel te onderdruk, soos siklosporien, sirolimus en takrolimus
- Prasikwantel - gebruik vir lintwurminfeksies
- Atovaquoon - gebruik vir longontsteking

Hormoon- en kankermedisyne:

- Sommige hormoonmedisyne (anti-estrogene) wat gebruik word vir borskanker of endometriose soos tamoksifeen, toremifeen en gestrinoon
- Sommige hormoonmedisyne (estrogeen, sistemiese hormone, progestogene) wat gebruik word vir voorbehoeding of sommige soorte kanker soos etinielestradiol, levonorgestrel of didrogesteroon
- Irinotekan - gebruik vir kanker
- Levotiroksien (tiroïedhormoon) wat gebruik word vir skildklierprobleme
- Sommige medisyne wat vir kanker (sitotoksika) gebruik word, soos imatinib

Pyn- en inflammasiemedisyne:

- Nie-steroïed anti-inflammatoriese middels (NSAIMs) soos etorikoksib, aspirien en indometasien
- Kortikosteroïede wat gebruik word vir inflammasie soos hidrokortisoon, betametasoon en prednisoloon
- Metadoon - gebruik vir heroïenonttrekking
- Medisyne wat vir pyn gebruik word, soos kodeïen, morfien, alfentaniel, fentaniel of petidien
- Parasetamol en DUOPIC150/75 kan die risiko van lewerskade verhoog

Ander medisyne:

- Ander antibiotiese medisyne soos kefasolien
- Medisyne wat vir diabetes gebruik word, soos chloorpropamied, tolbutamied, sulfonielureums, rosiglitasoon, nateglinied en repaglinied
- Medisyne wat gebruik word om spiere voor operasie te ontspan (narkose) soos halotaan en enfluraan
- Medisyne wat gebruik word om mans met erektiele disfunksie te help ('n toestand waar dit moeilik is om 'n ereksie te kry of te handhaaf), soos tadalafil
- Sommige medisyne wat gebruik word vir naarheid of braking, soos ondansetron en aprepitant
- Kinien - gebruik vir malaria
- Teofillien - gebruik vir hygende asemhaling of asemhalingsprobleme
- Klofazimien (gebruik in die behandeling van melaatsheid)
- Disulfiraam (medisyne wat gebruik word in die behandeling van chroniese alkoholisme)
- Piridoksien (Vitamien B6)
- Levodopa ('n dopamienvervangingsterapie wat gebruik word om Parkinson se siekte en parkinsonistiese simptome te beheer)

Die neem van DUOPIC 150/75 saam met kos, drank en alkohol

Isoniasied, wat in DUOPIC 150/75 vervat is, kan interaksie hê met voedsel wat histamien of tiramien bevat (bv. verouderde kase, verouderde vleis, sommige visse soos tuna, salm en makriel, wyn en bier), wat simptome veroorsaak, insluitend hoofpyn, sweet, blosing, vinnige, ongelyke of kragtige hartkloppings (palpitasies), duiseligheid, lighoofdig of flou voel (as gevolg van lae bloeddruk). Hierdie kosse moet vermy word indien u isoniasied ontvang (vervat in DUOPIC 150/75). U dokter sal verder kan adviseer.

Moenie alkohol drink terwyl u DUOPIC 150/75 neem nie. Dit verhoog u risiko vir lewerskade.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u DUOPIC 150/75 neem.

Veiligheid en doeltreffendheid van DUOPIC 150/75 is nie by swanger of borsvoedende vroue vasgestel nie.

Rifampisien, wat in DUOPIC 150/75 vervat is, kan die voorbehoedmiddel, "die pil", minder goed laat werk. Dit beteken dat u na 'n ander tipe voorbehoeding moet verander. U moet 'n betroubare versperringsmetode van voorbehoeding gebruik, soos kondome of ‘n inplanting terwyl u DUOPIC 150/75 neem. Indien u enige vrae het of onseker is hieroor, raadpleeg u dokter of apteker.

DUOPIC 150/75 gaan in moedersmelk oor en u moenie u baba borsvoed terwyl u DUOPIC 150/75 neem nie.

