Front Side

400 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

QULAM-CO (Film-coated tablet)
Abacavir 600 mg and lamivudine 300 mg
Sugar-free

IMPORTANT - HYPERSENSITIVITY REACTION
QULAM-CO contains abacavir. Patients taking **QULAM-CO** may develop a hypersensitivity reaction (serious allergic reaction). It is essential you read the information on this reaction in the "**Warnings and precautions**" section of this leaflet. There is also **an Alert Card** included in the **QULAM-CO** pack, to remind you and medical staff about **QULAM-CO** hypersensitivity. This card should be removed from the pack and kept with you at all times. The text on this card is shown below.
Patients taking **QULAM-CO** may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with **QULAM-CO** is continued.
CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking QULAM-CO if:
1) you get a skin rash OR
2) you get one or more symptoms from at least TWO of the following groups:
- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or generally ill feeling.

If you have discontinued **QULAM-CO** due to a hypersensitivity reaction, **YOU MUST NEVER TAKE QULAM-CO**, or any other medicine containing abacavir again, as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

Read all of this leaflet carefully before you start taking QULAM-CO
- 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.
- **QULAM-CO** 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 **QULAM-CO** is and what it is used for
2. What you need to know before you take **QULAM-CO**
3. How to take **QULAM-CO**
4. Possible side effects
5. How to store **QULAM-CO**
6. Contents of the pack and other information

1. What QULAM-CO is and what it is used for

QULAM-CO contains both abacavir and lamivudine. **QULAM-CO** belongs to a group of antiretroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs) and is used in combination with other antiretrovirals to treat Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age, weighing at least 40 kg.

2. What you need to know before you take QULAM-CO

Do not take QULAM-CO:
- If you are hypersensitive (allergic) to the active substances abacavir, lamivudine or any of the other ingredients in **QULAM-CO**.
- If you have serious liver disease, **QULAM-CO** may not be suitable for you.
- If you are below 12 years of age and or weigh less than 40 kg.
- If you are pregnant, intend to become pregnant or if you are breastfeeding your baby.
- If you are taking the following medicines:
  - cladribine (for hairy cell leukemia),
  - zalcitabine or emtricitabine (for HIV infection)

Warnings and precautions
Tell your doctor or healthcare professional before you take **QULAM-CO**.
Take special care with **QULAM-CO**:

Hypersensitivity reaction (serious allergic reaction):
QULAM-CO contains abacavir.
Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir containing products is not stopped.
Who gets these reactions?
Anyone taking **QULAM-CO** could develop a hypersensitivity reaction to abacavir, which could be life-threatening if they continue to take **QULAM-CO**.
Research has found that people with a gene called HLA-B (type 5701) are more likely to have a hypersensitivity reaction to abacavir. However, even if you do not have this gene type it is still possible for you to get this reaction. **If you know you have this gene type, be sure to tell your doctor before you take abacavir.**
What are the symptoms?
The most common symptoms of this reaction are:
- high temperature (fever) and a skin rash.

Other frequently observed signs or symptoms include:
- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, shortness of breath, cough, headache and severe tiredness.

Other symptoms may include:
- joint or muscle pain, discomfort, swelling of the neck, serious breathing problems and sore throat. Occasionally inflammation of the eye (conjunctivitis), ulcers in the mouth, low blood pressure or tingling or numbness of the hands or feet may occur.

When do these reactions happen?
The symptoms of this allergic reaction can occur at any time during treatment with **QULAM-CO**. However, they usually occur in the first six weeks of treatment and get worse with continued treatment.
If you are caring for a child who is being treated with **QULAM-CO**, it is important that you understand the information about this hypersensitivity reaction. If your child gets the symptoms described below it is essential that you follow the instructions given.
The hypersensitivity reaction can be life-threatening or fatal if treatment with QULAM-CO is continued. You should contact your doctor immediately for advice on whether you should stop taking QULAM-CO if:
1) you get a skin rash OR
2) you get one or more symptoms from at least TWO of the following groups:
- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal(stomach) pain
- severe tiredness or achiness or generally ill feeling.

Your doctor may advise you to stop taking **QULAM-CO**.
Always carry your Alert Card while you are taking QULAM-CO.
If you have stopped taking QULAM-CO:
If you have discontinued **QULAM-CO** due to a hypersensitivity reaction, **YOU MUST NEVER TAKE QULAM-CO, or any other medicine containing abacavir again as within hours** you may experience a life-threatening lowering of your blood pressure or death.
If you have stopped taking **QULAM-CO** for any reason, particularly because you think you are having side effects or for other illness:
It is important that you inform your doctor before restarting. Your doctor will check whether any symptoms you had before stopping may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, **you may be told never to take QULAM-CO or any other medicine containing abacavir again**. It is important that you follow this advice.
Reactions have developed in people who start taking abacavir again and had **only one** symptom on the Alert Card before they stopped taking it.
Reactions have developed in people who start taking abacavir again, but who had no symptoms before they stopped taking it.
If your doctor advises that you can start taking **QULAM-CO** again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.
If you are hypersensitive to **QULAM-CO** you should return all of your unused **QULAM-CO** to your doctor or pharmacist for proper disposal.
The **QULAM-CO** pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. **Detach this card and keep it with you at all times**.

