Proposed patient information leaflet for CAPCITURAS 150 mg and 500 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CAPCITURAS 150 mg film-coated tablets

CAPCITURAS 500 mg film-coated tablets

Capecitabine.

Contains sugar.

CAPCITURAS 150 mg: Each film-coated tablet contains 7,5 mg anhydrous lactose.

CAPCITURAS 500 mg: Each film-coated tablet contains 25,0 mg anhydrous lactose.

Read all of this leaflet carefully before you start taking CAPCITURAS

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

1. What CAPCITURAS is and what it is used for

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

CAPCITURAS is used for the treatment of colon, rectal, gastric, or breast cancers and may be used either alone or in combination with other anticancer medicines.

2. What you need to know before you take CAPCITURAS

Do not take CAPCITURAS:

- If you are hypersensitive (allergic) to capecitabine or any of the other ingredients of CAPCITURAS (see **What CAPCITURAS contains**).
- If you previously have had severe reactions to fluoropyrimidine therapy (a group of anticancer medicines, such as fluorouracil).
- If you have a known deficiency for the enzyme dihydropyrimidine dehydrogenase (DPD).
- If you have severely low levels of white cells or platelets in the blood (leukopenia, neutropenia or thrombocytopenia).
- If you have severe liver or kidney problems.
- If you are being treated now or have been treated in the last 4 weeks with brivudine, sorivudine or similar medicines as part of herpes zoster (chickenpox or shingles) therapy.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with CAPCITURAS:

- if you are taking any medicine to treat or prevent blood clots (such as warfarin). Your doctor will regularly do blood tests to monitor your bleeding time and may adjust the dose of your anticoagulant.
- if you have diarrhoea,

- if you cannot keep food or water in your body because of severe nausea and vomiting,
- if you are or become dehydrated,
- if you have a severe skin reaction,
- if you have or had 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 your heart),
- if you have calcium imbalances (seen in blood tests),
- if you have diabetes,
- if you have imbalances of ions in your blood (electrolyte imbalances, seen in tests),
- if you have liver or kidney problems,
- if you know that you have a deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD), (see also section Do Not Take CAPCITURAS)
- if you have a history of eye problems, as you may need extra monitoring of your eyes,
- if you have brain diseases (for example, cancer that has spread to the brain, or nerve damage (neuropathy).

DPD deficiency: DPD deficiency is a genetic condition that is not usually associated with health problems unless you receive certain medicines. If you have DPD deficiency and take CAPCITURAS, you are at an increased risk of severe side effects (listed under section **4 Possible side effects**). It is recommended to test you for DPD deficiency before start of treatment. (See also section Do Not Take CAPCITURAS).

Children and adolescents

CAPCITURAS should not be given to children and adolescents, as safety and efficacy have not been established.

Other medicines and CAPCITURAS

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

This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the other medicines.

Tell your doctor or pharmacist if you are currently using:

- sorivudine or brivudine (anti-viral medicine used for treatment of shingles or chickenpox). If you have taken brivudine you must wait for at least 4 weeks after stopping brivudine before starting to take CAPCITURAS. See also section **Do not take CAPCITURAS**,
- phenytoin (used to treat seizures [fits]),
- warfarin or coumarin (used to prevent blood clots),
- medicines used to treat folic acid deficiency,
- antacids (used for heartburn, reflux or stomach ulcers),
- allopurinol (used to treat gout),
- interferon alpha (used to treat hepatitis or certain forms of cancer),
- if you are having radiotherapy.

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 CAPCITURAS.

You should not take CAPCITURAS if you are pregnant or breastfeeding. If you are a woman who could become pregnant you should use effective contraception during treatment with CAPCITURAS 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 CAPCITURAS and for 3 months after the last dose.

Driving and using machines

CAPCITURAS can cause side effects, such as dizziness, nausea (feeling sick) and tiredness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how CAPCITURAS affects you.

CAPCITURAS contains anhydrous lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking CAPCITURAS.

3. How to take CAPCITURAS

Do not share medicines with any other person.

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of CAPCITURAS is based on your body surface area. This is calculated from your height and weight. 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 150 mg and 500 mg tablets for each dose.

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.

CAPCITURAS 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 medicines you may need to take the tablets over a different time period (e.g. every day, with no rest period).

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

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

If you take more CAPCITURAS than you should

If you take more CAPCITURAS than you should, contact your doctor as soon as possible before taking the next dose.

If you forget to take CAPCITURAS

Do not take the missed dose at all and do not take a double dose to make up for a forgotten dose. Instead, continue your regular dosing schedule and check with your doctor.

If you stop taking CAPCITURAS

There are no side effects caused by stopping treatment with CAPCITURAS. In case you are using warfarin, stopping CAPCITURAS might require that your doctor adjusts your warfarin dose. If you have any further questions on the use of CAPCITURAS, ask your doctor or pharmacist.

4. Possible side effects

CAPCITURAS can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CAPCITURAS. You may need urgent medical attention or hospitalisation.