Bestuur en gebruik van masjinerie

U kan duiselig of flou voel, probleme met sig hê of ander newe-effekte hê wat u vermoë om te bestuur kan beïnvloed terwyl u DUOPIC 150/75 neem.

Dit is nie altyd moontlik om te voorspel in watter mate DUOPIC 150/75 met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie 'n voertuig bestuur of masjinerie hanteer voordat u bewus is van die mate waartoe DUOPIC 150/75 u beïnvloed nie.

3. Hoe om DUOPIC 150/75 te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd DUOPIC 150/75 presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Hou aan om hierdie medisyne te neem

U moet die tablette elke dag neem vir die hele tyd wat die dokter u gesê het om dit te neem.

Die algemene dosis is:

Volwassenes en bejaardes wat minder as 38 kg weeg

2 tablette elke dag

Volwassenes en bejaardes wat minder as 55 kg weeg
3 tablette elke dag

Volwassenes en bejaardes wat meer as 55 kg weeg
4 tablette elke dag

Volwassenes en bejaardes wat meer as 71 kg weeg
5 tablette elke dag

Indien u bejaard is, kan u dokter u behandeling meer noukeurig monitor.

Kinders
Hierdie medisyne word nie aanbeveel vir gebruik by kinders nie.

Neem hierdie medisyne per mond
Sluk die tablette heel, met ‘n sluk water
Neem al u tablette tegelykertyd elke dag, as 'n enkele dosis

U dokter sal u inlig hoe lank u behandeling met DUOPIC 150/75 sal duur. Moenie die behandeling voortydig stop nie, want u TB sal nie behoorlik behandel word nie. Indien u die indruk het dat die effek van DUOPIC 150/75 te sterk of te swak is, lig u dokter of apteker in.

Indien u meer DUOPIC 150/75 neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Simptome van oordosis kan die volgende insluit:
Naarheid (voel naar), braking (opgooi), maagpyn, jeukerigheid, hoofpyn, voel moeg, slaperig, duiselig, lighoofdig, het vae of vreemde visioene (hallusinasies), flou val of voel flou, stuipaanvalle, disoriëntasie, onduidelikheid van spraak, koma, hiperglukemie, spierpyn, moegheid, gereelde urinering, dors, droë mond. Ander tekens van te veel medisyne neem sluit in vinnige hartklop, ongelyke hartslag, stuipaanvalle en hartaanval.

Indien u vergeet om DUOPIC 150/75 te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u ophou om DUOPIC 150/75 te neem

Moenie die tablette staak en weer begin nie. Dit kan die risiko van newe-effekte verhoog, en u TB sal nie behoorlik behandel word nie.

4. Moontlike newe-effekte

DUOPIC 150/75 kan newe-effekte hê.

Nie alle newe-effekte wat vir DUOPIC 150/75 aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u DUOPIC 150/75 neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak DUOPIC 150/75 en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- veluitslag of jeukerigheid.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op DUOPIC 150/75 gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

Gereelde newe-effekte

- u kneus makliker as gewoonlik. Of u kan 'n pynlike veluitslag van donkerrooi kolle onder die vel hê wat nie verdwyn wanneer u daarop druk nie (purpura). Dit kan wees as gevolg van 'n ernstige bloedingsprobleem.

Minder gereelde newe-effekte

- u kry makliker meer infeksies as normaal. Tekens sluit in koors, seer keel of mondsere. Dit kan wees omdat u 'n lae aantal witbloedselle het.
- u erge bloeding het.
- u het 'n skielike erge hoofpyn. Dit kan 'n teken wees van bloeding in die brein.

