

PATIENT INFORMATION LEAFLET FOR CUATRO

SCHEDULING STATUS

S4

CUATRO (oral granules)

Abacavir 30 mg, lamivudine 15 mg, lopinavir 40 mg and ritonavir 10 mg oral granules per capsule.

Contains sugar: sucrose 39,5 mg.

Contains sweeteners: aspartame 3 mg and saccharin sodium 3 mg per capsule.

Read all of this leaflet carefully before you start giving your child CUATRO:

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



1. What CUATRO is and what it is used for

CUATRO is a fixed dose combination capsule containing abacavir, lamivudine, lopinavir and ritonavir oral granules, which act by inhibiting formation of HIV-1 genetic material responsible for causing HIV-1 disease in your body.

CUATRO is indicated for the treatment of HIV-1 infection in children aged ≥ 3 months, weighing ≥ 3 to $\leq 19,9$ kg, and stabilised on concomitant use of the actives as separate formulations before switching to the fixed dose combination if similar doses of the actives can be achieved with CUATRO.

2. What you need to know before you use CUATRO

Do not use CUATRO:

- If your child is hypersensitive or allergic to CUATRO or any of its ingredients. Known hypersensitivity reactions to CUATRO include swelling, rash, fever, fatigue, malaise, gastrointestinal symptoms such as nausea, vomiting, diarrhoea and stomach pain and respiratory signs and symptoms such as breathing difficulties, sore throat and cough. Hypersensitivity to CUATRO occurs usually in the first six weeks of treatment, may involve multi-organ or whole body system and can be life-threatening. You must stop giving your child CUATRO and tell your doctor immediately if your child develops an allergic reaction anytime during treatment with CUATRO.
- If your child has moderate to severe liver impairment.
- If your child is being treated with any of the following medicines for other illnesses:
 - Alfuzosin (used treatment of enlarged prostate)
 - Ranolazine (used for chest pain due to angina)
 - Dronedarone (medicine for abnormal heart rhythms)

- Fusidic acid (an antibiotic)
- Apalutamide, Neratinib (medicine for cancer)
- Colchicine used for treating gout (if you have liver or kidney insufficiency)
- Astemizole (for allergies, e.g. hay fever)
- Medicines for depression such as blonanserin, lurasidone and pimozide)
- Ergot derivatives (ergotamine, dihydroergotamine, ergonovine, and methylergonovine), used for migraines
- Cisapride (used to stimulate bowel movements)
- Elbasvir/grazoprevir (for Hepatitis C viral disease)
- Lovastatin and simvastatin (for lowering fats in your body)
- Salmeterol (for asthma)
- Sildenafil (when used for the treatment of high blood pressure)
- Triazolam and midazolam (used for anxiety or sleeping problems)
- Rifampin (for treating tuberculosis or TB)
- Herbal products for treating depression: St. John's Wort (*Hypericum perforatum*).
- In pregnancy and breastfeeding.

Warnings and precautions

Combination antiretroviral treatment such as CUATRO is associated with complications that may need medical attention. Consult your child's doctor if the following problems arise during treatment:

- Too much acid in the body, which may be indicated by nausea, vomiting, abdominal pain, breathing difficulties and weight loss.
- Body fat redistribution indicated by central obesity, dorso-cervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement.

- Being prone to opportunistic infections including TB, flu, skin and/or eye infections.
Fever and generally feeling weak can be a sign of infections.
- Bone death and/or wasting. Your bones may become weakened and painful, this condition may be aggravated by corticosteroid use and alcohol consumption.
- Diabetes mellitus (high blood sugar), signs include increased appetite, increased thirst and frequent urination.
- Abdominal pain, this can be a sign of liver impairment or impaired function of the pancreas.
- Your child becomes prone to bleeding.
- Cardiovascular events (any complication associated with the heart not functioning as normal), if unsure please consult your doctor immediately. Tell your doctor if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of cardiovascular diseases such as high blood pressure, or diabetes.
- You have a history of or suffer from heart problems like abnormal heart rhythms, this can be life-threatening due to the risk of heart attacks.
- You previously developed resistance to other HIV medicines.
- You have haemophilia type A and B as there may be an increased risk of bleeding.

