PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CAXETA 150 Film-coated tablets

CAXETA 500 Film-coated tablets

(Capecitabine)

(Contains lactose)

Read all of this leaflet carefully before you take CAXETA.

- 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.
- CAXETA 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 CAXETA is and what it is used for

CAXETA belongs to the group of medicines called "cytostatic medicines ", which stop the growth of cancer cells. CAXETA contains capecitabine, which itself is not a cytostatic medicine. Only after being absorbed by the body (more in tumour tissue than in normal tissue) is it changed into an active anti-cancer medicine.

CAXETA is indicated for the treatment of colon, rectal, gastric, or breast cancers and may be used either alone or in combination with other anti-cancer medicines.

2. What you need to know before you take CAXETA

Do not take CAXETA:

- if you are hypersensitive (allergic) to capecitabine or any of the other ingredients of CAXETA (listed in section 6). You must inform your doctor if you know that you have an allergy or over-reaction to CAXETA.
- if you previously have had severe reactions to fluoropyrimidine therapy (a group of anticancer medicines such as fluorouracil);
- if you are pregnant or breast-feeding;
- if you have severely low levels of white cells or platelets in the blood (leucopenia, neutropenia or thrombocytopenia);
- if you have severe liver or kidney problems;
- If you have a known deficiency of the enzyme dihydropyrimidine dehydrogenase (DPD) that helps with the metabolism of uracil and thymine, which make up part of the structure of your genes;
- if you are being treated now or have been treated in the last 4 weeks with brivudine or sorivudine as part of herpes zoster (chickenpox or shingles) therapy.

Warnings and precautions

Take special care with CAXETA (tell your doctor):

- if you are taking blood thinning medicine such as warfarin;
- if you have liver or kidney diseases;
- If you experience yellowing of your eyes or skin, inform your doctor immediately;
- if you have or had other illnesses, such as heart problems (for example an irregular heartbeat or pains to the chest, jaw and back brought on by physical effort and due to problems with the blood flow to the heart);
- if you have brain diseases [for example, cancer that has spread to the brain, or nerve damage (neuropathy)];
- if you have calcium imbalances (seen in blood test);

- if you have diabetes (high blood sugar levels) or if your blood electrolyte levels (e.g sodium, potassium) are imbalanced;
- if you cannot keep food or water in your body because of severe nausea and vomiting;
- if you have diarrhoea while you are taking CAXETA, inform your doctor immediately. You may become dehydrated and your doctor will closely monitor and treat your condition;
- if you are dehydrated;
- if you have imbalances of ions in your blood (electrolyte imbalances, seen in tests);
- if you have a history of eye problems as you may need extra monitoring of your eyes;
- if you have a severe skin reaction that affects the palms of your hands and the soles of your feet (causing redness, swelling, tingling, burning, blisters, sores or pain, which can cause difficulty in walking or using of your hands);
- if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD);
- If you experience any infection while you are taking CAXETA inform your doctor immediately. CAXETA lowers your immune system and the ability of your body to fight infections;
- If you have previously received treatment for cancer (radiation therapy);
- If you have or recently had chicken pox or herpes zoster (shingles) infection;
- If you are elderly.

Dihydropyrimidine Dehydrogenase (DPD) deficiency:

DPD deficiency is a rare condition present at birth that is not usually associated with health problems unless you receive certain medicines. If you have an unrecognised DPD deficiency and take CAXETA, you are at an increased risk of acute early-onset of severe forms of the side effects listed under section 4 Possible side effects.
Contact your doctor immediately if you are concerned about any of the side effects or if you notice any additional side effects not listed in the leaflet (see section 4 Possible side effects).

Children and adolescents

CAXETA is not indicated in children below 18 years of age. Do not give CAXETA to children below 18 years of age as it is unlikely to be safe.

Other medicines and CAXETA

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

You must not take brivudine or sorivudine (anti-viral medicines for treatment of shingles or chickenpox) at the same time as CAXETA treatment (including during any rest periods when you are not taking any CAXETA tablets). If you have taken brivudine or sorivudine you must wait for at least 4 weeks after stopping brivudine or sorivudine before starting to take CAXETA.

