

SCHEDULING STATUS: **S4**

DUOPIC PAED, 75 mg, 50 mg, dispersible tablets

Rifampicin and Isoniazid

Sugar free.

Contains sweetener: aspartame 2 mg and saccharin sodium 2 mg (per tablet)

Read all of this leaflet carefully before you start giving DUOPIC PAED

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DUOPIC PAED has been prescribed for your child and you should not share this 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 DUOPIC PAED is and what it is used for
2. What you need to know before you give your child DUOPIC PAED
3. How to give your child DUOPIC PAED
4. Possible side effects
5. How to store DUOPIC PAED
6. Contents of the pack and other information

1. What DUOPIC PAED is and what it is used for

DUOPIC PAED contains rifampicin and isoniazid. They both belong to a group of medicines called tuberculostatics.

DUOPIC PAED is indicated for tuberculosis (also known as TB) of the lungs in children.

2. What you need to know before you give your child DUOPIC PAED

Do not give DUOPIC PAED:

- if your child is hypersensitive (allergic) or has a history of being hypersensitive to rifampicin, other rifampicins, isoniazid or any of the other ingredients of DUOPIC PAED (see section 6).
- if your child has yellowing of the skin or liver problems.
- if your child has kidney or liver problems, diabetes, history of gout, suffering from fits or a rare hereditary disease called porphyria, with symptoms like severe abdominal pain, constipation or diarrhoea, nausea and vomiting, red or brown urine.
- if you are taking medicine for HIV/AIDS called nevirapine or the combination of saquinavir and ritonavir.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with DUOPIC PAED:

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If your child has kidney or liver problems, your child should not be given DUOPIC PAED. If it is the only treatment option available, your doctor or healthcare provider will monitor your child's liver function via blood tests every two to four weeks.

DUOPIC PAED may cause liver problems. You should be attentive to symptoms of liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine, yellow discolouration of the skin (jaundice), persistent fatigue of greater than 3 days duration and abdominal pain and tenderness in your child. If these occur, you should immediately report this to your child's healthcare provider.

Your child's urine, stool, saliva, sweat and tears may change colour, and soft contact lenses may be permanently stained as a result of being given DUOPIC PAED.

If your child develops kidney problems or a blood disorder, where the red blood cells are destroyed faster than they can be made, your child should discontinue the treatment.

DUOPIC PAED may enhance the functioning of certain hormones and vitamin D.

Your healthcare provider will monitor your child closely as there is a possibility that your child may develop an allergic reaction towards DUOPIC PAED. For this reason, do not interrupt the treatment if not advised by your healthcare provider.

If your child gets flu-like symptoms such as fever, headache, muscle aches, etc. you should report this to your child's healthcare provider, since DUOPIC PAED may be the cause.

Your healthcare provider will monitor your child's blood counts during treatment, as your child may develop certain blood disorders.

DUOPIC PAED may reduce the functioning of certain medicine like antiretrovirals (used to treat HIV/AIDS), medicine for epilepsy (fits/seizures), immunosuppressants (medicine used to lower the functioning of the immune system) and warfarin (medicine used to treat blood clots).

If your child is allergic to ethionamide (used to treat TB), pyrazinamide (used to treat TB) or niacin (vitamin B3), you should inform your child's healthcare provider, because your child may also be allergic to DUOPIC PAED.

Tingling in the hands and feet (peripheral neuropathy) is the most common side effect of isoniazid, one of the active ingredients in DUOPIC PAED, particularly in HIV-positive and malnourished children being treated for TB. You should report any such symptoms to your child's healthcare provider. A certain vitamin, pyridoxine, should be administered routinely at doses of 5-10 mg per day during treatment with DUOPIC PAED, as it reduces the risk of developing a nerve called neuropathy.

If your child has diabetes, your child should be closely monitored.

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If your child has epilepsy or a history of psychiatric disease, you should report this to your child's healthcare provider, as these conditions may affect your child's ability to tolerate DUOPIC PAED.

If your child is taking cortisone or any cortisone-like medicine, you should report this to your child's healthcare provider, as the cortisone dose may have to be increased whilst taking DUOPIC PAED.

If your child experiences reappearance or worsening of symptoms of tuberculosis (paradoxical drug reaction), you should inform your child's healthcare provider immediately.

Other medicines and DUOPIC PAED

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

Taking any other medicines may affect how DUOPIC PAED works, or DUOPIC PAED may affect how the other medicines work.