The risk of HIV transmission to others

The current antiretroviral medicines including CUATRO do not prevent the risk of transmission of HIV to others through sexual contact or blood contamination. You need to take appropriate measures such as using condoms while having sexual intercourse or a protective barrier when you are about to be in contact with blood in order to protect yourself and others from the risk of HIV transmission.

Other medicines and CUATRO

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

Do not give your child CUATRO with the following medicines (see “Do not use CUATRO”):

- Alfuzosin (treatment of enlarged prostate).
- Sedatives like midazolam and triazolam (they are used for treating fits and sleeplessness).
- Lomitapide, lovastatin and simvastatin (treatment of high cholesterol or too much body fat).
- Sildenafil (used for high blood pressure).
- Dronedarone (used for abnormal heart rhythms).
- Herbal product, St John’s Wort (*Hypericum perforatum*), for treatment of depression.
- Ergot alkaloids (dihydroergotamine, ergotamine and methylergonovine), they are used to treat migraines.
- Colchicine (for treating gout).
- Pimozide (for depression associated with bipolar disorder).
- Cisapride (used to increase bowel motility).
- Rifampin, used for treating TB.
- Neratinib (for cancer).
- Salmeterol (for asthma).
- Astemizole (for allergies such as hay fever).
- Ganciclovir (antiviral medicine used to treat infections caused by a virus called cytomegalovirus).

- Foscarnet (belongs to a group of medicines called anti-viral medicines). 1.3.1.1.3 page 25 line 462

Tell your doctor if your child is taking any of the following medicines his/her dose may need to be adjusted and/or it may be necessary to monitor his/her health:

- Other medicines for treating HIV disease.
- Medicines used for treating abnormal heart rates such as amiodarone and systemic lidocaine.
- Digoxin (used for heart conditions)
- Anticoagulants, e.g., warfarin and rivaroxaban (medicines to prevent blood clots).
- Anticonvulsants (medicines for fits or seizures such as phenobarbitone, phenytoin, carbamazepine, lamotrigine and valproate).
- Antidepressants (bupropion and trazodone).
- Medicines for treating parasitic infections: atovaquone used in the prevention and/or treatment of malaria.
- Corticosteroids (dexamethasone, budesonide, prednisone and fluticasone propionate).
- High blood pressure medicines (felodipine, nifedipine, nifedipine and bosentan).
- Quetiapine (for mental disorders).
- Medicines for lowering blood cholesterol such as atorvastatin and rosuvastatin.
- Immuno-suppressants, medicines that compromise your immune system, including ciclosporin, tacrolimus and sirolimus.
- Medicines for treating fungal infections (e.g., athlete's foot and mouth or vaginal thrush) including ketoconazole itraconazole and voriconazole.
- Medicines for treating bacterial infections such as clarithromycin and trimethoprim/sulphamethoxazole (if your child is suffering from kidney insufficiency).
- TB medicines such as rifampicin, rifabutin, delamanid and bedaquiline.

- Pain relief medicines like methadone and fentanyl.
- Oral/ patch contraceptives (ethinyl estradiol).
- Medicines for erectile dysfunction such as tadalafil, sildenafil, avanafil and vardenafil.
- Cancer medicines including abemaciclib, dasatinib, ibrutinib, nilotinib, venetoclax, vincristine, vinblastine.

CUATRO with food and drink

CUATRO must be taken with age appropriate food (e.g. soft porridge) or drink (e.g. milk).

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 CUATRO.

Do not take CUATRO if you are pregnant or breastfeeding.

Driving and using machines

CUATRO might impair vision. Caution is advised as CUATRO may negatively affect your/ and your child's ability to drive or operate machinery.

CUATRO contains sucrose (39,5 mg per capsule of oral granules)

If you have been told by your doctor that your child has an intolerance to some sugars, contact your child's doctor before taking CUATRO.

CUATRO contains aspartame (3 mg per capsule of oral granules)

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

CUATRO contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

3. How to use CUATRO

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

Always give or take CUATRO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

CUATRO must be given with age-appropriate food such as soft porridge or liquid (e.g. milk).

The usual dose according to weight is given in **Table 1**.

Table 1: Twice daily administration of CUATRO with food.