- Long term use of **QULAM-CO** may lead to an increase of acid in your body, and includes signs such as nausea, vomiting, stomach pain and cramps, weight loss, shortness of breath or fast breathing and fatigue. You may have a condition known as "lactic acidosis". Stop taking **QULAM-CO** and consult your doctor immediately.
- **QULAM-CO** may cause mitochondrial dysfunction which leads to poor growth, developmental delays and muscle weakness in infants exposed to **QULAM-CO**. Take your child, to your doctor immediately if your child appears pale, weak, sleepy all the time, is breathing faster, the heart is beating faster, the child does not appear to be putting on weight, is vomiting, has fever, sore throat, mouth ulcers, appears stiff, has convulsions (fits) or behaving abnormally. Your doctor will perform additional medical and laboratory tests on your child.
- **QULAM-CO** may cause inflammation of the pancreas. Inform your doctor if you experience severe upper stomach pain with nausea (feeling sick) and vomiting.
- **QULAM-CO** may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face and/or gain fat around the abdomen (tummy) and internal organs; get larger breasts or fatty lumps on the back of the neck (buffalo hump). If you notice changes in your body shape, tell your doctor.
- If you are with advanced HIV infection (AIDS), you have a weak immune system and are more likely to develop serious infections (opportunistic infections). When you start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:
  - Old, hidden infections flaring up again as the body fights them
  - The immune system attacking healthy body tissue (auto-immune disorders).

If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms inform your doctor.
- If you have ever had liver disease, including hepatitis B or C then talk to your doctor. You may need extra check-ups, including blood tests, while taking your medication.
- There may be an increased risk for heart attacks in patients using **QULAM-CO**. Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Don't stop taking **QULAM-CO** unless your doctor advises you to do so.
- You will need to take **QULAM-CO** every day. **QULAM-CO** helps to control your condition and delay disease progression, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor. Do not stop taking your medicine without first talking to your doctor.
- **QULAM-CO** will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:
- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** - for example, don't share needles.
- **QULAM-CO** may increase weight, blood cholesterol, triglyceride, lactic acid, sugar levels and cause insulin resistance. Your doctor will perform blood tests at regular intervals to monitor cholesterol, triglyceride, lactic acid and sugar levels.

Other medicines and QULAM-CO:
Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Abacavir or lamivudine in **QULAM-CO** may interact with certain other medicines:
- **QULAM-CO** should not be taken with cladribine (for hairy cell leukemia), zalcitabine, emtricitabine (for HIV infection), high doses of co-trimoxazole (antibiotic)
- Tell your doctor if you are taking methadone (used to treat addiction), as your doctor may need to change your methadone dose.
- Tell your doctor if you are taking phenytoin (for epilepsy). Your doctor may need to monitor you while you are taking **QULAM-CO**.
- Medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.

QULAM-CO with food and drink and alcohol
QULAM-CO can be taken with or without food.

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 **QULAM-CO**.
You should not take QULAM-CO if you are pregnant.

You should not breastfeed your baby while taking **QULAM-CO**. Additionally, it is recommended that HIV infected women do not breastfeed their infants under any circumstances in order to avoid transmission of HIV from mother to child.

Driving and using machinery:
QULAM-CO is unlikely to affect your ability to drive or operate machinery. If you have any concerns consult your doctor.

3. How to take QULAM-CO:

- Do not share medicines prescribed for you with any other person.
- Always take **QULAM-CO** exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.
- Take **QULAM-CO** for as long as your doctor recommends. Do not stop unless your doctor advises you to.
- Take great care not to miss any doses if at all possible. Swallow the tablet whole with water.
- The usual dose in adults and adolescents from 12 years of age, who weigh at least 40 kg, is one tablet daily.

If you take more QULAM-CO than you should:
In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

If you forget to take QULAM-CO:
It is important to take **QULAM-CO** as prescribed to ensure you get maximum benefit. If you forget to take a dose, take it as soon as you remember and then continue as before. Do not take a double dose to make up for forgotten individual doses. It is important to take **QULAM-CO** regularly because irregular intake may increase the risk of hypersensitivity reactions.

If you stop taking QULAM-CO:
If you have stopped taking **QULAM-CO** for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. In some cases, your doctor will ask you to restart **QULAM-CO** under direct medical supervision. If your doctor thinks that there is a possibility that your symptoms were related to a hypersensitivity reaction, you may be told never to take **QULAM-CO** or any other medicine containing abacavir again.

