

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CAGOL 600/ 50/300 mg film-coated tablets

abacavir/ dolutegravir/lamivudine

Contains Sugar (Mannitol 184.380 mg)

Read all of this leaflet carefully before you start taking CAGOL

- 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.
- **CAGOL** 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 **CAGOL** is and what it is used for
2. What you need to know before you take **CAGOL**
3. How to take **CAGOL**
4. Possible side effects
5. How to store **CAGOL**
6. Contents of the pack and other information

1. What CAGOL is and what it is used for

CAGOL contains 3 medicines: abacavir, dolutegravir and lamivudine. Abacavir and

lamivudine belong to a group of antiretroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs) and dolutegravir belongs to a group of antiretroviral medicines called integrase inhibitors (INIs).

CAGOL is used to treat HIV (human immunodeficiency virus) in combination with other antiretroviral medicines in adults aged 18 and older. **CAGOL** is used when a you have HIV and have never taken antiretroviral medicines or if you have no resistance to any of the three medicines that **CAGOL** contains.

2. What you need to know before you take **CAGOL**

Do not take **CAGOL**

- if you are hypersensitive (allergic) to abacavir, lamivudine, dolutegravir, or to any other medicine containing any of these individual ingredients, or any of the other ingredients of **CAGOL**
- if you are taking another medicine called dofetilide or pilsicainide (to treat heart conditions)
- if you are taking a medicine called metformin (to treat diabetes)
- if you have moderate to severe liver disease
- if you are pregnant, intend to become pregnant or if you are breastfeeding your baby
- if you have moderate to severe renal disease

Warnings and precautions

Take special care with **CAGOL**:

- If you develop a rash. Some people taking **CAGOL** have had allergic reactions.
- Changes in body fat develop in some patients taking **CAGOL**. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), in the

breasts and around the trunk. Loss of fat from the legs, arms and face may also happen.

- If you get any symptoms of infection while you are taking **CAGOL**:
People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.
- If you experience joint aches, pain, stiffness or difficulty in movement, contact your doctor.
- You may continue to develop infections and other complications of HIV and therefore need to remain under close observation by your healthcare professional.
- **CAGOL** does not prevent the risk of infecting others by sexual contact or blood contamination. Therefore, take the necessary precautions.
- If you develop stomach pains, nausea and vomiting inform your healthcare provider as this could be caused by pancreatitis.
- Possible signs of lactic acidosis (build-up of an acid in the blood) may occur. Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your healthcare provider right away if you get signs of lactic acidosis.
Signs include: nausea, vomiting, loss of appetite, stomach pain and shortness of breath.
- Risk of cardiovascular events
It cannot be excluded that abacavir may increase the risk of having cardiovascular events.
Tell your doctor if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of heart cardiovascular diseases such as high

blood pressure, or diabetes. Do not stop taking **CAGOL** unless your doctor advises you to do so.

- Inform your healthcare provider if you are using any other ARV medicines which contain etravirine, efavirenz, nevirapine or tipranavir with ritonavir or TB (tuberculosis) medicines containing rifampicin.
- Do not take other ARV medicines which contain the same ingredients as **CAGOL** (dolutegravir, abacavir and/ or lamivudine).
- If you are taking calcium or iron supplements take them 2 hours before food or 6 hours after food.
- If you have HIV and also hepatitis, your doctor will monitor you even after stopping treatment.

Children and adolescents

Do not give **CAGOL** to children under 18 years.

Other medicines and CAGOL

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Do not take **CAGOL** with these medicines:

- Dofetilide or pilsicainide (used to treat heart conditions)
- Metformin (used to treat diabetes)

Some medicines can affect how **CAGOL** works, or make it more likely that you will have side effects. These include:

- Medicines called antacids (used to treat indigestion and heartburn). Do not take an antacid 6 hours before you take **CAGOL**, or for at least 2 hours after you take it.

- Calcium and iron supplements. Do not take a calcium or iron supplement 6 hours before you take **CAGOL**, or for at least 2 hours after you take it.
- Emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat HIV infection
- Rifampicin, to treat tuberculosis (TB) and other bacterial infections
- Trimethoprim/sulfamethoxazole, an antibiotic to treat bacterial infections
- Phenytoin and phenobarbital, to treat epilepsy
- Oxcarbazepine and carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort (*Hypericum perforatum*, a herbal remedy used for depression).
- Methadone, used as a heroin substitute. Abacavir increases the rate at which methadone is removed from the body. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or you may need extra checkups.

CAGOL with food

CAGOL can be taken with or without food.

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 this medicine.

You should not take **CAGOL** if you are pregnant or breastfeeding your baby.

Taking **CAGOL** at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If you get pregnant while taking **CAGOL**, tell your doctor. Your doctor may need to review your treatment.

Driving and using machines

Dizziness and impaired concentration may occur when taking **CAGOL**. If this happens, do not drive or use machines that require you to be alert.