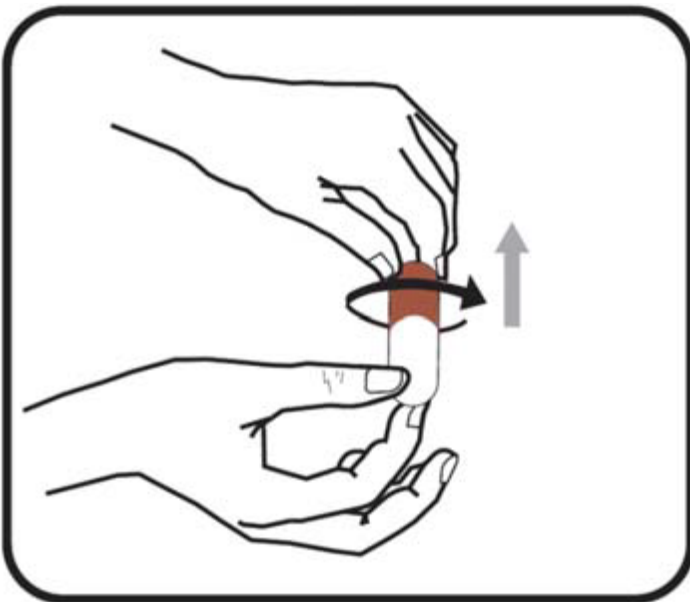
Weight (in kg)	Number of capsules to be administered	
	In the morning	In the evening
3,0 to 5,9	2	2
6,0 to 9,9	3	3
10, 0 to 13,9	4	4
14,0 to 19,9	5	5

Caution: Capsules should not be swallowed whole:

Contents of CUATRO capsules should be administered with age-appropriate soft food/liquid, as described below.

Method of administration with milk/drinking water:

- Obtain the prescribed number of capsules needed for a dose.
- Dose the required number of capsules one by one.
- Hold one capsule vertically with the brown cap at the top and white body at the bottom and then gently tap on top of the capsule. Open the capsule by gently twisting and pulling up the cap.



- Pour the contents of capsule into a spoon.



- Add milk/drinking water to the spoon till the spoon fills and feed to the child immediately.

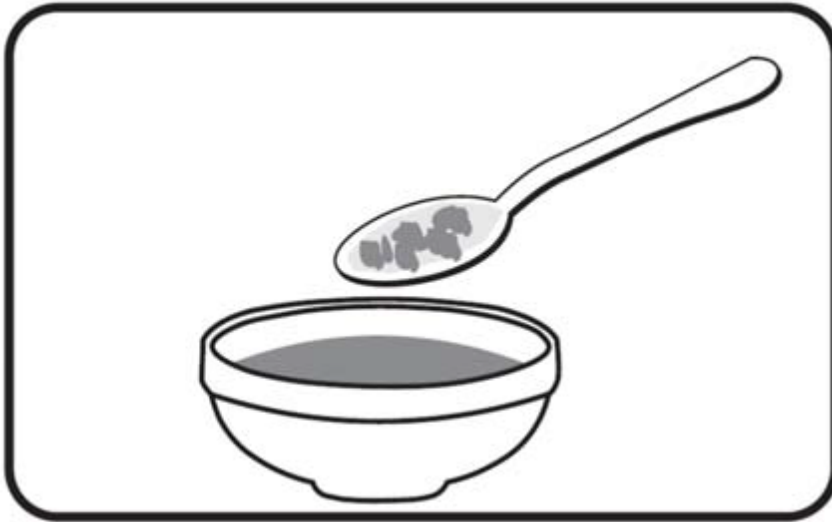


- Repeat this step for the prescribed number of capsules. Additional milk/drinking water can be taken after each dose if required.