4. Possible side effects:

QULAM-CO can have side effects.
Not all side effects reported for **QULAM-CO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **QULAM-CO**, please consult your doctor, pharmacist or other health care professional for advice.
If any of the following happens, stop taking **QULAM-CO** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- A serious allergic reaction known as a hypersensitivity reaction, see '**Hypersensitivity reaction**' in "**Warnings and precautions**". It is important that you read and understand the information about this serious reaction.
- Hives; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **QULAM-CO**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Adult respiratory distress syndrome (ARDS) occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. The fluid keeps your lungs from filling with enough air, which means less oxygen reaches your bloodstream. This deprives your organs of the oxygen they need to function.
- Respiratory failure (a condition in which your blood doesn't have enough oxygen or has too much carbon dioxide) with symptoms of shortness of breath and confusion.
- A failure of the bone marrow to produce new red blood cells (pure red cell aplasia). Symptoms include fatigue, shortness of breath with exertion, rapid or irregular heart rate, pale skin, frequent or prolonged infections, unexplained or easy bruising, nosebleeds and bleeding gums, prolonged bleeding from cuts, skin rash, dizziness and headache.
- Swelling under the skin of face, throat, limbs and genitals (angioedema) with difficulty in breathing.
- Lactic acidosis characterised by nausea (feeling sick), vomiting, diarrhoea, abdominal (stomach) pain, difficulty or abnormality in breathing, fatigue and weight loss.
- Liver damage – nausea; stomach pain; low fever; loss of appetite; dark urine; clay-coloured stools; jaundice (yellowing of the skin or eyes).
- Kidney damage – little or no urination, swelling in the ankles and feet, shortness of breath, nausea and vomiting, metallic taste in the mouth.
- Fever, chills, sore throat, cough, or other signs of infection.
- Skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) and a more severe form causing skin peeling on large parts of your body surface (toxic epidermal necrolysis).
- Inflammation of the pancreas - severe upper stomach pain with nausea (feeling sick) and vomiting.
- Changes in body shape because of changes in fat distribution.
- Stiffness in the joints, aches and pains (especially in the hip, knee or shoulder), difficulty moving as these are signs of osteonecrosis (see "**Warnings and precautions**").
- Breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis) characterised by dark, reddish urine, decreased amount of urine, weakness and muscle pain.

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
- Unwarranted fear of being overweight (anorexia)
- Headache and difficulty falling or staying asleep
- Cough, nasal symptoms
- Deep, rapid, difficult breathing
- Nausea, abdominal pain, vomiting, diarrhoea
- Joint pain and muscle disorders
- Fever, lack of energy and tiredness, general feeling of being unwell.

Less frequent side effects:
- Weakness, numbness and pain from nerve damage, usually in the hands and feet (peripheral neuropathy)
- Rashes, hair loss
- Mouth ulceration
- Sore throat
- Swollen ankles, feet and legs, swollen lymph glands, low blood pressure, eye infection (conjunctivitis)
- Tingling or numbness of the skin, arms or legs (paraesthesia)
- Breakdown of muscle tissue.

Side effects that may show up in blood tests are:
- Low red blood cell count (anaemia), low white blood cell count (neutropenia, or leucopenia),
- Decrease in the number of cells involved in blood clotting (thrombocytopenia)
- An increase in an enzyme called amylase
- An increase in the level of liver enzymes
- Elevated creatine phosphokinase
- Elevated creatinine
- Increased weight and increased levels of sugar and fats (triglycerides and cholesterol) in the blood.

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

Reporting of side effects:
If you get side effects, talk to your doctor or 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 or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **QULAM-CO**.

5. How to store QULAM-CO:

Store at or below 30 °C.
Protect from light and moisture.
Keep in original packaging until required for use.

Keep the container tightly closed and in the carton until required for use.

Keep blisters in the carton until required for use.

Store all medicines out of the reach of children.
Do not take the medicine after the expiry date stated on the bottle or blister and 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 QULAM-CO contains:
- The active substances are abacavir 600 mg and lamivudine 300 mg.
- The other ingredients are colloidal silicon dioxide, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, povidone. The tablets are coated with coating made up of hydroxypropyl methylcellulose, polyethylene glycol, polysorbate, titanium dioxide and FD & C yellow no. 6 aluminium lake.

What QULAM-CO looks like and contents of the pack:
Orange coloured, modified capsule shaped, biconvex, film coated tablets with deep breakline on one side and plain on other side.

HDPE container
Tablets are packed in a 75 ml round white HDPE container with 38 mm neck finish, closed with a white 38 mm closure with HS 123 white printed liner, packed in an outer carton. Each HDPE container contains a 1 g silica gel sachet.
Pack sizes include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Blister pack
Tablets are packed in a blister containing cold form laminate 25 µm OPA/45 µm aluminium foil/60 µm PVC as the forming material and plain 25 µm aluminium foil with 6-8 gsm heat seal lacquered as the lidding material, packed in a pre-printed carton.
Pack sizes include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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Registration Number(s)
QULAM-CO: 55/20.2.8/0077

