Scheduling status:

S4

PATIENT INFORMATION LEAFLET

DARUNAVIR 75/150/400/600 (film coated tablets)

Product name, strength and pharmaceutical form:

Read all of this leaflet carefully before you start taking PARANVIR 75/150/400/600

• Keep this leaflet; you may need to read It again.

• If you have further questions, please ask your doctor or your pharmacist.

• PARANVIR 75/150/400/600 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 **PARANVIR 75/150/400/600** is and what it is used for
2. What you need to know before you take **PARANVIR 75/150/400/600**
3. How to take **PARANVIR 75/150/400/600**
4. Possible side effects
5. How to store **PARANVIR 75/150/400/600**
6. Contents of the pack and other information

1. What PARANVIR 75/150/400/600 is and what it is used for:

PARANVIR 75/150/400/600 (darunavir ethanolate) belongs to a class of medicine known as antiviral medicines.

PARANVIR 400/600 is indicated for the treatment of HIV (Human immunodeficiency virus) infection with a low dose of ritonavir for antiretroviral treatment-experienced adults.

PARANVIR 75/150 is indicated for the treatment of HIV (Human immunodeficiency virus) infection with a low dose of ritonavir for antiretroviral treatment-experienced children from 6 to less than 18 years old.

2. What you need to know before you take PARANVIR 75/150/400/600:

Contact your doctor if you are not sure if you belong to a patient group described below.

Do not take PARANVIR 75/150/400/600 if:

- you or your child are hypersensitive to darunavir or any of its ingredients,
- your child is below the age of three years,
- you or your child have severe liver problems,
- you or your child are hypersensitive to ritonavir,
- you or your child are taking a combined product containing lopinavir/ ritonavir or quetiapine,

- you or your child are taking other medicines that depend on liver enzymes to break it down and which may be associated with life threatening adverse effects,
- you or your child are taking any of the following medicines:

➢ carbamazepine, phenobarbitone or phenytoin,

➢ rifampicin or rifabutin,

- sildenafil (when used for high blood pressure),

➢ alfuzosin,

➢ dihydroergotamine, ergonovine, ergotamine or methyergonovine,

➢ herbal products such as St. John's Wort (Hypericum perforatum),

➢ lovastatin or simvastatin,

➢ pimozide,

➢ midazolam or triazolam,

➢ ketoconazole, itraconazole or voriconazole,

➢ buprenorphine or naloxone,

➢ amiodarone,

➢ colchicine if you have kidney or liver problems,

➢ cisapride,

➢ dabigatran or ticagrelor,

➢ antihistamines for example astemizole,

➢ bosentan,

➢ boceprevir or telaprevir.

Warnings and Precautions

Take special care with PARANVIR 75/150/400/600:

The presence of other medical conditions may affect the use of **PARANVIR 75/150/400/600.** Tell your doctor or pharmacist if any of the following applies to you or your child, as you may require special monitoring or a lower dose:

- if you have kidney or liver problems,
- if you are elderly (over 65 years old),
- if you develop symptoms of fat redistribution,
- if you develop Immune Reconstitution Inflammatory Syndrome (IRIS) or other autoimmune disease whereby the body's natural defences attack the body's own healthy tissue,
- if you develop and bone pain, limping, limited range of motion (osteonecrosis),
- if you get any opportunistic infections due to a low immune system,
- if you have any sexual contact or blood exposure as **PARANVIR** does not prevent the risk of HIV transmission,
- if you develop signs of a skin rash which can become very severe and painful (Steven-Johnson Syndrome),
- if you are allergic to sulphur,
- if you get diabetes (high blood glucose and lipid levels),
- if you are using oral contraceptives,
- if you are using sildenafil, vardenafil or tadalafil for other uses except high blood pressure,
- if you have a disorder in which blood does not clot normally (haemophilia).

Children (and adolescents)

The safety of **PARANVIR** in children aged between three and less than six years have not been established. **PARANVIR** should not be taken by children who have not had prior HIV treatment.

Other medicines with PARANVIR 75/150/400/600:

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

The following medicines or substances may increase or decrease blood levels and increase the risk of adverse events associated with **PARANVIR**, so please inform your doctor if you or your child are taking any of the following medicines before you start treatment with **PARANVIR**:

- Antiretrovirals (ARVs) to treat the Human Immunodeficiency Virus (HIV) such as:
  - etravirine,
  - efavirenz,
  - nevirapine,
  - rilpivirine,
  - ritonavir,
  - combination product containing lopinavir and ritonavir,
  - saquinavir,
  - atazanavir,
  - indinavir.
  - Other medicines
- alfuzosin for improving urination in men,