3. How to take CAGOL

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

Always take **CAGOL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose of **CAGOL** is one tablet once a day.

Swallow the tablet with some liquid.

When your **CAGOL** supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to **CAGOL** and become more difficult to treat.

Your doctor will tell you how long your treatment with **CAGOL** will last. Do not stop treatment unless your doctor advises you to.

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

If you take more CAGOL than you should

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

Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take CAGOL

If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. Do not take a double dose to make up for a missed dose.

If you stop taking CAGOL

When your **CAGOL** supply starts to run low, get more from your health care provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to **CAGOL** and become more difficult to treat.

4. Possible side effects

CAGOL can have side effects.

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

Hypersensitivity Reactions

CAGOL contains abacavir and dolutegravir. Both of these active ingredients can cause a serious allergic reaction known as a hypersensitivity reaction. Anyone taking **CAGOL** could develop a hypersensitivity reaction, which could be life threatening if they continue to take **CAGOL**. You are more likely to develop this reaction if you have a gene called HLA-B*5701 (but you can get a reaction even if you don't have this gene).

The most common symptoms for hypersensitivity reactions are:

fever (high temperature) and skin rash.

Other common for hypersensitivity reactions symptoms are:

nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness.

Other symptoms for hypersensitivity reactions include:

pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, headache, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

These are all very serious side effects. If you have them, stop taking CAGOL and tell your doctor immediately or go to the casualty department at your nearest hospital. You may need urgent medical attention or hospitalisation.

Side effects that occur frequently:

- anorexia
- difficulty in sleeping (*insomnia*)
- abnormal dreams
- headache
- dizziness

- feeling sick (*nausea*)
- diarrhoea
- being sick (*vomiting*)
- wind (*flatulence*)
- stomach (*abdominal*) pain
- stomach (*abdominal*) discomfort
- rash
- itching (*pruritus*)
- lack of energy (*fatigue*)
- tiredness
- general feeling of being unwell
- fever (*high temperature*)

Side effects that occur less frequently:

- a decreased number of cells involved in blood clotting (*thrombocytopenia*)
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)

an inflammatory condition which may develop as the immune system becomes stronger ('*IRIS*'). Symptoms of IRIS include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.
- inflammation of the liver (*hepatitis*)
- Increases in liver enzymes (AST, ALT)

Side effects that occur with frequency unknown:

- abdominal distention
- GORD (gastro-oesophageal reflux disease)

- Somnolence (use feel drowsy)
- depression (feelings of deep sadness and unworthiness)
- nightmares
- sleep disorders
- an increase in sugar (glucose) in the blood an increase in triglycerides (type of fat) in the blood

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **CAGOL**.

5. How to store CAGOL

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from moisture.

Store in the original container.

Keep the container tightly closed.

Do not use after the expiry date stated on the label/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 CAGOL contains

The active substances are 600 mg of abacavir as abacavir sulphate, 50 mg of dolutegravir as dolutegravir sodium and 300 mg of lamivudine per tablet.

The other ingredients are:

magnesium stearate, mannitol, microcrystalline cellulose, povidone and sodium starch glycolate.

The tablets are coated with:

A coating solution which contains FD&C blue #2/ Indigo carmine aluminum lake, macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, titanium dioxide (CI 778910).

What CAGOL looks like and contents of the pack

Light blue to blue, oval shaped, film-coated tablets debossed with "EM" on one side and "35" on the other side.

28's: 28 tablets are packed in a 75 ml, white opaque, wide mouth round HDPE (High Density Polyethylene) high wall container. The HDPE container is closed with a 38 mm, white opaque, continuous thread (screw), polypropylene closure with HS130-20 liner. A HDPE canister containing 1 g activated silica gel, with a printed label, free from dust and visual defects is included in each container.

30's: 30 tablets are packed in a 75 ml, white opaque, wide mouth round HDPE (High Density Polyethylene) high wall container. The HDPE container is closed with a 38 mm, white opaque, continuous thread (screw), polypropylene closure with HS130-20 liner. A HDPE canister containing 1 g activated silica gel, with a printed label, free from dust and visual defects is included in each container. The container is packed in an outer carton along with a

leaflet.

90's: 90 tablets are packed in a 200 ml, white opaque, wide mouth round HDPE (High Density Polyethylene) high wall container. The HDPE container is closed with a 38 mm, white opaque, continuous thread (screw), polypropylene closure with HS130-20 liner. A HDPE canister containing 2 g activated silica gel, with a printed label, free from dust and visual defects is included in each container. The container is packed in an outer carton along with a leaflet.

Holder of Certificate of Registration

Emcure Pharmaceuticals SA (Pty) Ltd.

Arizona House, First floor, South Wing, Aspen Business Park

1 Madison Avenue, Aspen Lakes, Extension 13

Johannesburg South,

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