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

QULAM-CO
PM04344120

335 mm

Back Side

400 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

QULAM-CO (Filmbedekte tablet)
600 mg Abakavir en 300 mg lamivudien
Suikervry

BELANGRIK – HIPERSENSITIWITEITSREAKSIE
QULAM-CO bevat abakavir. Pasiënte wat **QULAM-CO** gebruik, kan 'n hipersensitiwiteitsreaksie (ernstige allergiese reaksie) ontwikkel. Dit is noodsaaklik dat jy die inligting oor hierdie reaksie in die "**Waarskuwings en voorsorgmaatreëls**" afdeling van hierdie inligtingstuk lees. Daar is ook 'n **Waarskuwingskaart** by die **QULAM-CO** verpakking ingesluit, om jou en mediese personeel te herinner aan **QULAM-CO** hipersensitiwiteit. Hierdie kaart moet uit die verpakking verwyder word en te alle tye by jou gehou word. Die teks op hierdie kaart word hieronder getoon. Pasiënte wat **QULAM-CO** neem, kan 'n hipersensitiwiteitsreaksie (ernstige allergiese reaksie) ontwikkel **wat lewensgevaarlik kan wees** indien behandeling met **QULAM-CO** voortgesit word. **KONTAK ONMIDDELLIK JOU DOKTER vir advies oor of jy die gebruik van QULAM-CO moet staak indien:**
1) jy 'n veluitslag kry OF
2) jy een of meer simptome uit minstens TWEE van die volgende groepe kry:
- koors
- kortasem, seer keel of hoes
- naarheid of braking of diaree of abdominale pyn
- erge moegheid of pyn of algemene siek gevoel.

Indien jy **QULAM-CO** gestaak het weens 'n hipersensitiwiteitsreaksie, **MOET JY NOOIT WEER QULAM-CO NEEM NIE**, of enige ander medisyne wat abakavir bevat, aangesien jy **binne ure** 'n lewensgevaarlike verlaging van jou bloeddruk of dood kan ervaar.

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy QULAM-CO begin gebruik
- Hou hierdie inligtingstuk. Dit is moontlik dat jy dit weer sal wil deurlees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **QULAM-CO** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **QULAM-CO** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **QULAM-CO** gebruik
3. Hoe om **QULAM-CO** te gebruik
4. Moontlike newe-effekte
5. Hoe om **QULAM-CO** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat QULAM-CO is en waarvoor dit gebruik word

QULAM-CO bevat beide abakavir en lamivudien. **QULAM-CO** behoort aan 'n groep antiretrovirale middels naamlik nukleosied analoog trutranskriptase inhibeerders (NTTI's) en word in kombinasie met ander antiretrovirale middels gebruik om infeksie met Menslike Immuniteitsgebreksvirus (MIV) te behandel in volwassenes en adolessente vanaf 12 jarige ouderdom, wat ten minste 40 kg weeg.

2. Wat jy behoort te weet voordat jy QULAM-CO gebruik

Moet nie QULAM-CO gebruik nie
- Indien jy hipersensitief (allergies) vir die aktiewe bestanddele abakavir, lamivudien of enige van die ander bestanddele in **QULAM-CO** is.
- Indien jy 'n ernstige lewersiekte het is **QULAM-CO** dalk nie geskik vir jou nie.
- Indien jy jonger as 12 jaar oud is en/of minder as 40 kg weeg.
- Indien jy swanger is, beplan om swanger te raak of indien jy jou baba borsvoed.
- Indien jy die volgende medisyne neem:
- Kladribien (vir harige sel leukemie),
- Salsitabien of emtrisitabien (vir MIV-infeksie).

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter of professionele gesondheidsorgwerker voordat jy **QULAM-CO** neem: Spesiale sorg moet geneem word met **QULAM-CO**:

Hipersensitiwiteitsreaksie (ernstige allergiese reaksie):
QULAM-CO bevat abakavir.
Abakavir kan 'n ernstige allergiese reaksie, bekend as 'n hipersensitiwiteitsreaksie veroorsaak, wat lewensgevaarlik kan wees indien behandeling met abakavir bevattende middels nie gestaak word nie.
Wie kry hierdie reaksies?
Enige persoon wat **QULAM-CO** gebruik, kan 'n hipersensitiwiteitsreaksie op abakavir ontwikkel, wat lewensgevaarlik kan wees indien hulle aanhou om **QULAM-CO** te neem. Navorsing het bevind dat mense met die HLA-B (tipe 5701) geen, meer geneig is om 'n hipersensitiwiteitsreaksie op abakavir te hê. Selfs as jy nie hierdie geentipe het nie, is dit steeds moontlik vir jou om hierdie reaksie te kry. **Indien jy bewus daarvan is dat jy hierdie geentipe het, maak seker dat jy jou dokter daarvan vertel voordat jy abakavir neem**.
Wat is die simptome?
Die mees algemeenste simptome van hierdie reaksie is:
- hoë temperatuur (koors) en 'n veluitslag.

Ander tekens of simptome wat algemeen waargeneem word sluit in:
- naarheid (siek voel), braking (siek word), diaree, abdominale (maag) pyn, kortasem, hoes, hoofpyn en erge moegheid.