Your child should not be given DUOPIC PAED with any of the following:

- nevirapine (used to treat HIV infection)
- saquinavir/ritonavir combination (used to treat HIV infection)
- inhalation anaesthetics (used during surgery)
- ketoconazole (a medicine used to treat fungal infections)
- aluminium hydroxide (medicine used to treat diseases related to the gastric acid)
- disulfiram (medicine used for the treatment of chronic alcoholism).

DUOPIC PAED may reduce the activity of the following medicines:

- azathioprine, ciclosporin (used to lower the functioning of the immune system)
- chloramphenicol, doxycycline (antibiotic)
- cimetidine (used to treat stomach ulcer)
- clofibrate (treats high cholesterol)
- corticosteroid (lowers inflammation in the body)
- dapsone (used to treat leprosy)
- diazepam (used to treat anxiety and fits)
- fluconazole, itraconazole, ketoconazole (used to treat fungus infections)
- haloperidol (used to treat mood disorders)
- hexobarbitone (sedative)
- methadone (pain medication)
- oral hypoglycaemic medicines (used to treat diabetes)
- phenytoin (used to treat fits/seizures)
- quinine (used to treat malaria)
- sulfasalazine (used to treat arthritis)
- thyroid hormones

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- theophylline (used to treat asthma)
- zidovudine, delavirdine, efavirenz (used to treat HIV)
- beta-adrenoceptor blocking medicine (used to treat abnormal heart rhythms i.e. acebutolol and atenolol)
- digoxin (used to treat various heart conditions)
- disopyramide, lorcinide, mexiletine, propafenone, quinidine, tocainide, verapamil (used to treat abnormal heart rhythm)
- calcium-channel blocking medicines (used to treat high blood pressure i.e. amlodipine, nifedipine)
- oral contraceptives
- narcotics
- analgesics (pain medication)
- barbiturates (used to treat anxiety and fits/seizures).

DUOPIC PAED may enhance the effects of some medicine:

- phenytoin (used to treat fits/seizures)
- primidone (used to treat seizures and tremors)
- carbamazepine (used to treat fits/seizures)
- ethosuximide (used to treat absence seizures)
- benzodiazepines (tranquilizers i.e. diazepam, triazolam)
- warfarin (used to treat blood clots)
- theophylline (used to treat respiratory problems).

Take special care when giving DUOPIC PAED with the following medicines:

- cycloserine (used to treat TB) as side effects may be worse
- disulfiram (used to treat alcoholism) as side effects may be worse
- alcohol may affect the effect of DUOPIC PAED
- alfentanil (pain medication during surgery) may affect the effect of DUOPIC PAED
- aminosalicylic acid (antibiotic used to treat TB) may affect the effect of DUOPIC PAED
- large doses of pyridoxine (Vitamin B6) may affect the effect of DUOPIC PAED
- antacids may reduce the absorption of DUOPIC PAED and reduce the effect
- concurrent use of chronically used paracetamol, alcohol and other medicine which may cause liver toxicity, may increase the possibility of DUOPIC PAED causing liver toxicity.
- ARV's like stavudine and zalcitabine can cause a nerve disease called peripheral neuropathy (symptoms include tingling of the hands and feet).

The active ingredients in DUOPIC PAED may also interact with a number of other medicines, including the following:

- medicines used to treat HIV infection (e.g. tenofovir alafenamide, emtricitabine, efavirenz, tenofovir disoproxil fumarate, abacavir, nevirapine, etravirine, dolutegravir, maraviroc)
- medicines to treat fungal infections (e.g. voriconazole)
- certain antibiotics (e.g. clarithromycin, chloramphenicol, ethionamide)

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- medicines to treat malaria (e.g. quinine, chloroquine, mefloquine, lumefantrine, amiodaquine, artemisinin)
- immunosuppressant medicines (e.g. ciclosporin, tacrolimus)
- medicines to treat heart conditions (e.g. verapamil, digoxin, atenolol, lidocaine, amlodipine, enalapril)
- medicines to treat cholesterol (e.g. simvastatin, atorvastatin)
- some medicines to treat diabetes (e.g. glibenclamide)
- medicines to treat epileptic seizures (e.g. carbamazepine, valproic acid, phenobarbitone, lamotrigine)
- medicines used to help you sleep (benzodiazepines, e.g. flurazepam, triazolam, midazolam, zolpidem)
- medicines for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol, amitriptyline)
- medicines used during surgery (narcotics, e.g. enflurane)
- levothyroxine (use to treat thyroid conditions)
- pain killers, e.g. morphine, codeine
- praziquantel (used to treat worm infections).