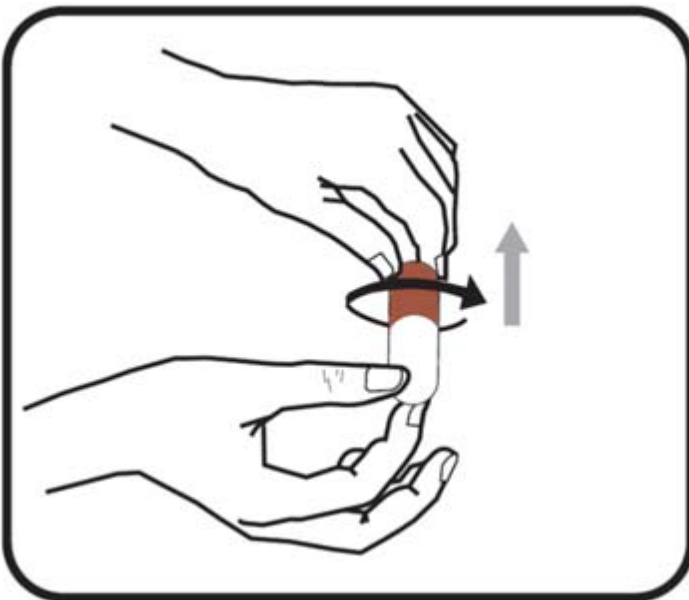
Method of administration with soft food (e.g. porridge or mashed fruit):

- Prepare porridge/ fruit and cool to room temperature.

- Obtain the prescribed number of capsules needed for a dose.
- Dose the required number of capsules one by one.
- Take a small amount of porridge or fruit on the spoon.



- Hold one capsule vertically with the brown cap at the top and white body at the bottom and then gently tap on top of the capsule. Open the capsule by gently twisting and pulling up the cap.



- Pour the contents of capsule on the spoon containing porridge / fruit and feed to the child immediately. The porridge/ fruit with the drug sprinkled on top should be swallowed immediately and should not be stored for future use.



- Repeat this step for the prescribed number of capsules.
- Administration of the required dose should be followed by more food or drinking water/ milk, to ensure that no granules remain in the mouth.

Your doctor will tell you how long your treatment with CUATRO will last. Do not stop treatment early because your child's HIV disease may become worse.

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

If you give more CUATRO 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 give CUATRO

Do not give a double dose to make up for forgotten individual doses. Give your child the next dose as soon as you remember and continue with treatment at the normal dosing times thereafter.

4. Possible side effects

CUATRO can have side effects.

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

If any of the following happens, stop giving your child CUATRO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions (e.g. skin rash, swollen face or limbs).
- Irregular (too high or slow) heart rates, this might be risk factor for stroke.
- Heart attack.
- Liver disease or liver failure (symptoms include abdominal pain, nausea and vomiting).
- Yellowing of the skin and/or eyes, also known as jaundice.
- Kidney disease, including kidney stones, signs include severe back pain and pain on the sides of your body and groin area and painful and frequent urination.

- Steven-Johnson syndrome, a life-threatening condition indicated by fever, fatigue and development of painful widespread blisters and ulcers on the skin, mouth area, face and limbs.
- Erythema multiforme, life threatening conditions affecting the skin, symptoms include itchy and/or sore, mostly reddish-looking skin rash, fever, feeling weak, eye pain and joint aches.

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

- High blood pressure (may be indicated by nosebleeds and shortness of breath).
- Diarrhoea (runny tummy, possibly with nausea and vomiting).
- Any form of infections such as flu-like illness, sore throat, persistent coughs, coughing bloody phlegm, occurrence of boils on your skin, blisters or cold sores in your mouth or groin, urine retention and burning urine (may be a sign of urinary tract infection), ear infection, sneezing and stomach bug. Usually, infections are accompanied by fever and fatigue.
- Diabetes, high blood sugar (excessive thirst, sweating and frequent urination may be a sign of high blood sugar).
- Frequent lightheadedness (also called postural hypotension).

Less frequent side effects:

- Anaemia, you may feel unusually faint and appear pale.

- Blood clots (this condition is asymptomatic but risk factors include tenderness, pain, discolouration and swelling around affected veins).
- Cholecystitis (also known as gall stones, you might experience severe belly pain accompanied by nausea and vomiting).
- Asthma.
- Breathlessness.
- Chest pain.
- Eczema (skin disorder with skin becoming rough and blistered, with bleeding and itchiness).
- Appearance of moles and lumps on the skin.
- Encephalopathy (brain injury/ brain dysfunction, numerous parts of the body are affected by this syndrome, symptoms include loss of cognitive function, inability to concentrate, not being in control of emotions, impaired muscle function/ breathing/ body movements).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headaches.
- Insomnia/ sleeplessness.
- Rash.
- Buffalo hump (accumulation of body fat around neck and shoulder).
- Abnormal exhaustion.
- Abdominal pain (stomach ache).
- Abnormal stools.
- Indigestion.

