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
2. What you need to know before you take CAXETA
3. How to take CAXETA
4. Possible side effects
5. How to store CAXETA
6. Contents of the pack and other information

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

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

Tel: +27(0) 12 643 2000

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Registration numbers

CAXETA 150: 47/26/1287

CAXETA 500: 47/26/1288

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/

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

CAXETA 150 Filmbedekte tablette

CAXETA 500 Filmbedekte tablette

(Kapesitabien)

(Bevat laktose)

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om CAXETA te neem**.**

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief vir jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- CAXETA is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat CAXETA is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy CAXETA neem
3. Hoe om CAXETA te neem
4. Moontlike newe-effekte
5. Hoe om CAXETA te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat CAXETA is en waarvoor dit gebruik word

CAXETA behoort aan ‘n groep medisyne wat "sitostatiese middels" genoem word, wat verhoed dat kankerselle groei. CAXETA bevat kapesitabien, wat opsigself nie ‘n sitostatiese middel is nie. Slegs nadat dit deur die liggaam geabsorbeer is (meer in kankerweefsel as in normale weefsel), word dit verander na aktiewe anti-kanker medisyne.

CAXETA word aangedui vir die behandeling van kolon-, rektale, maag- of borskanker en kan óf alleen óf in kombinasie met ander anti-kanker medisyne gebruik word.

2. Wat jy moet weet voordat jy CAXETA neem

Moenie CAXETA neem nie:

- as jy hipersensitief (allergies) is vir kapesitabien of vir enige van die ander bestanddele van CAXETA (gelys in afdeling 6). Jy moet jou dokter inlig as jy weet dat jy ‘n allergie of oorreaksie teen CAXETA het.
- as jy voorheen ernstige reaksies teen fluoropirimidien-terapie gehad het (‘n groep anti-kanker medisyne soos fluoro-urasiel);
- as jy swanger is of borsvoed;
- as jy ernstige lae vlakke van witboedselle of plaatjies in die bloed het (leukopenie, neutropenie of trombositopenie);
- as jy ernstige lewer- of nierprobleme het;
- as jy weet dat jy ‘n bekende tekort aan die ensiem, dihidropirimidien-dehidrogenase (DPD), besit wat help met die metabolisme van urasiel en timidien, wat deel uitmaak van die struktuur van jou gene;
- as jy nou behandel word, of as jy in die afgelope 4 weke behandel was, met brivudien of sorivudien as deel van herpes zoster-terapie (waterpokkies of gordelroos).

Waarskuwings en voorsorgmaatreëls:

Tref spesiale voorsorg met CAXETA (lig jou dokter in):

- as jy bloedverdunningsmiddels soos warfarien gebruik;
- as jy lewer- of niersiektes het;
- as jy vergeling van jou oë of vel ervaar, moet jy jou dokter onmiddellik inlig;

- as jy ander siektetoestande het of gehad het, soos hartprobleme (byvoorbeeld ‘n onreëlmatige hartklop of pyn in die borskas, kakebeen en rug wat aangebring word deur fisiese inspanning en as gevolg van probleme met die bloedvloei na die hart);

- as jy breinsiektes het [byvoorbeeld kanker wat na die brein versprei het of senuweeskade (neuropatie)];

- as jy kalsiumwanbalans het (waargeneem in bloedtoets);

- as jy diabetes (hoë bloedsuikervlakke) het of as jou bloedelektrolietvlakke (bv. natrium, kalium) in wanbalans is;

- as jy nie kos of water in jou liggaam kan inhou nie as gevolg van erge naarheid en braking;

- as jy diarree het terwyl jy CAXETA neem, moet jy jou dokter onmiddellik inlig. Jy kan gedehidreer raak en jou dokter sal jou noukeurig monitor en jou toestand behandel;

- as jy gedehidreer is;

- as jy wanbalans van ione in jou bloed het (elektrolietwanbalans, waargeneem in toetse);

- as jy ‘n geskiedenis van oogprobleme het, aangesien jy bykomende monitering van jou oë mag benodig;

- as jy ‘n ernstige velreaksie het wat die palms van jou hande en voetsole affekteer (wat rooiheid, swelling, tinteling, branderigheid, blase, sere of pyn veroorsaak, wat kan veroorsaak dat jy sukkel om te loop of jou hande te gebruik);