Taking any of these medicines together with DUOPIC PAED may either be unsuitable or require dose adjustment.

DUOPIC PAED with food, drink and alcohol

DUOPIC PAED should be dispersed in as little as 5 ml of water, or chewed, taken orally, on an empty stomach as a single dose.

DUOPIC PAED should be taken at least 1 hour before aluminium containing antacids are used.

Patients should not drink alcohol while taking DUOPIC PAED as this increases the risk of liver damage.

When taken with cheese or fish (histamine- or tyramine-rich food) DUOPIC PAED may cause redness/itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, and/or light-headedness. If your child experiences these side effects, your child should avoid eating cheese and fish while taking DUOPIC PAED.

Pregnancy and breastfeeding

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 healthcare provider for advice before taking DUOPIC PAED.

Driving and using machines

DUOPIC PAED may cause dizziness, impaired concentration, and drowsiness.

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It is not always possible to predict to what extent DUOPIC PAED may interfere with your daily activities. You should ensure that your child does not engage in the above activities until they are aware of the measure to which DUOPIC PAED affects them.

DUOPIC PAED contains aspartame

Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to give your child DUOPIC PAED

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

Always give DUOPIC PAED exactly as your healthcare provider has instructed you. You should check with your healthcare provider or pharmacist if you are unsure.

For the continuation phase of TB treatment:

The dose of DUOPIC PAED is decided on the basis of your child's body weight.

The usual dose is:

Weight	Number of dispersible tablets
4 - 7 kg	1 dispersible tablet
8 - 11 kg	2 dispersible tablets
12 - 15 kg	3 dispersible tablets
16 - 24 kg	4 dispersible tablets
25 kg +	Adult dosages recommended

For children weighing 25 kg and above, adult dosages are recommended.

Your healthcare provider will tell you how long your child's treatment with DUOPIC PAED will last. Do not stop treatment early because your child's infection may come back.

If you have the impression that the effect of DUOPIC PAED is too strong or too weak, tell your healthcare provider or pharmacist.

If you give your child more DUOPIC PAED 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:

- your child may also get a reddish-orange discolouration of the skin and mucous membranes, facial swelling and itching
- high blood glucose levels, vomiting, gastrointestinal disturbances, slurring of speech, fits/seizures, coma, hallucinations, difficulty breathing, central nervous system depression, fatalities.

If you forget to give your child DUOPIC PAED

Give your child DUOPIC PAED as soon as you remember, then continue to give DUOPIC PAED at the usual times. Do not give a double dose to make up for forgotten individual doses.

If you stop giving you child DUOPIC PAED

You should not stop giving your child DUOPIC PAED without speaking to your child's healthcare provider. Stopping treatment with DUOPIC PAED too early may no longer protect your child from the infection and can cause it to come back.

4. Possible side effects

DUOPIC PAED can have side effects.

Not all side effects reported for DUOPIC PAED are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while being given DUOPIC PAED, please consult your healthcare provider for advice.

If any of the following happens, stop giving your child DUOPIC PAED and tell your healthcare provider 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.

These are all very serious side effects. If your child has them, your child may have had a serious reaction to DUOPIC PAED. Your child may need urgent medical attention or hospitalisation.

Tell your healthcare provider immediately or go to the casualty department at your nearest hospital if you notice your child has any of the following:

- diarrhoea that is serious, lasts a long time or has blood in it with
- stomach pain or fever as this can be a sign of serious bowel inflammation,
- hepatitis (swelling and inflammation of the liver, characterised by symptoms such as, abdominal pain or distension, dark urine and pale or clay-coloured stools, fatigue, fever, general itching, yellowing of the skin or eyes, loss of appetite, nausea and vomiting), jaundice,
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis),
- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters),
- muscle weakness, involuntary twitching, poor decision making or concentration, trembling, difficulty speaking (toxic encephalopathy),
- renal failure,
- sudden increase in blood pressure (hyperreflexia), bleeding in the brain,
- toxic exfoliative dermatitis (a severe inflammation of the entire skin surface).