Stop taking CAPCITURAS immediately and contact your doctor if any of the following symptoms occur:

- *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, and redness of hands and/or feet.
- *Fever or Infection:* if you have a temperature of 38 °C or greater, or other signs of infection.
- *Chest pain:* if you experience pain localised to the centre of the chest, especially if it occurs during exercise.
- *Stevens-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.

Most side effects usually improve after treatment discontinuation. 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.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sepsis (fever, difficulty breathing, low blood pressure, confusion, rapid heartrate),
- frequent infections such as fever, severe chills, sore throat or mouth ulcers,

- decreases in the number of white blood cells or red blood cells (seen in tests),
- bleeding or bruising more easily than normal,
- changes in the way your heart beats (beating faster or slower than usual, irregular heartbeat), chest pain and heart attack (pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath),
- liver failure (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick) of blood, yellowing of skin or eyes).

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration),
- dehydration, loss of appetite, weight loss,
- sleeplessness, feeling depressed or anxious,
- headache, sleepiness, dizziness, tingling or numbness of your hands and feet (pins and needles), taste changes,
- eye irritation, increased tears, conjunctivitis (red, itchy, burning eyes, sometimes with a discharge), dry eyes, eye pain, visual impairment, double vision,
- inflammation of the veins (thrombophlebitis),
- difficulty breathing, nose bleeds, cough, runny nose,
- pain or discomfort in your stomach area, intestinal bleeding, constipation, indigestion, flatulence, dry mouth, mouth sores or pain, bloating, rectal bleeding,
- problems with liver function (seen in blood tests) and increased bilirubin in the blood,
- rash, hair loss, kin reddening, dry skin, itching, skin discolouration, skin loss, skin inflammation, nail disorder, excessive sweating night sweats,
- pain in the joints, or in the limbs (extremities), back pain, jaw pain, muscle spasms,

- abnormal physical weakness or lack of energy, fever, swelling in the limbs, generally feeling unwell,
- abnormal sense of touch,
- ringing in the ears, difficulty hearing,
- high or low blood pressure, hot flushes,
- hiccups, change in voice, pain or abnormal sensation in the mouth,
- bruising or reaction at the injection site (caused by medicines given by injection at the same time).
- cold sores or other herpes infections.

Side effects occurring less frequently:

- blood or protein in the urine, pain while urinating,
- infections of the lungs or respiratory system, urinary tract infection, infection of the skin, infections in the nose and throat,
- fungal infections (including those of the mouth), influenza, gastroenteritis (inflammation of the lining of the intestines), tooth abscess,
- lumps under the skin (lipoma)
- decreases in blood cells including platelets, thinning of blood (seen in tests),
- decrease in blood potassium, sodium, magnesium, calcium, increase in blood sugar and fats,
- confusion, panic attacks, decreased libido,
- speech impairment, memory impairment, balance problems, nerve pain,
- sensation of spinning or swaying, ear pain,
- blood clots in the deep veins, coldness of limbs, purple spots on the skin,
- bowel obstruction, collection of fluid in the stomach area, inflammation of the small or large intestine, the stomach or the oesophagus, difficulty swallowing, stomach pain or discomfort, heartburn, blood in the stool,
- jaundice (yellowing of skin and eyes),

- blisters, skin sores or hives, skin sensitivity to 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, loss of bladder control, increase in blood creatinine (sign of kidney problems),
- unusual vaginal bleeding,
- swelling (oedema), chills, shivering,
- narrowing or blockage of tear duct (lacrimal duct stenosis)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of CAPCITURAS.

5. How to store CAPCITURAS

- Store at or below 25 °C.
- Keep the blister in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CAPCITURAS contains

The active substance is capecitabine.

CAPCITURAS 150 mg: Each film-coated tablet contains 150 mg capecitabine.

CAPCITURAS 500 mg: Each film-coated tablet contains 500 mg capecitabine.

The other ingredients are anhydrous lactose, croscarmellose sodium, Hypromellose, magnesium stearate, microcrystalline cellulose, iron oxide red (E172), iron oxide yellow (E172), talc and titanium dioxide (E171).

What CAPCITURAS looks like and contents of the pack

CAPCITURAS 150 mg: Light pink coloured, capsule shaped, biconvex film-coated tablet debossed with CAP on one side and 150 on the other side.

CAPCITURAS 500 mg: Dark pink coloured, capsule shaped, biconvex film coated tablet debossed with CAP on one side and 500 on the other side.

Clear PVC/PVdC/aluminium foil blister strips placed in an outer carton.

Pack size:

CAPCITURAS 150 mg: 60 tablets

CAPCITURAS 500 mg: 60 or 120 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Alturas Healthcare (Pty) Ltd

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1459

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This leaflet was last revised in

Not revised yet.

Registration number

CAPCITURAS 150 mg: Will be allocated by SAHPRA upon registration.

CAPCITURAS 500 mg: Will be allocated by SAHPRA upon registration.