- buprenorphine used for pain and naloxone used to treat drug overdose,
- bepridil, lidocaine, quinidine and amirodarone used to treat irregular heartbeat,
- digoxin to treat heart failure,
- warfarin used to prevent blood clots,
- clonazepam, phenobarbitone, phenytoin or carbamazepine used to prevent convulsions,
- colchicine used to treat gout (acid crystals in the joints),
- felodipine, nifedipine, nicardipine, amlodipine, diltiazem and verapamil used to treat high blood pressure and decrease the heart's workload,
- rifampicin or rifabutin used to treat infections such as tuberculosis,
- clarithromycin antibiotic,
- dexamethasone to treat inflammation,
- bosentan used to treat high blood pressure,
- dihydroergotamine, ergonovine, ergotamine, methylergonovine used to treta migraines,
- inhaled corticosteroids such as fluticasone, betamethasone, budesonide, mometasone, prednisone or triamcinolone,
- taleprevir and boceprevir used to treat Hepatitis C Virus,
- rosuvastatin, simvastatin, lovastatin, pravastatin or atorvastatin used to treat high cholesterol,
- omeprazole or ranitidine used to treat stomach ulcers,
- inhaled salmeterol used to treat asthma,
- immunosuppressant medicines (ciclosporin, tacrolimus, sirolimus),

- ketoconazole, itraconazole or voriconazole used to treat fungal infections,
- antimalarials (artemether or lumefantrine),
- methadone used to treat drug addiction,
- midazolam or triazolam used as to make you sleep or to treat mental health,
- oestrogen or progestogen contraceptives,
- fentanyl, oxycodone, tramadol used to treat pain,
- sildenafil, vardenafil or tadalafil used to treat difficulty having or maintaining an erection,
- pimozide used to treat uncontrolled movements or outbursts,
- paroxetine, sertraline, trazodone, amitriptyline, desipramine, imipramine or nortriptyline used as antidepressants,
- St. John's Wort (Hypericum perforatum) used to treat depression,
- risperidone to treat mental conditions,
- dasatinib, nilotinib, vinblastine, vincristine or everolimus used to treat cancer,
- carvedilol, metoprolol or timolol to treat heart failure and high blood pressure.

PARANVIR 75/150/400/600 with food and drink:

PARANVIR should be taken with food.

Swallow whole tablets with a drink of water or milk.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PARANVIR.

Do not take **PARANVIR** while you are pregnant or breastfeeding.

Driving and using machinery:

Side effects associated with **PARANVIR** include dizziness which may occur. This side effect may alter and negatively affect your ability to drive or operate machines.

3. HOW TO TAKE PARANVIR 75/150/400/600:

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

Always take **PARANVIR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

PARANVIR must be taken with food.

The usual dose of **PARANVIR** is:

- Adults: 600 mg twice a day or 800 mg daily depending on the level of infection.
- Children from 6 to 18 years: the dose varies and is dependent on the weight of the child.

  Speak to your doctor who will confirm the exact dose for you.

  Your doctor will tell you how long your treatment will last.

If you have the impression that the effect of **PARANVIR** is too strong or too weak, tell your doctor or pharmacist.

If you take more PARANVIR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PARANVIR:

If a dose of **PARANVIR** and ritonavir was missed within 12 hours (once daily dose) or 6 hours (twice a day dose) of the time it is usually taken, then you can take the prescribed dose with food as soon as possible.

If you missed a dose by more than 12 hours (once daily dose) or 6 hours (twice a day dose), do not take a double dose to make up for forgotten individual doses. In this case continue with your normal dosing schedule.

4. Possible side effects:

PARANVIR 75/150/400/600 can have side effects.

Not all side effects reported for **PARANVIR** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **PARANVIR**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, see a doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to **PARANVIR**. 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:

- heart attack,
- changes in the way your heart beats, for example if you notice it beating faster or slower than normal (tachycardia, bradycardia or palpitations),
- chest pain (angina),
- brief stroke like attacks resulting in drooping of one side of the face (transient ischaemic attacks),
- shortness of breath (dyspnoea),
- signs of recurrent infection such as a fever, chills or sore throat,
- passing more urine than usual.

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

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- high blood glucose test results, increase in urination and thirst (diabetes mellitus), loss of weight, abnormal blood lipid tests, increase in cholesterol,

- difficulty sleeping,
- headache, pain and numbness on the hands and feet (peripheral neuropathy), dizziness,
- diarrhoea, nausea, stomach pain, vomiting, indigestion, bloating and swelling if the belly, passing of gas (flatulence), abnormal pancreatic enzyme test (increased blood amylase),
- abnormal liver enzyme tests (increased alanine aminotransferase),
- painful muscles,
- male breasts enlargement,
- lack of energy, feeling tired.