- as jy weet dat jy ‘n gedeeltelike tekort aan die aktiwiteit van die ensiem, dihidropirimidien-dehidrogenase (DPD) het;

- as jy enige infeksie ervaar terwyl jy CAXETA neem, moet jy jou dokter onmiddellik inlig. CAXETA verlaag jou immuunstelsel en die vermoë van jou liggaam om infeksie te beveg;

- as jy voorheen behandeling vir kanker ontvang het (bestralingsterapie);

- as jy het of onlangs waterpokkies of herpes zoster (gordelroos)-infeksie gehad het;

- as jy bejaard is.

Dihidropirimidien-dehidrogenase (DPD) tekort:

DPD-tekort is ‘n seldsame toestand teenwoordig by geboorte wat nie normaalweg met hartprobleme geassosieer word nie, tensy jy sekere medisyne ontvang. As jy ‘n onherkenbare DPD-tekort het en CAXETA neem, het jy ‘n verhoogde risiko om akute vroeë-aanvang van ernstige vorme van die newe-effekte te ervaar wat onder afdeling 4, Moonlike newe-effekte, gelys word.

Kontak onmiddelllik jou dokter as jy bekommerd is oor enige van die newe-effekte of as jy enige bykomende newe-effekte ervaar wat nie in hierdie inligtingstuk opgeneem is nie (sien afdeling 4, Moonlike newe-effekte).

Kinders en adolessente

CAXETA word nie aanbeveel by kinders onder die ouderdom van 18 jaar nie. CAXETA moet nie aan kinders onder die ouderdom van 18 jaar toegedien word nie, aangesien dit onwaarskynlik is dat dit veilig is.

Ander medisyne en CAXETA

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).

Jy moet nie brivudien of sorivudien (anti-virale medisyne vir die behandeling van gordelroos of waterpokkies) op dieselfde tyd as behandeling met CAXETA neem nie (insluitend tydens die rusperiodes wanneer jy nie enige CAXETA tablette neem nie).

As jy brivudien of sorivudien gebruik het, moet jy vir ten minste 4 weke wag nadat jy opgehou het om brivudien of sorivudien te neem, voordat jy begin om CAXETA te neem.

Jy moet ook veral versigtig wees deur jou dokter in te lig indien jy enige van die volgende gebruik:

- medisyne vir toevalle of bewerigheid (bv. fenitoïen),

- medisyne vir jig (bv. allopurinol),
- bloedverdunningsmiddels (bv. koumarien, warfarien),
- interferon alfa,
- bestralingsterapie en sekere middels wat gebruik word om kanker te behandel (leukovorien, foliniese suur, oksaliplatien, bevasisumab, sisplatien, irinotekan),
- medisyne wat gebruik word om foliensuurtekort te behandel.
- teensuurmiddels, medisyne wat gebruik word om maagsere of suurrefluks te behandel,
- entstowwe.

CAXETA saam met voedsel en drinkgoed

Neem CAXETA nie later as 30-minute ná maaltye nie. **Moenie die tablette fynmaak of verdeel nie.** Indien jy nie tablette heel kan insluk nie, moet jy jou gesondheidsorgverskaffer inlig.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, vermoed dat jy swanger mag wees of as jy beplan om swanger te raak, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Swangerskap

Jy moet nie CAXETA neem as jy swanger is of vermoed dat jy swanger mag wees nie. CAXETA kan ernstige skade aan jou ongebore baba veroorsaak en jy moet onmiddellik jou dokter kontak.

Borsvoeding

Jy moet nie borsvoed as jy CAXETA neem nie en vir 2 weke ná die laaste dosis.

Vrugbaarheid

As jy ‘n vrou is wat swanger kan raak, moet jy doeltreffende voorbehoeding gebruik tydens behandeling met CAXETA en vir 6 maande ná die laaste dosis.

As jy ‘n manlike pasiënt is en jou vroulike maat swanger kan raak, moet jy doeltreffende voorbehoeding tydens behandeling met CAXETA gebruik en vir 3 maande ná die laaste dosis.

Bestuur en gebruik van masjinerie

CAXETA kan jou duiselig, naar of moeg laat voel. Dit is daarom moontlik dat CAXETA jou vermoë om ‘n motor te bestuur of masjinerie te hanteer, kan affekteer.