Onbekende frekwensie

- Pellagra: simptome kan diarree, veluitslag (veral in sonblootgestelde areas), geestelike verwarring en geheueprobleme insluit. In ernstige gevalle kan onbehandelde pellagra dodelik wees.
- Nuwe of skielike verergering van kortasem en hygende asemhaling, moontlik met hoes of koors. Dit kan simptome van inflammasie van die longe wees (interstisiële longsiekte/ longontsteking).
- inflammasie van die lewer – vergeling van die vel en wit deel van oë, toename in die bloedvlak van lewerensieme.
- Ernstige veluitslag, insluitend Stevens-Johnson se sindroom, toksiese epidermale nekrolise. Dit kan voorkom as rooierige teikenagtige makules of sirkelvormige kolle, dikwels met sentrale blase op die romp, velafskilfering, sere van mond, keel, neus, geslagsdele en oë, en kan voorafgegaan word deur koors en griepagtige simptome. Sien ook afdeling 2.
- Wydverspreide uitslag, hoë liggaamstemperatuur, verhoging van lewerensieme, bloedafwykings (eosinofilie), vergrote limfknope en betrokkenheid van ander liggaamsorgane (geneesmiddelreaksie met eosinofilie en sistemiese simptome wat ook bekend staan as GRESS of geneesmiddel-hipersensitiwiteitsindroom). Sien ook afdeling 2.
- kortasem en hygende asemhaling.
- u voel verward, slaperig, en kry ‘n koue klam vel, vlak of moeilike asemhaling, 'n jagende hartklop, of u vel is bleker as normaal. Hierdie kan tekens van skok wees.
- 'n Rooi, skubberige wydverspreide uitslag met knoppe onder die vel en blase, wat gepaard gaan met koors met die aanvang van behandeling (akute algemene eksantemateuse pustulose). Sien ook afdeling 2.
- U het bloed in u urien of 'n toename of afname in hoeveelheid urien wat u produseer. U kan ook swelling kry, veral van die bene, enkels of voete. Dit kan veroorsaak word deur ernstige nierprobleme.
- U het kouekoors, moegheid, buitengewone bleek velkleur, kortasem, vinnige hartklop of donkerkleurige urien. Dit kan tekens wees van 'n ernstige tipe bloedarmoede.
- Eosinofiliese agranulositose: Dit is 'n seldsame toestand waar u liggaam te veel van sekere soorte witbloedselle, genaamd eosinofiele het, wat inflammasie en allergiese reaksies kan veroorsaak. Dit kan ook beteken dat u te min ander soorte witbloedselle (genaamd granulosiete) het, wat u meer kwesbaar maak vir infeksies.
- Vitamien K-afhanklike stollingsversteurings: Dit is probleme met u bloedstollingstelsel wat veroorsaak word deur 'n gebrek aan vitamien K. Vitamien K is nodig vir u liggaam om sekere proteïene te produseer wat u bloed behoorlik help stol. Sonder genoeg daarvan,

kan u dalk probleme ondervind om op te hou bloei.

- U bloei uit u neus, oor, tandvleis, keel, vel of maag. Tekens sluit in 'n gevoel van gevoeligheid en swelling in u maag, pers kolle op u vel en swart of teeragtige stoelgang.
- Erge waterige diarree wat nie sal ophou nie, en u swak laat voel, en u het koors. Dit kan iets wees wat 'pseudomembraan-kolitis' genoem word.
- Geestelike probleme met ongewone gedagtes en vreemde visioene (hallusinasies).
- Stuipaanvalle wat erger word, of u begin stuipaanvalle kry.
- Inflammasie van die pankreas, wat erge pyn in die buik en rug veroorsaak (pankreatitis, frekwensie nie bekend nie).
- Griepagtige simptome, insluitend kouekoors, koors, hoofpyn, duiseligheid en beenpyne.
- Vergeling van die vel of wit van die oë, of urien wat donkerder word en ontlasting ligter, moegheid, swakheid, malaise, verlies aan eetlus, naarheid of braking wat veroorsaak word deur lewerprobleme of lewerbesering.
- Bloedklonte in klein bloedvate (trombotiese mikroangiopatie) - simptome kan verhoogde kneusing, bloeding, koors, uiterste swakheid, hoofpyn, duiseligheid of lighoofdigheid insluit. U dokter kan veranderinge in u bloed en die funksie van u niere bevind.
- Simptome wat verband hou met serebellêre sindroom: swak koördinasie, swak balans, verandering in spraak, onwillekeurige oogbewegings.
- Paradoksale geneesmiddelreaksies (simptome van tuberkulose kan terugslaan of nuwe simptome kan voorkom na aanvanklike verbetering tydens behandeling).