- Nausea.
- Vomiting.
- Flatulence.
- Muscle spasm/ pain.
- Muscle weakness.
- Back pain.
- Heavy menstrual periods.
- Lack of menstruation.
- Alopecia (loss of body hair).

Less frequent side effects:

- Pain.
- Fever.
- Fatigue.
- General discomfort.
- Chills.
- Migraine (severe and recurrent headaches).
- Cushing's syndrome.
- Weight gain.
- Weight loss.
- Dehydration.
- Increased appetite.
- Lactic acidosis (too much acid in your body generally indicated by muscle weakness and rapid breathing).
- Obesity.

- Anorexia.
- Abnormal dreams.
- Agitation.
- Anxiety.
- Confusion.
- Depression.
- Emotional lability.
- Decreased libido.
- Nervousness.
- Apathy (being emotionally detached).
- Abnormal thinking.
- Amnesia (memory loss).
- Drowsiness.
- Dizziness.
- Impaired or involuntary muscle movements.
- Inability to control body movements.
- Increased muscle tension.
- Facial paralysis.
- Loss of taste.
- Taste perversion.
- Tingling or a feeling of pins and needles.
- Tremors.
- Convulsions (fits or seizures).
- Abnormal vision.
- Eye disorder.

- Being disorientated.
- Ringing in the ears.
- Varicose vein (enlarged veins, mostly occurring on your legs).
- Enlarged abdomen (inflated belly).
- Constipation.
- Dry mouth.
- Difficulty swallowing.
- Belching.
- Heartburn.
- Bowel incontinence.
- Acne.
- Dry skin.
- Skin rash that makes your skin appear scaly.
- Nail disorder.
- Itchiness.
- Seborrhea (increased skin secretions similar to having oily skin problem).
- Skin ulcer.
- Skin discolouration.
- Increased sweating.
- Stretch marks.
- Joint pain.
- Abnormal ejaculation.
- Breasts in men.
- Impotence.
- Breast enlargement.

Side effects with unknown frequencies:

- Pink eye, may be itchy or burning.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By **reporting** side effects, you can help provide more information on the safety of CUATRO.

5. How to store CUATRO

Store all medicines out of reach of children.

Store at or below 30 °C in the original container.

6. Contents of the pack and other information**What CUATRO contains**

CUATRO oral granules contain abacavir sulfate equivalent to 30 mg abacavir, lamivudine 15 mg, lopinavir 40 mg and ritonavir 10 mg as the active ingredients.

Contains sugar: sucrose 39,5 mg.

Contains sweeteners: aspartame 3 mg and saccharin sodium 3 mg per capsule.

The inactive ingredients are amino methacrylate copolymer, aspartame, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, saccharin sodium, sodium starch glycolate, starch, stearic acid, strawberry cream flavour permaseal, sucrose and vegetarian capsule.

The strawberry cream flavour permaseal is made up of modified waxy maize starch- 1450, nature identical flavouring substance, natural flavouring substance, propyleneglycol-1520 and waxy maize maltodextrin.

Constituents of the vegetarian capsule: black iron oxide (E172), hypromellose, red iron oxide (E172), titanium dioxide, yellow iron oxide (E172) and printing ink (Opacode® Monogramming Ink S-1-8114 Black and Opacode® Monogramming Ink S-1-8115 Black).

What CUATRO looks like and contents of the pack

CUATRO occurs as oral granules in a capsule.

CUATRO is described as being white to off white-coloured blend filled in capsule of size “00” having white opaque body spin printed with 3TC-ABC in black ink and brown opaque cap spin printed with LPV-RTV in black ink.

CUATRO is marketed in packs of 120's in white HDPE containers that are fitted with lined non-CRC caps and contain one 3 g silica gel dessicant.

Holder of the certificate of registration

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

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4052

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