Ander simptome kan insluit:
- gewrigs- of spierpyn, ongemak, swelling van die nek, ernstige probleme met asemhaling en seer keel. Soms kan infeksie van die oog (konjunktivitis), sere in die mond, lae bloeddruk of tinteling of gevoelloosheid van die hande of voete voorkom.

Wanneer vind hierdie reaksies plaas?
Die simptome van hierdie allergiese reaksie kan enige tyd tydens behandeling met **QULAM-CO** voorkom, maar hulle kom gewoonlik binne die eerste ses weke van behandeling voor en vererger met volgehoue gebruik.
Indien jy 'n kind versorg wat met **QULAM-CO** behandel word, is dit belangrik dat jy die inligting oor hierdie hipersensitiwiteitsreaksie verstaan. Indien jou kind die simptome ontwikkel wat hieronder beskryf word, is dit noodsaaklik dat jy die instruksies volg wat gegee word.
Die hipersensitiwiteitsreaksie kan lewensgevaarlik of fataal wees indien behandeling met QULAM-CO voortgesit word. Jy moet onmiddellik jou dokter kontak vir advies oor of jy die gebruik van QULAM-CO moet staak indien:
1) jy 'n veluitslag kry OF
2) jy een of meer simptome uit minstens TWEE van die volgende groepe kry:
- koors
- kortasem, seer keel of hoes
- naarheid of braking of diaree of abdominale (maag) pyn
- erge moegheid of pyn of algemene siek gevoel.

Jou dokter kan jou aanraai om op te hou om **QULAM-CO** te gebruik.
Dra altyd jou Waarskuwingskaart terwyl jy QULAM-CO gebruik.
Indien jy opgehou het om QULAM-CO te gebruik:
Indien jy **QULAM-CO** gebruik gestaak het weens 'n hipersensitiwiteitsreaksie, **MOET JY NOOIT WEER QULAM-CO GEBRUIK NIE**, **of enige ander medisyne wat abakavir bevat nie**, **aangesien jy binne ure** 'n lewensgevaarlike verlaging van jou bloeddruk of dood kan ervaar. Indien jy gebruik van **QULAM-CO** weens enige rede gestaak het, maar veral omdat jy vermoed dat jy newe-effekte kry of vir ander siektes:
Dit is belangrik dat jy jou dokter kontak voordat jy weer begin. Jou dokter sal kyk of enige simptome wat jy gehad het voordat jy opgehou het, moontlik verband hou met hierdie hipersensitiwiteitsreaksie. Indien jou dokter dink dat daar dalk 'n moontlikheid bestaan dat hulle verwant was, **kan jy aangesê word om nooit weer QULAM-CO of enige ander medisyne wat abakavir bevat, te gebruik nie**. Dit is belangrik dat jy hierdie advies volg.
Reaksies het ontwikkel in mense wat weer abakavir begin gebruik het, en wat net **een simptoom** op die Waarskuwingskaart gehad het voordat hulle opgehou het om dit te neem.
Reaksies het ontwikkel in mense wat weer abakavir begin gebruik het, maar wat geen simptome gehad het voordat hulle opgehou het om dit te neem nie.
Indien jou dokter aanbeveel dat jy weer **QULAM-CO** kan begin gebruik, kan jy moontlik gevra word om jou eerste doserings te neem in 'n plek waar jy geredelike toegang tot mediese sorg sal hê, indien jy dit sou benodig.
Indien jy hipersensitief is vir **QULAM-CO**, moet jy al jou ongebruikte **QULAM-CO** aan jou dokter of apteker terugbesorg vir behoorlike wegdoening.
Die **QULAM-CO** verpakking sluit 'n Waarskuwingskaart in om jou en mediese personeel te herinner aan hipersensitiwiteitsreaksies. **Maak hierdie kaart los en hou dit te alle tye by jou**.

- Langtermyn gebruik van **QULAM-CO** kan lei tot 'n toename van suur in jou liggaam, en sluit tekens soos naarheid, braking, maagpyn en krampe, gewigsverlies, kortasem of vinnige asemhaling en moegheid in. Jy kan 'n toestand hê wat bekend staan as "laktiese asidose". Hou op om **QULAM-CO** te neem en raadpleeg onmiddellik jou dokter.
- **QULAM-CO** kan mitochondriale disfunksie veroorsaak wat lei tot swak groei, ontwikkelingsagterstande en spierswakheid in babas wat aan **QULAM-CO** blootgestel word. Neem jou kind onmiddellik na jou dokter indien jou kind bleek, swak, die hele tyd slaperig lyk, vinniger asemhaal, die hart vinniger klop, dit lyk of die kind nie gewig aansit nie, braak, koors het, seer keel, mondsere, kom styf voor, kry stuiptrekkings (aanvalle) of tree abnormaal op. Jou dokter sal addisionele mediese en laboratoriumtoetse op jou kind uitvoer.
- **QULAM-CO** kan ontsteking van die pankreas veroorsaak. Stel jou dokter in kennis indien jy erge boonste maagpyn met naarheid (siek voel) en braking ervaar.
- **QULAM-CO** kan jou liggaamsvorm verander deur die verspreiding van liggaamsvet te verander. Jy kan vet van jou bene, arms en gesig verloor en/of vet rondom die abdomen (maag) en interne organe optel; groter borste of vetterige bulte op die agterkant van die nek (buffelskof) kry. As jy veranderinge in jou liggaamsvorm opmerk, vertel jou dokter.
- Indien jy gevorderde MIV-infeksie (VIGS) het, het jy 'n swak immuunstelsel en is jy meer geneig om ernstige infeksies (opportunistiese infeksies) te ontwikkel. Wanneer jy met behandeling begin, word die immuunstelsel sterker, sodat die liggaam infeksies begin beveg.