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte

- Hoofpyn
- Duiseligheid
- Naar voel of braak
- Koors, kouekoors
- Verhoogde bloedresultate soos bilirubien, lewerensieme

Minder gereelde newe-effekte

- Diarree
- Waterretensie (edeem) wat geswelde gesig, maag, arms of bene kan veroorsaak
- Stuiptrekkings

- Korttermyn geheueverlies, angs, minder waaksaam wees of stadiger reageer
- Tydelike sigverlies

Onbekende frekwensie van newe-effekte

- Gewigsverlies, nagsweet en koors. Dit kan tekens wees van 'n bloedtoestand genaamd eosinofilie
- Verminderde eetlus
- Inflammasie van die bloedvate
- Blosende vel of jeukerigheid
- Galbulte
- Pynlike sere en blase op u vel en in u mond
- Hardlywigheid, ongemak op die maag of droë mond
- Spierswakheid of pyn of verlies aan spierreflekse
- Swaar bloeding na die geboorte van u baba, fetale bloed wat in die moeder se sirkulasie invloei, voor of tydens die bevalling
- Onreëlmatige menstruasie
- U het een van 'n groep afwykings wat senuwee- of velprobleme kan veroorsaak (porfirie)
- Duiseligheid, voel lighoofdig en val flou, veral indien u vinnig staan of regop sit (as gevolg van lae bloeddruk)
- Balans-probleme met duiseligheid (vertigo)
- Ongewone velsensasies soos gevoelloosheid, tinteling, prikkeling, branderigheid of kruip-gevoel op die vel (parestesie)
- Aknee
- Naarheid, braking, slegte spysvertering
- Borsvergroting by mans
- Verhoogde dors, meer gereeld toilet toe gaan en moeg voel, u bloedsuiker kan hoog wees
- Outo-teenliggaampies kan u gewrigte, vel, spiere en ander dele van u liggaam beskadig
- Koors
- Haarverlies

U mag 'n verkleuring (geel, bruin, oranje of rooi kleur) in u tande, urien, sweet, slym (sputum), speeksel of trane sien. Dit is redelik algemeen en u hoef nie bekommerd te wees nie. Die kleur kan egter sagte kontaklense permanent vlek. Die kleur in trane kan 'n geruime tyd aanhou nadat u opgehou het om DUOPIC 150/75 te neem.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u

dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldings-platform (who-umc.org), wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van DUOPIC 150/75 te verskaf.
U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-posadres te gebruik: Adcock.AEReports@adcock.com.

5. Hoe om DUOPIC 150/75 te bêre

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
PVC/PVDC stulpverpakking: Bêre teen of benede 25 °C. Bêre in die oorspronklike houer om teen lig en vog te beskerm.
Aluminiumfoelie stulpverpakking: Bêre teen of benede 30 °C.
Moenie gebruik ná die vervaldatum wat op die kartonboksie aangedui word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat DUOPIC 150/75 bevat

Die aktiewe bestanddele is rifampisien 150 mg en isoniasied 75 mg.
Die ander bestanddele is:
Tabletkern – askorbiensuur, kolloïdale silikondioksied, kruispovidoon, magnesiumstearaat, mikrokristallyne sellulose en voorgegelatiniseerde stysel.
Bedekkingsmateriale – hipromellose, ysteroksiedrooi, poliëtileenglikol 4000, simetikoon-emulsie, talk en titaniumdioksied.

Hoe DUOPIC 150/75 lyk en die inhoud van die verpakking

DUOPIC 150/75 tablette is baksteenrooi-gekleurde kapsuulvormige bikonvekse filmbedekte tablette, breeklyn aan die een kant en gewoon aan die ander kant.

DUOPIC 150/75 tablette is verpak in Alu/Alu stulpverpakkings of PVC/PVDC stulpverpakkings. Die stulpstroke word in 'n buitenste kartonboksie met 'n biljet verpak.

PASIËNT INLIGTINGSBILJET

Verpakkingsgroottes: 56, 84, 90 of 672 tablette.

Nie alle verpakkingsgroottes en verpakkingstipes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie

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Hierdie biljet is mees onlangs hersien op

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