Also, you need to be particularly careful by telling your doctor if you are taking any of the following:

- medicines for seizures or tremors (e.g. phenytoin),
- gout medicines (e.g. allopurinol),
- blood-thinning medicines (e.g. coumarin, warfarin),
- interferon alpha,
- radiotherapy and certain medicines used to treat cancer (leucovorin, folinic acid, oxaliplatin, bevacizumab, cisplatin, irinotecan),
- medicines used to treat folic acid deficiency,
- Antacids, medication used to treat stomach ulcers or acid reflux,
- Vaccines.

CAXETA with food and drink

Take CAXETA no later than 30 minutes after meals. **Do not crush or cut tablets.** If you cannot swallow CAXETA tablets whole, tell your healthcare provider.

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.

Pregnancy

You must not take CAXETA if you are pregnant or think you might be. CAXETA can cause severe damage to your unborn baby and you should contact you doctor immediately.

Breastfeeding

You must not breastfeed if you are taking CAXETA and for 2 weeks after the last dose.

Fertility

If you are a woman who could become pregnant you should use effective contraception during treatment with CAXETA and for 6 months after the last dose.

If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with CAXETA and for 3 months after the last dose.

Driving and using machines

CAXETA may make you feel dizzy, nauseous or tired. It is therefore possible that CAXETA could affect your ability to drive a car or operate machinery.

It is not always possible to predict to what extent CAXETA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CAXETA affects them.

CAXETA contains lactose

CAXETA contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take CAXETA.

3. How to take CAXETA

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

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

CAXETA should only be prescribed by a doctor experienced in the use of anticancer medicines.

CAXETA tablets are for adults only.

Swallow the tablet whole with a sufficient quantity of liquid (e. g. one glass of water).

Do not crush or cut the tablet.

Your doctor will prescribe a dose and treatment regimen that is right for you. CAXETA tablets are usually taken for 14 days followed by a 7 day rest period (when no tablets are taken). This 21 day period = one treatment cycle. In combination with other agents you may need to take the tablets over a different time period (e.g. every day, with no rest period). Your doctor will tell you what dose you need to take, when to take it and for how long you need to take it.

Your doctor may want you to take a combination of tablets.

- Take these tablets in the combination prescribed by your doctor;
- Take the tablets within 30 minutes after the end of a meal (breakfast and dinner);
- It is important that you take all your medication as prescribed by your doctor.

Your doctor will tell you how long your treatment with CAXETA will last. If you have the impression that the effect of CAXETA is too strong or too weak, tell your doctor or pharmacist.

If you take more CAXETA than you should

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

You might get the following side effects if you take a lot more CAXETA than you should: feeling or being sick, diarrhoea, inflammation or ulceration of the gut or mouth, pain or bleeding from the intestine or stomach, or bone marrow depression (reduction in certain kinds of blood cells). Tell your doctor immediately if you experience any of these symptoms.

Take this leaflet and the rest of the remaining tablets with you, so the doctor will know what you have taken.

If you missed a dose of CAXETA

Do not take a double dose to make up for forgotten individual doses. Instead, continue your regular dosing schedule and check with your doctor.

If you stop taking CAXETA

Do not stop taking CAXETA without consulting your doctor.

There are no side effects caused by stopping treatment with CAXETA tablets. In case you are using warfarin, stopping CAXETA might require that your doctor adjusts your warfarin dose.

If you have any further questions on the use of CAXETA, ask your doctor or pharmacist.

4. Possible side effects

CAXETA can have side effects.

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

If any of the following happens stop taking CAXETA and tell your doctor immediately or go to the casualty department of your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- *Steven-Johnson syndrome:* if you experience painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (e.g., mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system (e.g., bronchitis) and/or fever.