Simptome van infeksie en inflammasie kan ontwikkel, wat veroorsaak word deur óf:
- Ou, versteekte infeksies wat weer opvlam soos die liggaam dit beveg
- Die immuunstelsel wat gesonde liggaamsweefsel aanval (outoïmmuun afwykings).

Indien jy tekens van inflammasie of infeksie, of agteruitgang daarvan opmerk, vertel onmiddellik jou dokter.
- Sommige pasiënte wat kombinasie antiretrovirale behandeling gebruik, kan 'n beensiekte naamlik osteonekrose ontwikkel (afsterf van beenweefsel wat veroorsaak word deur verlies van bloedtoevoer na die been). Tekens van osteonekrose is gewrigstyfheid, skete en pyne (veral van die heup, knie en skouer) en moeilike beweging. Indien jy enige van hierdie simptome opmerk, stel jou dokter in kennis.
- Indien jy al ooit 'n lewersiekte gehad het, insluitend hepatitis B of C, praat dan met jou dokter. Jy sal moontlik ekstra ondersoeke nodig hê, insluitend bloedtoetse, terwyl jy jou medikasie gebruik.
- Daar kan 'n verhoogde risiko vir hartaanvalle wees in pasiënte wat **QULAM-CO** gebruik. Vertel jou dokter indien jy hart probleme het, as jy rook, of ander siektes het wat jou risiko vir hartsiektes soos hoë bloeddruk of diabetes kan verhoog. Moet nie ophou om **QULAM-CO** te gebruik nie, tensy jou dokter jou aanraai om dit te doen.
- Jy sal **QULAM-CO** elke dag moet neem. **QULAM-CO** help om jou toestand te beheer en siekte vooruitgang te vertraag, maar dit is nie 'n kuur vir MIV-infeksie nie. Jy kan voortgaan om ander infeksies en ander siektes wat met MIV siekte geassosieer word, te ontwikkel. Jy moet gereeld in kontak met jou dokter bly. Moet nie ophou om jou medisyne te neem sonder om eers met jou dokter te praat nie.
- **QULAM-CO** sal nie verhoed dat jy MIV-infeksie aan ander mense oordra nie. Om ander mense te beskerm teen besmetting met MIV:
- **Gebruik 'n kondoom** wanneer jy orale of penetrerende seks het.
- **Moet nie bloedoordrag waag nie** – moet byvoorbeeld nie naalde deel nie.
- **QULAM-CO** kan gewig, bloedcholesterol, trigliseriede, melksuur, suikervlakke laat toeneem en insulienweerstandigheid veroorsaak. Jou dokter sal bloedtoetse met gereelde tussenposes uitvoer om cholesterol, trigliseriede, melksuur en suikervlakke te monitor.

Ander medisyne en QULAM-CO
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.) Abakavir of lamivudien in **QULAM-CO** kan interaksies veroorsaak met sekere ander medisyne:
- **QULAM-CO** moet nie saam met kladribien (vir harige sel leukemie), salsitabien, emtrisitabien (vir MIV-infeksie), hoë doserings ko-trimoksasool (antibiotikum) geneem word nie.
- Lig jou dokter in as jy metadoon gebruik (wat gebruik word om verslawing te behandel), aangesien jou dokter moontlik jou metadoondosis sal verander.
- Vertel jou dokter as jy fenitoïen (vir epilepsie) gebruik. Jou dokter sal jou dalk moet monitor terwyl jy **QULAM-CO** gebruik.
- Medisyne (gewoonlik vloeistowwe) wat sorbitol en ander suikeralkohol bevat (soos xylitol, mannitol, laktitol of maltitol), indien gereeld geneem.

QULAM-CO met voedsel en drank en alkohol
QULAM-CO kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **QULAM-CO** gebruik.
Jy moet nie QULAM-CO gebruik as jy swanger is nie.
Jy moet nie jou baba borsvoed terwyl jy **QULAM-CO** neem nie. Daarbenewens word dit aanbeveel dat MIV geïnfekteerde vrouens onder geen omstandighede hul babas borsvoed nie, om sodoende die oordrag van MIV van moeder na kind te verhoed.