Dit is nie altyd moontlik om te voorspel tot watter mate CAXETA met die daaglikse aktiwiteit van ‘n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie betrokke raak in bogenoemde aktiwiteite nie, totdat hulle weet tot watter mate CAXETA hulle affekteer.

CAXETA bevat laktose

CAXETA bevat laktose. Pasiënte met die seldsame oorerflike toestande van laktose/fruktose of galaktose-onverdraagsaamheid, moet nie CAXETA neem nie.

3. Hoe om CAXETA te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem CAXETA altyd presies soos wat jou dokter of apteker dit voorgeskryf het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

CAXETA kan slegs deur ‘n dokter wat ervare is met die gebruik van anti-kanker medisyne voorgeskryf word.

CAXETA tablette is slegs bedoel vir volwassenes.

Sluk die tablet heel in met ‘n voldoende hoeveelheid vloeistof (bv. een glas water).

Moenie die tablet fynmaak of verdeel nie.

Jou dokter sal ‘n dosis en behandelingsplan voorskryf wat vir jou geskik is. CAXETA tablette word gewoonlik vir 14 dae geneem, gevolg deur ‘n rusperiode van 7 dae (wanneer geen tablette geneem word nie). Hierdie 21-dag periode is gelyk aan een behandelingsiklus.

In kombinasie met ander middels, mag dit vir jou nodig wees om die tablette oor ‘n ander tydperk te neem (bv. elke dag, met geen rusperiode nie). Jou dokter sal jou inlig oor die dosis wat jy moet neem, wanneer jy dit moet neem en vir hoe lank jy dit moet neem.

Jou dokter kan vereis dat jy ‘n kombinasie van tablette moet neem.

- Neem hierdie tablette in die kombinasie soos deur jou dokter voorgeskryf.
- Neem die tablette binne 30-minute ná ‘n maaltyd (ontbyt en aandete).
- Dit is belangrik dat jy al jou medikasie moet neem soos wat dit deur jou dokter voorgeskryf is.

Jou dokter sal jou inlig oor hoe lank jou behandeling met CAXETA sal duur. As jy onder die indruk is dat die effek van CAXETA te sterk of te swak is, moet jy jou dokter of apteker inlig.

As jy meer CAXETA geneem het as wat jy behoort te neem

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Jy kan die volgende newe-effekte ervaar as jy heelwat meer CAXETA geneem het as wat jy behoort te neem: mislike gevoel of naar wees, diarree, inflammasie of sere in die ingewande of mond, pyn of bloeding van die ingewande of maag of beenmurgonderdrukking (afname in sekere soorte bloedselle). Lig jou dokter onmiddellik in as jy enige van hierdie simptome ervaar.

Neem hierdie inligtingstuk en die res van die oorblywende tablette saam met jou sodat die dokter kan weet wat jy geneem het.

As jy ‘n dosis van CAXETA oorgeslaan het

Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie. In plaas daarvan, moet jy voortgaan met jou normale dosisskedule en dit met jou dokter kontroleer.

As jy ophou om CAXETA te neem

Moenie ophou om CAXETA te neem sonder om dit met jou dokter te bevestig nie.

Daar is geen newe-effekte wat veroorsaak word wanneer behandeling met CAXETA tablette gestaak word nie. In die geval van die gebruik van warfarien, kan die staking van CAXETA vereis dat jou dokter jou warfarien-dosis aanpas.

Vra jou dokter of apteker as jy enige verdere vrae oor die gebruik van CAXETA het.

4. Moontlike newe-effekte

CAXETA kan newe-effekte hê.

Nie alle newe-effekte wat vir CAXETA aangemeld is, is in hierdie inligtingstuk ingesluit nie. Raadpleeg asseblief jou gesondheidsorgverskaffer vir advies indien jou algemene gesondheid sou versleg of as jy enige ongewenste effekte ervaar terwyl jy CAXETA neem.