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

- *Diarrhoea:* if you have an increase of 4 or more bowel movements compared to your normal bowel movements each day or any diarrhoea at night;
- *Vomiting:* if you vomit more than once in a 24-hour time period;
- *Nausea:* if you lose your appetite, and the amount of food you eat each day is much less than usual;
- *Stomatitis:* if you have pain, redness, swelling or sores in your mouth and/or throat;
- *Hand-and-foot skin-reaction:* if you have pain, swelling, redness or tingling of hands and/or feet;
- *Fever:* if you have a temperature of 38 °C or greater;
- *Infection:* if you experience signs of infection caused by bacteria or virus, or other organisms;
- *Chest pain:* if you experience pain localised to the centre of the chest, especially if it occurs during exercise;
- *Steven-Johnson syndrome:* if you experience painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (e.g., mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system (e.g., bronchitis) and/or fever;
- feeling weak, unexplained bruising or bleeding (nose bleeds, bleeding gums or pinpoint bleeds on your skin);
- yellowing of your skin and eyes, also called jaundice;
- bladder infection, blood in urine, increased night time urination, loss of bladder control;
- pain in joints, limbs or back, swelling of joints;
- *DPD Deficiency:* if you have a known DPD deficiency, you are at an increased risk of acute early-onset of toxicity and severe, life-threatening, or fatal adverse reactions caused by capecitabine (e.g., stomatitis, mucosal inflammation, diarrhoea, neutropenia, and neurotoxicity).

If caught early, these side effects usually improve within 2 to 3 days after treatment discontinuation. If these side effects continue, however, contact your doctor immediately. Your doctor may instruct you to restart treatment at a lower dose.

Hand and foot skin-reaction can lead to loss of fingerprint, which could impact your identification by fingerprint scan.

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:

- diarrhoea, nausea, vomiting, stomatitis (sores in mouth and throat) and abdominal pain,
- hand-and-foot skin-reaction (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red), rash, dry or itchy skin,
- tiredness,
- loss of appetite (anorexia),
- decreases in the number of white blood cells or red blood cells (seen blood in tests),
- dehydration, weight loss,
- sleeplessness (insomnia), depression,
- headache, sleepiness, dizziness, abnormal sensation in the skin (numbness or tingling sensation), taste changes,
- eye irritation, increased tears, eye redness (conjunctivitis),
- inflammation of the veins (thrombophlebitis),
- shortness of breath, nose bleeds, cough, runny nose,
- cold sores or other herpes infections,
- infections of the lungs or respiratory system (e.g., pneumonia or bronchitis),
- bleeding from the gut, constipation, pain in upper abdomen, indigestion, excess wind, dry mouth,
- skin rash, hair loss (alopecia), skin reddening, dry skin, itching (pruritus), skin discolouration, skin loss, skin inflammation, nail disorder,
- pain in the joints, or in the limbs (extremities), chest or back,
- fever, swelling in the limbs, feeling ill,
- problems with liver function (seen in blood tests) and increased blood bilirubin (excreted by the liver).

These side effects can become severe; therefore, it is important that you always contact your doctor immediately when you start to experience a side effect. Your doctor may instruct you to decrease the dose and/or temporarily discontinue treatment with CAXETA. This will help reduce the likelihood that the side effect continues or becomes severe.

Less frequent side effects:

- blood infection, urinary tract infection, infection of the skin, infections in the nose and throat, fungal infections (including those of the mouth), influenza, gastroenteritis, tooth abscess,
- lumps under the skin (lipoma),
- decreases in blood cells including platelets, thinning of blood (seen in tests),
- allergy,
- diabetes, decrease in blood potassium, malnutrition, increased blood triglycerides,
- confusional state, panic attacks, depressed mood, decreased libido,
- difficulty speaking, impaired memory, loss of movement coordination, balance disorder, fainting, nerve damage (neuropathy) and problems with sensation,
- blurred or double vision,
- vertigo, ear pain,
- irregular heartbeat and palpitations (arrhythmias), chest pain and heart attack (infarction),
- blood clots in the deep veins, high or low blood pressure, hot flushes, cold limbs (extremities), purple spots on the skin,
- blood clots in the veins in the lung (pulmonary embolism), collapsed lung, coughing up blood, asthma, shortness of breath on exertion,
- bowel obstruction, collection of fluid in the abdomen, inflammation of the small or large intestine, the stomach or the oesophagus, pain in the lower abdomen, abdominal discomfort, heartburn (reflux of food from the stomach), blood in the stool,
- jaundice (yellowing of skin and eyes),
- skin ulcer and blister, reaction of the skin with sunlight, reddening of palms, swelling or pain of the face,
- joint swelling or stiffness, bone pain, muscle weakness or stiffness,
- fluid collection in the kidneys, increased frequency of urination during the night, incontinence, blood in the urine, increase in blood creatinine (sign of kidney dysfunction),
- unusual bleeding from the vagina,

- swelling (oedema), chills and rigors,

Some of these side effects are more frequent when CAXETA is used with other medicines for the treatment of cancer.