The following side effect have been reported less frequently:

- sores around mouth or genitals (herpes simplex),
- irregular blood results,
- allergic reactions, swelling swollen throat, abnormal voice changes, red itchy bumps on skin (immune reconstitution syndrome),
- irregular thyroid function or blood tests,
- crystals in joints causing sudden severe episodes of pain and swelling (gout), change in appetite, changes in weight, increase in blood glucose, excessive thirst and drinking, abnormal blood lipid and pancreatic enzyme tests (increase in pancreatic lipase and amylase values), other abnormal blood tests such as an increase in blood lactate dehydrogenase, increase in low density lipoprotein and decrease in high density lipoprotein,

- abnormal dreams or nightmares, depression, mental confusion, excessive feelings of worry or fear (anxiety), sleep disorder, decreased sexual drive, altered mood, restlessness
- lack of energy, feeling sleepy (somnolence), decreased sense of touch or sensation, feelings of pins and needles on the arms, hands, legs or feet, impaired sense of taste, disturbance in attention, memory impairment, fainting, sudden involuntary, violent and irregular movement (convulsion), loss of taste function of the tongue, unable to detect sweetness or bitterness (ageusia), change in sleep pattern,
- eye infection, itchiness, swelling and redness (conjunctival hyperaemia),
- dry eye,
- visual disturbance,
- high blood pressure,
- nose bleeds,
- swelling of the pancreas and stomach, acid reflux, small shallow sores on the inside of the mouth, dry mouth, stomach pain, constipation, burping, burning sensation in the mouth, vomiting blood, swelling of the lips, dry lips, white, swollen tongue, abnormal pancreatic enzyme tests,
- abnormal liver function, blood and liver enzyme tests,
- weak bones that may break easily (osteopenia, osteoporosis, osteonecrosis), abnormal blood result (increase in creatine phosphokinase), muscle spasms, muscle weakness, pain in joints or extremities, joint stiffness, breakdown of muscles which may indicate

kidney damage. Symptoms include dark, reddish urine, decrease in urine output and weakness of muscle (rhabdomyolysis),

- frequent urination, kidney stones, acute kidney failure, increased blood creatine, bilirubin and protein detected in urine, painful urination, urination frequently at night, the need to urinate more often than usual, decreased creatine renal clearance,
- unable to keep or maintain an erection.

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

You can also report any side effects via drugsafety@cipla.com or telephone: 080 222 6662 (toll free). In addition you can report any side effect reactions to SAHPRA via “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 this medicine.

5. How to store PARANVIR 75/150/400/600:

Store at or below 30 °C.

KEEP OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information:

What PARANVIR contains:

PARANVIR 75:

Each film coated tablet contains 75 mg of darunavir (as darunavir ethanolate).

PARANVIR 150:

Each film coated tablet contains 150 mg of darunavir (as darunavir ethanolate).

PARANVIR 400:

Each film coated tablet contains 400 mg of darunavir (as darunavir ethanolate).

PARANVIR 600:

Each film coated tablet contains 600 mg of darunavir (as darunavir ethanolate).

Sugar free

The other ingredients are colloidal silicon dioxide, crospovidone, magnesium stearate and silicified microcrystalline cellulose. The film coat is composed of opadry white 85F28751 (75 and 150 mg tablets), opadry orange (400 and 600 mg tablets).

What PARANVIR 75/150/400/600 looks like and contents of the pack:

PARANVIR 75: White to off-white, capsule shaped, biconvex film coated tablet debossed with 'DNV' on one side and '75' on other side.

PARANVIR 150: White to off white, oval shaped, biconvex, film coated tablet, debossed with 'DNV' on one side and '150' on other side.

PARANVIR 400: Light orange coloured, oval shaped, biconvex, film coated tablet, debossed with 'DNV' on one side and '400' on other side.

PARANVIR 600: Orange coloured, oval shaped, biconvex, film coated tablet, debossed with 'DNV' on one side and '600' on other side.

PARANVIR is presented as follows:

PARANVIR 75:

150 cc HDPE bottle with a 38 mm non child-resistant closure containing 480 tablets per carton

PARANVIR 150:

150 cc HDPE bottle with a 38 mm non child-resistant closure containing 240 tablets per carton

PARANVIR 400:

85 cc HDPE bottle with a 38 mm non child-resistant closure containing 60 tablets per carton

PARANVIR 600:

150 cc HDPE bottle with a 38 mm non child-resistant closure containing 60 tablets per carton

Holder of Certificate of Registration and Manufacturer:

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

1474 South Coast Road

Mobeni

Durban

4052

This leaflet was last revised in:

TBC

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

QR code placeholder