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

Tell your healthcare provider if you notice any of the following in your child:

Frequent side effects:

- weakness, numbness and pain from nerve damage, usually in the hands and feet,
- redness of eyes, discoloration of soft contact lenses,
- diarrhoea, abdominal pain, nausea, loss of appetite, vomiting,
- elevated liver activity blood test results,
- disturbances of menstrual cycle,
- flushing, reddish discoloration of body fluids like urine, tears, saliva and sweat, lower blood pressure, shock,
- skin reactions which consist of redness and itching, with or without a rash,
- muscle weakness and muscle disease,
- constipation, dry mouth.

Less frequent side effects:

- worsening of porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin),
- impaired memory,
- medicine induces psychosis,
- headache, lack of energy, impaired balance or coordination, difficulty concentration, dizziness, seizures/fits,
- pink eye,
- stomach inflammation, swelling or inflammation of the large intestine,
- sun allergy, redness and peeling of the skin over large areas of the
- body, skin condition called pemphigoid (symptoms include itching skin, large blisters), a rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or organ,
- inflammation of the kidney,
- several blood disorders,
- confusion, generalised numbness,
- blurred vision, eye irritation,
- loss of hearing,
- hypersensitivity skin reactions, an inflammation of the blood vessels that causes changes in the blood vessel walls, medicine-induced hypersensitivity reaction that presents with skin rash, involvement of internal organs like liver, lung, or kidney,
- flu syndrome, a fever reaction with flu-like symptoms, fungal overgrowth i.e. sore mouth or tongue,
- swollen lymph nodes, reactions which is similar to a disease called Lupus (an inflammatory disease caused when the immune system attacks its own tissues),
- a condition in which too much acid accumulates in the body,
- psychotic reactions (characterised by delusions, hallucinations and confusion), memory impairment,

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- nerve condition associated with pins and needles, loss of tendon reflexes, increase in frequency of fits in epileptic patients,
- blurred vision or loss of vision, with or without eye pain,
- vertigo,
- pellagra (a disease caused by a lack of the vitamin niacin (vitamin B3). Symptoms include inflamed skin, diarrhoea, dementia, and sores in the mouth), acne,
- urinary retention,
- male breast enlargements.

Side effects with an unknown frequency:

- bleeding into the skin, bruising and slow blood clotting after an injury (thrombocytopenia),
- shortage of white blood cells, accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis),
- hallucinations (strange visions or sounds),
- tremors, sleeplessness,
- vision problems due to death or inflammation of cells in your eye,
- flatulence, constipation,
- joint pain,
- a lung disease that occurs when lung tissue becomes damaged and scarred, inflammation of lung tissue, shortness of breath, wheezing,
- ulcerative colitis (chronic, inflammatory bowel disease that causes inflammation in the digestive tract), gastrointestinal bleeding,
- swelling of the face, arms and legs,
- hair loss, hives,
- rheumatic syndrome (autoimmune and inflammatory diseases that cause your immune system to attack your joints, muscles, bones and organs).

If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider or pharmacist.

Reporting of side effects

If your child gets side effects, talk to your doctor or pharmacist or nurse. 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 PAED.

5. How to store DUOPIC PAED

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Protect from moisture and light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the carton.

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- 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 PAED contains

The active ingredients are rifampicin 75 mg and isoniazid 50 mg.

The other ingredients are:

Ascorbic acid, aspartame, colloidal silicon dioxide, colour ponceau 4R supra, crospovidone, flavour raspberry SD 9.07677, flavour strawberry SD 9.01737, magnesium stearate, microcrystalline cellulose, pregelatinized starch, saccharin sodium.

What DUOPIC PAED looks like and contents of the pack

Brick red coloured, flat faced bevelled edged, mottled, circular uncoated tablet plain on both sides with characteristic flavour.

Pack sizes: 28, 30, 56, 60, 84, 90, 112, 120 dispersible tablets

Aluminium strip pack:

6 or 10 or 28 dispersible tablets shall be packed per strip using plain strip aluminium foil as a base material and plain strip aluminium foil as a lidding material. Strips are packed into a printed outer carton.

Aluminium blister pack:

5 or 28 dispersible tablets shall be packed per blister using plain aluminium foil as a lidding material and cold forming Alu-Alu foil base material. Blisters are packed into a printed outer carton.

Not all pack types and pack sizes may be marketed.

Holder of Certificate of Registration

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