CAPTAB

Capecitabine 150mg Film-Coated Tablets/ Capecitabine 500mg Film-Coated Tablets

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What CAPTAB is used for

Captab is used in the treatment of colon, rectal, gastric, or breast cancers. Furthermore, Captab is used to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.

Captab may be used either alone or in combination with other medicines.

How CAPTAB works

Captab belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Captab contains 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).

Before you use CAPTAB

- *When you must not use it*

Do not take Captab if you:

- If you previously have had severe reactions to fluoropyrimidine therapy (a group of anticancer medicines such as fluorouracil)
- You are allergic to capecitabine or any of the other ingredients of this medicine (listed at the end of this leaflet). You must inform your doctor if you know that you have an allergy or over-reaction to this medicine.
- If you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- 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 liver or kidney disease
- If you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- If you are being treated now or have been treated in the last 4 weeks with brivudine as part of herpes zoster (chickenpox or shingles) therapy.

Children and adolescents

Captab is not indicated in children and adolescents. Do not give Captab to children and adolescents.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You must not take Captab if you are pregnant or think you might be.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking Captab:

- if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD).
- if you have liver or kidney disease.
- 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 the heart).
- if you have calcium imbalances (seen in blood tests).
- if you have diabetes,
- if you cannot keep food or water in your body because of severe nausea and vomiting,
- if you have diarrhea,
- if you are or become 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.

Captab contains anhydrous lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- *Taking other medicines*

Before starting treatment, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the medicines.

You must not take brivudine (an anti-viral medicines for treatment of shingles or chickenpox) at the same time as capecitabine treatment (including during any rest periods when you are not taking any capecitabine tablets).

If you have taken brivudine you must wait for at least 4 weeks after stopping brivudine before starting to take capecitabine.
See also section "When you must not use it."

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

- Gout medicine (Allopurinol),
- Blood- thinning medicines (coumarin, warfarin),
- Medicines for seizures or tremors (Phenytoin),
- interferon alpha.
- Radiotherapy and certain medicines used to treat cancer (folinic acid, oxaliplatin, bevacizumab, cisplatin, irinotecan).
- Medicines used to treat folic acid deficiency.

How to use CAPTAB

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

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

Your doctor will prescribe a dose and treatment regimen that is right for *you*. The dose of Captab is based on your body surface area. This is calculated from your height and weight. The usual starting dose for adults is 1250 mg/ m^2 administered twice daily (morning and evening; equivalent to 2500 mg/m2 total daily dose).

Your doctor will tell you what dose you need to take, when to take it and for how long you need to take it.

- *When to use it*

You should take Captab no later than 30 minutes after meals.

Your doctor may want you to take a combination of 150 mg and 500 mg tablets for each dose.

- Take the tablets morning and evening as prescribed by your doctor.
- Take the tablets within 30 minutes after the end of a meal (breakfast and dinner) and swallow whole with water. Do not crush or cut tablets. If you cannot swallow Captab tablets whole, tell your healthcare provider.
- It is important that you take all your medicine as prescribed by your doctor.

- *How long to use it*

Captab tablets are usually taken for 14 days followed by a 7 day rest period (when no tablets are taken). This 21 day period is one treatment cycle.

In combination with other medicines the usual dose for adults may be less than 1250 mg/m2 of body surface area, and you may need to take the tablets over a different time period (e.g. every day, with no rest period).

There are no side effects caused by stopping treatment with capecitabine. In case you are using coumarin anticoagulants (containing e.g. phenprocoumon), stopping capecitabine might require that your doctor adjusts your anticoagulant dose.

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

- *If you forget to use it*

Do not take the missed dose at all.
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 use too much (overdose)*

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

You might get the following side effects if you take a lot more capecitabine 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.

While you are using it

- *Things you must do*

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 Captab, you are at an increased risk of acute early-onset of severe forms of the side effects listed under section 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 "Side effects").

Pregnancy and breast-feeding
If you are a woman who could become pregnant you should use effective contraception during treatment and If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment.

- *Things you must not do*

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Pregnancy and breast-feeding You must not breast-feed if you are taking Xeloda and for 2 weeks after the last dose.

- *Things to be careful of*

Driving and using machines
Captab may make you feel dizzy, nauseous or tired. It is therefore possible that Captab could affect your ability to drive a car or operate machines.

Side effects

Like all medicines, CAPTAB can cause side effects, although not everybody gets them.

STOP taking Captab immediately and contact your doctor if any of these 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, redness or tingling of hands and/or feet

- *Chest pain:* if you experience pain localised to the centre of the chest, especially if it occurs during exercise.

- increased kidney dysfunction on those with preexisting compromised kidney function

In additional to above, when Captab is used alone, very common side effects, which may affect more than 1 in 10 people are:

- Abdominal Pain
- Rash, Dry or Itchy skin
- Tiredness
- Loss of appetite (Anorexia)

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. You doctor may instruct you to decrease the dose and/ or temporarily discontinue treatment with Captab. This will help reduce the likelihood that the side effect continues or become severe.

Other side effects are:

Common side effects include:

- Decreases in the number of white blood cells or red blood cells (seen 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

- 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)

Uncommon side effects include:

- 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 common when capecitabine is used with other medicines for the treatment of cancer. Other side-effects seen in this setting are the following:

Very common side effects:

- Decrease in the number of count
- Appetite decreased
- Nerve pain
- Excess tear production
- Water retention

- Sore throat
- Constipation
- Hair fall

Common side effects:

- Infection: if you experience signs of infection caused by bacteria or virus, or another organism
- If you have high temperature.
- Hypersensitivity
- Decrease in blood sodium, magnesium or calcium,
- Sleep disorders and anxiety
- Vein inflammation
- Pain or dry eyes
- Ringing or buzzing in the ears (tinnitus).
- Irregular heart rate or Myocardial ischemia (obstruction of blood flow to the heart muscle)
- Flushing (sudden reddening of the face, neck, or upper chest due to increased blood flow)
- Hiccups
- Abdominal pain, gastric, acid reflux
- Inflammation of skin, itch, night sweats.
- Pain in the jaw, 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)

Rare side effects

- Severe kidney failure secondary to dehydration

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of CAPTAB

- *Storage*

Keep out of the reach and sight of children.

Store below 30 °C.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

150MG:
Capecitabine 150 mg Film Coated Tablets is Light pink colored, capsule shaped, biconvex film coated tablet debossed with CAP one side and 150 on other side
Each pack contains 30 film-coated tablets (3 blisters of 10 tablets) and 60 film-coated tablets (6 blisters of 10 tablets).
500MG:
Capecitabine 500 mg Film Coated Tablets is Dark pink colored, capsule shaped, biconvex film coated tablet debossed with CAP one side and 500 on other side.
Each pack contains 30 film-coated tablets (3 blisters of 10 tablets) and 120 film-coated tablets (12 blisters of 10 tablets).

- *Ingredients*

Active ingredient
150mg: Each tablet contains 150mg capecitabine
500mg: Each tablet contains 500mg capecitabine
Inactive ingredients
Lactose Anhydrous, Microcrystalline Cellulose, Croscarmellose Sodium, Hydroxy propyl methyl cellulose, Magnesium Stearate, Opadry Pink.

- *MAL number(s):* MAL23066015ACZ, MAL23066016ACZ

Manufacturer
Shilpa Medicare Limited
Unit 4, Pharmaceutical Formulations SEZ, Plot No's S-20 to S-26, Pharma SEZ, TSIIC, Green Industrial Park, Polepally (V), Jadcherla (M), Mahabubnagar (Dt), 509301 Telangana, India.

Product Registration Holder
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