Indien enige van die volgende gebeur, staak die gebruik van CAXETA en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak;
- *Steven-Johnson se sindroom:* as jy ‘n pynlike rooi of perskleurige uitslag wat versprei en blasies en/of ander letsels wat op die slymvliesmembrane begin verskyn (bv. mond en lippe) ervaar, veral as jy voorheen ligsensitiwiteit, infeksies van die respiratoriese stelsel (bv. brongitis) en/of koors gehad het.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teen CAXETA gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- *Diarree:* as jy ‘n toename van 4 of meer stoelgange het vergeleke met jou normale stoelgangpatroon elke dag of enige diarree saans;
- *Braking:* as jy meer as een keer in ‘n 24-uur tydperk opgooi;
- *Naarheid:* as jy jou eetlus verloor en die hoeveelheid voedsel wat jy elke dag inneem veel minder as gewoonlik is;
- *Stomatitis:* as jy pyn, rooiheid, swelling of sere in jou mond en/of keel het;
- *Voet-en hand-velreaksie:* as jy pyn, swelling, rooiheid of tinteling van jou hande en/of voete het;
- *Koors:* as jy ‘n koors van 38 °C of hoër het;
- *Infeksie:* as jy tekens van infeksie ervaar wat deur bakterieë of virusse of ander organismes veroorsaak is;
- *Borskaspyn:* as jy pyn ervaar wat gelokaliseer is in die middel van jou borskas, veral as dit voorkom tydens oefening;
- *Steven-Johnson se sindroom*: as jy pynlike rooi of perserige uitslag ervaar wat versprei en blasies en/of ander letsels in die slymvliesmembrane (bv. monde en lippe) begin verskyn, veral as jy voorheen ligsensitiwiteit, infeksies van die respiratoriese stelsel (bv. brongitis en/of koors gehad het;
- swak voel, onverklaarbare kneusing of bloeding (neusbloeding, bloeding van die tandvleise of speldepunt-bloedings op jou vel);
- vergeling van jou vel en oë, ook geelsug genoem;
- blaasinfeksie, bloed in urine, verhoogde urinering in die nag, verlies aan blaasbeheer;
- pyn in gewrigte, ledemate of rug, swelling van gewrigte;
- *DPD-tekort:* as jy ‘n bekende DPD-tekort het, het jy ‘n verhoogde risiko vir akute vroeë-aanvang van toksisiteit en ernstige, lewensbedreigende of noodlottige ongewenste reaksies veroorsaak deur kapesitabien ervaar (bv. stomatitis, onsteking van die slymvliese, diarree, neutropenie en neurotoksisiteit).

As dit betyds gediagnoseer word, verbeter hierdie newe-effekte gewoonlik binne 2 tot 3 dae nadat behandeling onttrek is. As hierdie newe-effekte egter voortduur, moet jy jou dokter dadelik kontak. Jou dokter mag aanraai dat jy behandeling teen ‘n laer dosis hervat.

Voet-en-hand-velreaksie kan lei tot verlies van vingerafdruk, wat ‘n impak op die identifisering van jou vingerafdruk-skandering kan hê.

Hierdie is almal ernstige newe-effekte. Jy mag dringend mediese bystand nodig hê.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- diarree, naarheid, braking, stomatitis (sere in die monde n keel) en abdominale pyn,
- hand-en-voet velreaksie (palms van die hande en voetsole tintel, word gevoelloos, pynlik, opgeswel of rooi), uitslag, droë of jeukerige vel,
- moegheid,
- verlies aan eetlus (anoreksie),
- afname in die aantal witbloedselle of rooibloedselle (waargeneem in bloedtoetse),
- dehidrasie, gewigsverlies,
- slapeloosheid (insomnie), depressie,
- hoofpyn, slaperigheid, duiseligheid, abnormale sensasie op die vel (gevoelloosheid of tintelende sensasie), smaakveranderinge,
- oogirritasie, verhoogde trane, oogrooiheid (konjunktivitis),
- inflammasie van die are (tromboflebitis),
- kortasemigheid, neusbloeding, hoes, loopneus,
- koorsblare of ander herpes infeksies,
- infeksies van die longe of respiratoriese stelsel (bv. longontsteking of brongitis),
- bloeding vanuit die ingewande, hardlywigheid, pyn in die boonste gedeelte van die maag, slegte spysvertering, oormatige winderigheid, droë mond,
- veluitslag, haarverlies (alopesie), vel word rooi, droë vel, jeuk (pruritis), velverkleuring, verlies van vel, inflammasie van die vel, naelversteuring,

- pyn in die gewrigte of in die ledemate (ekstremiteite), borskas of rug,
- koors, swelling in die ledemate, voel siek,
- probleme met lewerfunksie (waargeneem in bloedtoetse) en verhoogde bilirubien in bloed (uitgeskei in die lewer).