Bestuur en gebruik van masjinerie
Dit is onwaarskynlik dat **QULAM-CO** jou vermoë om te bestuur of masjinerie te bedryf, sal affekteer. Indien jy enigsins bekommerd is, raadpleeg jou dokter.

3. Hoe om QULAM-CO te gebruik

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Neem altyd **QULAM-CO** presies soos jou dokter dit voorgeskryf het. Raadpleeg jou dokter of apteker indien jy onseker is.
- Neem **QULAM-CO** vir so lank as wat jou dokter dit aanbeveel. Moet nie ophou tensy jou dokter jou aanraai om dit te doen nie.
- Neem spesiale sorg om indien enigsins moontlik, geen dosisse oor te slaan nie. Sluk die tablet heel in, met water.
- Die gewone dosis in volwassenes en adolessente vanaf 12 jarige ouderdom, wat minstens 40 kg weeg, is een tablet per dag.

Indien jy meer QULAM-CO neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om QULAM-CO te neem
Dit is belangrik om **QULAM-CO** te neem soos voorgeskryf om te verseker dat jy maksimum voordeel kry. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou en gaan dan voort soos voorheen.
Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie. Dit is belangrik om **QULAM-CO** gereeld te neem omdat ongereelde inname die risiko van hipersensitiwiteitsreaksies kan verhoog.

Indien jy ophou om QULAM-CO te neem
Indien jy gebruik van **QULAM-CO** weens enige rede gestaak het, maar veral omdat jy vermoed dat jy newe-effekte kry of vir ander siektes, is dit belangrik dat jy jou dokter kontak voordat jy weer begin. In sommige gevalle sal jou dokter jou vra om weer met **QULAM-CO** onder direkte mediese toesig te begin. Indien jou dokter dink dat daar dalk 'n moontlikheid bestaan dat jou simptome verwant was aan 'n hipersensitiwiteitsreaksie, kan jy aangesê word om nooit weer **QULAM-CO** of enige ander medisyne wat abakavir bevat, te gebruik nie.

4. Moontlike newe-effekte

QULAM-CO kan newe-effekte hê.
Nie al die newe-effkte wat vir **QULAM-CO** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **QULAM-CO** gebruik, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **QULAM-CO** te neem en vertel onmiddellik vir jou dokter, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- 'n Ernstige allergiese reaksie bekend as 'n hipersensitiwiteitsreaksie, sien '**Hipersensitiwiteitsreaksie**' in "**Waarskuwings en voorsorgmaatreëls**". Dit is belangrik dat jy die inligting oor hierdie ernstige reaksie lees en verstaan.
- Galbulte; swelling van die gesig, lippe, mond, tong of keel wat probleme kan veroorsaak om te sluk of asem te haal.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige allergiese reaksie op **QULAM-CO** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal as jy enige van die volgende opmerk:
- Volwasse respiratoriese noodsindroom (VRNS) vind plaas wanneer vloeistof in die klein, elastiese lugsakkies (alveoli) in jou longe ophoop. Die vloeistof keer dat jou longe met genoeg lug vul, wat beteken dat minder suurstof jou bloedstroom bereik. Dit ontneem jou organe van die suurstof wat hulle nodig het om te funksioneer.
- Respiratoriese versaking ('n toestand waarin jou bloed nie genoeg suurstof het nie, of te veel koolsuurgas het) met simptome van kortasem en verwarring.
- Die beenmurg misluk om nuwe rooibloedselle te produseer (suiwer rooi sel vormingsgebrek). Simptome sluit in moegheid, kortasem met inspanning, vinnige of onreëlmatige harttempo, bleek vel, gereelde of langdurige infeksies, onverklaarbare of maklike kneusing, neusbloedings en bloeiende tandvleise, langdurige bloeding van snye, veluitslag, duiseligheid en hoofpyn.
- Swelling onder die vel van gesig, keel, ledemate en geslagsdele (angioëdeem) met moeilike asemhaling.
- Laktiese asidose gekenmerk deur naarheid (siek voel), braking, diaree, abdominale (maag) pyn, moeilike of ongewone asemhaling, vermoeidheid en gewigsverlies.
- Lewerskade – naarheid; maagpyn; lae koors; verlies van eetlus; donker uriene; klei kleurige stoelgange; geelsug (vergeling van die vel of oë).
- Nierskade – min of geen urinering, swelling van die enkels en voete, kortasem, naarheid en braking, metaalsmaak in die mond.
- Koors, koue rillings, seer keel, hoes, of ander tekens van infeksie.
- Veluitslag, wat blase kan vorm en soos klein teikens lyk (donker sentrale kolle omring deur 'n ligter area, met 'n donker ring om die rand) (veelvuldige eriteem).
- 'n Wydverspreide uitslag met blase en afskilferende vel, veral rondom die mond, neus, oë en geslagsdele (Stevens Johnson sindroom) en 'n meer ernstige vorm wat velafskilfering op groot dele van jou liggaamsoppervlak veroorsaak (toksiese epidermale nekrolise).
- Ontsteking van die pankreas - erge boonste maagpyn met naarheid (siek voel) en braking.
- Veranderinge in liggaamsvorm as gevolg van veranderinge in vetverspreiding.
- Styfheid in die gewrigte, skete en pyne (veral in die heup, knie of skouer), moeilike beweging aangesien hierdie tekens van osteonekrose is (sien "**Waarskuwings en voorsorgmaatreëls**").
- Afbreek van spierweefsel wat 'n skadelike proteïen in die bloed vrystel (rabdomiolise) wat gekenmerk word deur donker, rooierige uriene, verminderde hoeveelheid uriene, swakheid en spierpyn.

