

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 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 liver damage.
- If you are taking saquinavir or ritonavir for an HIV infection (see 'Other medicines and DUOPIC 150/75' section below).

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 having 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 have 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.
- Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), 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.)

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

- Saquinavir or ritonavir used for HIV infection

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-aminosalicylic acid (PAS) and cycloserine. PAS and DUOPIC 150/75 should be taken at least 8 hours apart

Tell your doctor if you are taking any of the following medicines:

- Heart and blood medicines
- Medicines for high blood pressure
- Medicines for heart problems or to control your heartbeat
- Medicines used to thin the blood such as warfarin

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- Medicines used to lower cholesterol
- Water tablets (diuretics) such as eplerenone

Mental health, epilepsy and motor neurone medicines:

- Medicines for thought disorders known as 'antipsychotics' such as haloperidol
- Medicines used for epilepsy such as phenytoin and carbamazepine
- Medicines to help you sleep (barbiturates)
- Medicines to calm or reduce anxiety (hypnotics, anxiolytics)
- 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
- Some medicines used for an HIV infection such as stavudine and zalcitabine
- Some medicines used for viral infections such as indinavir, efavirenz, amprenavir, nelnavir, atazanavir, lopinavir, nevirapine, daclatasvir, simeprevir, sofosbuvir and telaprevir
- Medicines used for bacterial infections (antibiotics)
- 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, fentanyl or pethidine

Other medicines:

- Other antibiotic medicines such as cefazolin
- Medicines used for diabetes
- Medicines used to relax muscles before surgery (anaesthetics) such as halothane
- 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

Taking DUOPIC 150/75 with food and drink

Isoniazid 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. Your doctor will be able to advise further.

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.

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.

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

- serious skin rashes including Steven-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.
- 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.

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- 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.

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

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 “**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 DUOPIC 150/75.

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 and isoniazid.

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.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

South Africa

Customer Care: 0860 ADCOCK / 232625

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