Hierdie newe-effekte kan ernstig raak; daarom is dit belangrik dat jy altyd jou dokter dadelik kontak as jy begin om 'n newe-effek te ervaar. Jou dokter sal jou aansê om jou dosis te verlaag en/of behandeling met CAXETA tydelik te staak. Dit sal help om die moontlikheid te verlaag dat die newe-effek aanhou of erger raak.

Minder dikwelse newe-effekte:

- bloedinfeksie, urienweginfeksie, infeksie van die vel, infeksie in die neus en keel, fungusinfeksie (insluitend dié van die mond), griep, gastro-enteritis, tandabses,
- knoppe onder die vel (lipome),
- afname in bloedselle insluitend plaatjies, verdunning van bloed (waargeneem in toetse),
- allergie,
- diabetes, afname in kalium in bloed, wanvoeding, verhoogde trigliseriede in bloed,
- verwarde toestand, angsaanvalle, onderdrukte gemoed, afname in libido,
- sukkel om te praat, belemmerde geheue, verlies aan bewegingskoördinasie, balansversteuring, floute, skade aan senuwees (neuropatie) en probleme met sensasie,
- belemmerde of dubbele visie,
- vertigo, oorpyn,
- onreëlmatige hartklop en palpitasie (aritmieë), borskaspyn en hartaanval (infarksie),
- bloedklonte in die diep vate, hoë of lae bleoddruk, warmgloede, koue ledemate (ekstremiteite), pers kolle op die vel,
- bloedklonte in die are in die long (pulmonêre embolisme), platgevalde long, hoes bloed op, asma, kortasemigheid met inspanning,

- dermobstruksie, versameling van vog in die abdomen, inflammasie van die dun- of dikderm, die maag of die slukderm, pyn in die onderste gedeelte van die maag, abdominale ongemak, sooibrand (terugvloei van voedsel vanaf die maag), bloed in die stoelgang,
- geelsug (vergeling van vel en oë),
- velverswering en blasievorming, reaksie van die vel op sonlig, rooi word van die handpalms, swelling of pyn van die gesig,
- swelling of styfheid van gewrigte, beenpyn, swakheid of styfheid van spiere,
- vogopeenhoping in die niere, verhoogde herhalende urinering in die nag, inkontinensie, bloed in die urine, verhoging in bloedkreatinien (teken van wanfunksie van die nier),
- ongewone bloeding uit die vagina,
- swelling (edeem), koue rillings en styfheid,

Sommige van hierdie newe-effekte kom meer dikwels voor wanneer CAXETA saam met ander medisyne gebruik word vir die behandeling van kanker.

Ander newe-effekte wat in hierdie verband waargeneem word, is die volgende:

Dikwelse newe-effekte:

- verlaging in natrium, magnesium of kalsium in die bloed, verhoging in bloedsuiker (soos waargeneem in bloedtoetse)
- senuweepyn,
- suising of gonsing in die ore (tinnitus), gehoorverlies,
- onsteking in die are,
- hik, verandering in stemtoon,
- pyn of veranderde/abnormale sensasie in die mond, pyn in die kakebeen,
- sweet, nagsweet,

- spierspasma,
- moeilike urinering, bloed of proteïen in die urine,
- kneusing of reaksie by die inspuitplek (veroorsaak deur medisyne wat deur ‘n inspuiting gelyktydig toegedien word).

Minder dikwelse newe-effekte:

- vermoeidheid
- swakheid
- gewigsverlies
- vernouing of blokkering van die traanbuis (lakrimale buis-stenose),
- nier- en lewerversaking,
- inflammasie wat lei tot wanfunksie of obstruksie van galafskeiding (cholestatiese hepatitis),
- spesifieke veranderinge in die elektrokardiogram (QT-verlenging),
- sekere tipes van disritmie (probleme met hartklop) (insluitend ventrikulêre fibrillasie, torsade de pointes en bradikardie),
- inflammasie van die oog wat oogpyn veroorsaak en moontlik probleme met sig,
- inflammasie van die vel wat rooi skubberige gedeeltes veroorsaak as gevolg van ‘n siekte van die immuunstelsel,
- ernstige velreaksie soos veluitslag, verswering en blasievorming wat verband mag hou met sere in die mond, neus, geslagsdele, hande, voete en oë (rooi en geswelde oë).