Al hierdie newe-effekte is ernstig. Jy mag dringende mediese aandag benodig.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte
- Ongegronde vrees om oorgewig te wees (anoreksie)
- Hoofpyn en probleme om aan die slaap te raak of aan die slaap te bly
- Hoes, nasale simptome,
- Diep, vinnige, moeilike asemhaling,
- Naarhaid, abdominale pyn, braking, diaree,
- Gewrigspyn en spierafwykings
- Koors, gebrek aan energie en moegheid, algemene siek gevoel.

Minder gereelde newe-effekte
- Swakheid, gevoelloosheid en pyn van senuwee skade, gewoonlik in die hande en voete (perifere neuropatie)
- Uitslae, haarverlies,
- Seervorming in mond,
- Seer keel,
- Geswelde enkels, voete en bene, geswelde limfkliere, lae bloeddruk, infeksie van die oog (konjunktivitis),
- Tinteling of gevoelloosheid van die vel, arms of bene (parestesie)
- Afbreek van spierweefsel.

Newe-effekte wat in bloedtoetse kan voorkom, is:
- Lae rooibloedseltelling (anemie), lae witbloedseltelling (neutropenie, of leukopenie),
- Vermindering in die aantal selle betrokke by bloedstolling (trombositopenie),
- 'n Toename in 'n ensiem genoem amilase,
- 'n Toename in die vlak van lewerensieme,
- Verhoogde kreatienfosfokinase,
- Verhoogde kreatinien,
- Gewigstoename en verhoogde vlakke van suiker en vette (trigliseriede en cholesterol) in die bloed.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ervaar, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **QULAM-CO**.

5. Hoe om QULAM-CO te bewaar

Bewaar by of benede 30 °C.
Beskerm teen lig en vog.
Stoor in die oorspronklike verpakking totdat dit benodig word vir gebruik.
Hou die houer dig toe en in die buitenste karton totdat dit benodig word vir gebruik.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Bewaar alle medisyne buite bereik van kinders.
Moet nie die medisyne na die vervaldatum wat aangebring is op die bottel of stulpstrook en buitenste karton gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat QULAM-CO bevat
- Die aktiewe bestanddele is 300 mg abakavir en 300 mg lamivudien.
- Die ander bestanddele is kolloïdale silikondioksied, lae-gesubstitueerde hidroksipropielsellulose, magnesiumstearaat, mikrokristallyne sellulose, povidoon. Die tablette is bedek met 'n deklaag wat bestaan uit hidroksipropielmetielsellulose, poliëtileenglikool, polisorbaat, titaandioksied en FD & C geel nr. 6 aluminiumlak.

Hoe QULAM-CO lyk en inhoud van die pak
Oranje gekleurde, gemodifiseerde kapsuulvormige, bikonvekse, filmbedekte tablette met 'n diep breeklyn aan die een kant en glad aan die ander kant.

HDPE houer
Tablette word verpak in 'n 75 ml ronde wit HDPE-houer met 38 mm nekafwerking, toegemaak met 'n wit 38 mm kinderbestande sluiting met HS 123 wit gedrukte voering, verpak in 'n buitenste karton. Elke HDPE houer bevat 'n 1 g silikagel sakkie.
Verpakkingsgroottes sluit 28 of 30 tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Stulpstrook verpakking
Tablette word in 'n stulpstrook verpak wat kouevorm laminaat 25 µm OPA/45 µm aluminiumfoelie/60 µm PVC as die vormingsmateriaal bevat en gewone 25 µm aluminiumfoelie met 6-8 gsm hitteseëllakt as die dekmateriaal bevat, verpak in 'n voorafgedrukte karton.
Verpakkingsgroottes sluit 28 of 30 tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
04 September 2023

Registrasienommer
55/20.2.8/0077

Toegang tot die ooreenstemmende professionele inligting
Die toepaslike professionele inligting kan verkry word by https://www.macleodssaproducts.co.za/ of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: QULAM CO (ABACAVIR 600 MG LAMIVUDINE 300 MG TABLETS)	
2. Country: South Africa (Private Market)	**3. Packaging component: Patient Information**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 400 (L) x 335 (W) mm**
9. Design / Style: Booklet type	**10. Item code No.: PM04344120**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41709 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Abacavir 600 mg and Lamivudine 300 mg Tablets\SA Private Market\QULAM-CO PIL - PM04344120.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	23/09/2026				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04344120		