Other side effects seen in this setting are the following:

Frequent side effects:

- decrease in blood sodium, magnesium or calcium, increase in blood sugar (as seen in blood tests)
- nerve pain,
- ringing or buzzing in the ears (tinnitus), loss of hearing,
- vein inflammation,
- hiccups, change in voice,
- pain or altered/abnormal sensation in the mouth, pain in the jaw,
- sweating, night sweats,
- muscle spasm,
- difficulty in urination, blood or protein in the urine,
- bruising or reaction at the injection site (caused by medicines given by injection at the same time).

Less frequent side effects:

- weariness,
- weakness,
- loss of weight,
- narrowing or blockage of tear duct (lacrimal duct stenosis),
- kidney and liver failure,
- inflammation leading to dysfunction or obstruction in bile secretion (cholestatic hepatitis),
- specific changes in the electrocardiogram (QT prolongation),
- certain types of dysrhythmia (problems with heartbeat) (including ventricular fibrillation, torsade de pointes, and bradycardia),
- eye inflammation causing eye pain and possibly eyesight problems,

- inflammation of the skin causing red scaly patches due to an immune system illness,
- severe skin reaction such as skin rash, ulceration and blistering which may involve ulcers of the mouth, nose, genitalia, hands, feet and eyes (red and swollen eyes).

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.

This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CAXETA.

Suspected adverse reactions can also be reported directly to the Holder of the Registration Certificate (HCR) via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5. How to store CAXETA

Store all medicines out of sight and reach of children.

Store at or below 25 °C.

Keep blister strips in outer carton until required for use.

Do not use after the expiry date stated on the label and carton. Return all unused medicine to your pharmacist.

Do not dispose of any unused medicine in drains or sewerage systems (e.g., toilets). Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What CAXETA contains

The active ingredient is capecitabine.

Each CAXETA 150 mg film-coated tablet contains 150 mg of capecitabine.

Each CAXETA 500 mg film-coated tablet contains 500 mg of capecitabine

The other ingredients are: Croscarmellose sodium, hypromellose, lactose anhydrous, microcrystalline cellulose, magnesium stearate, opadry II pink 30F540003 (150 mg), opadry II orange 30F530001 (500 mg), purified water, and talc.

What CAXETA looks like and contents of the pack

CAXETA 150:

Light peach coloured, oval shaped, biconvex film-coated tablets debossed with "150" on one side and plain on other side.

Blister Pack 60's: 6 blisters of 10 tablets packaged in the Aluminum/Aluminum blister consists of Triple Layer laminate made up of 25 OPA/45 AL/ 60 PVC forming material film and Push through aluminum foil with 6-8 g heat seal lacquer lidding foil.

Bottle Pack 60's: 60 Tablets packaged in 30 mL HDPE bottles, closed with 33 mm child resistant polypropylene caps (CRC) with FS5-4 induction liner, one 2 g silica gel canister is kept in each bottle.

CAXETA 500:

Peach coloured, oval shaped, biconvex film-coated tablets debossed with "500" on one side and plain on other side.

Blister Pack 120's: 12 blisters of 10 tablets packaged in the Aluminum/Aluminum blister consists of Triple Layer laminate made up of 25 OPA/45 AL/ 60 PVC forming material film and Push through aluminum foil with 6-8 g heat seal lacquer lidding foil.

Bottle Pack 120's: 120 Tablets packaged in 150 mL HDPE bottles, closed with 38 mm child resistant polypropylene caps (CRC) with FS5-4 induction liner, two 2 g silica gel canisters are kept in each bottle.

Holder of Certificate of Registration

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This leaflet was last revised in

17 February 2026

Registration numbers

CAXETA 150: 47/26/1287

CAXETA 500: 47/26/1288

Access to the corresponding professional information

16 February 2021

Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website:

https://sunpharma.com/south-africa-products/