Jy moet jou dokter of apteker inlig as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte

As jy newe-effekte ervaar, moet jy met jou dokter, apteker of verpleegkundige praat.

Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk opgeneem is nie.

Jy kan ook newe-effekte by SAHPRA aanmeld *via* die SAHPRA Med Safety-toepassing (Medsafety X SAHPRA) en eReporting-platform (whoumc.org) wat aanlyn beskikbaar is op SAHPRA se webblad. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van CAXETA te verskaf.

Vermoedelike ongewenste effekte kan ook direk aan die houer van die registrasiesertifikaat aangemeld word *via* e-pos: pharmacovigilance.africasme@sunpharma.com of

tel: +27(0) 12 643 2000.

5. Hoe om CAXETA te bewaar

- Bewaar alle medisyne buite die sig en bereik van kinders.
- Bewaar by of onder 25 °C.
- Hou die stulpstroke in die buitenste karton tot benodig vir gebruik.
- Moenie ná die vervaldatum soos op die etiket en karton gedruk, gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.
- Vra jou apteker oor hoe jy van ongebruikte medisyne ontslae kan raak. Hierdie maatreëls help om die omgewing te bewaar.

6. Inhoud van die verpakking en ander inligting

Wat CAXETA bevat

Die aktiewe bestanddeel is kapesitabien.

Elke CAXETA 150 mg filmbedekte tablet bevat 150 mg kapesitabien.

Elke CAXETA 500 mg filmbedekte tablet bevat 500 mg kapesitabien

Die ander bestanddele is : Natriumkroskarmellose, hipromellose, anhidriese laktose, mikrokristallyne sellulose, magnesiumstearaat, opadry II pienk 30F540003 (150 mg), opadry II oranje 30F530001 (500 mg), gesuiwerde water en talk.

Hoe CAXETA lyk en inhoud van die verpakking

CAXETA 150:

Ligte perske-kleurige, ovaalvormige, bikonvekse filmbedekte tablette ingepers met "150" op die een kant en skoon op die ander kant.

Stulpverpakking van 60: 6 stulpstroke van 10 tablette elk verpak in Aluminium/Aluminium stulpstroke bestaande uit drielagige laminaat wat bestaan uit 25 OPA/45 AL/ 60 PVC-vormende materiaalfilm en ‘n deurdrukbare aluminiumfoelie met 6-8 g hitte-seëllak bedekkende foelie.

Bottelverpakking van 60: 60 Tablette word verpak in 30 mL HDPE-bottels, verseël met 33 mm kinderbestande polipropileen-proppe met ‘n FS5-4 induksie-voering. Daar is ‘n 2 g silikagel-houertjie binne-in elke bottel.

CAXETA 500:

Perske-kleurige, ovaalvormige, bikonvekse filmbedekte tablette ingepers met "500" op die een kant en skoon op die ander kant.

Stulpverpakking van 120 tablette: 12 stulpstroke van 10 tablette elk verpak in Aluminium/Aluminium stulpstroke bestaande uit drielagige laminaat wat bestaan uit 25 OPA/45 AL/ 60 PVC-vormende materiaalfilm en ‘n deurdrukbare aluminiumfoelie met 6-8 g hitte-seëllak bedekkende foelie.

Bottelverpakking van 120 tablette: 120 Tablette word verpak in 150 mL HDPE-bottels, verseël met 38 mm kinderbestande polipropileen-proppe met n FS5-4 induksie-voering. Daar is ‘n 2 g silikagel-houertjie binne-in elke bottel.

Houer van die registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd.

Lautreweg 14, Stormill, Uitbreiding1,

Roodepoort, 1724

Suid-Afrika

Tel: +27(0) 12 643 2000

Hierdie inligtingstuk was laas hersien op

17 Februarie 2026

Registrasienommers

CAXETA 150: 47/26/1287

CAXETA 500: 47/26/1288