Patient Information Leaflet

CAPELODA 150 mg / 500 mg TABLETS

SCHEDULING STATUS:

S4

PROPRIETARY NAME, **STRENGTH AND PHARMACEUTICAL FORM:**

CAPELODA 150 (Film-coated tablets)

CAPELODA 500 (Film-coated tablets)

Read all of this leaflet carefully before you start taking CAPELODA.

- Keep this leaflet; you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CAPELODA 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 CAPELODA CONTAINS:

The active ingredient in CAPELODA is capecitabine.

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

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

Inactive ingredients in both formulations include croscarmellose sodium, hypromellose, iron oxide red, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, and titanium dioxide.

Contains Sugar: Lactose Monohydrate.

WARNING:

If you are taking blood thinning medication (anticoagulants), such as warfarin, you will have to go for more regular blood tests and follow-up while you are taking CAPELODA. The combination of CAPELODA and blood thinning medicines may cause bleeding complications. Such complications may occur within days or only after several months of start of therapy with CAPELODA. It may also develop after treatment with CAPELODA has been stopped. Age older than 60 years and a diagnosis of cancer independently increase your risk of blood clotting disorders.

WHAT CAPELODA IS USED FOR:

CAPELODA is used to treat breast cancer and colon cancer, including cancer of both the colon and rectum and gastric cancer. CAPELODA may be given in combination with other anticancer medicines or as standalone therapy. Your doctor will decide whether or not you qualify for treatment with CAPELODA and whether or not it should be combined with other medicines.

BEFORE YOU TAKE CAPELODA:

Do NOT take CAPELODA if you:

- Are hypersensitive or allergic to capecitabine or any of the other ingredients of CAPELODA.
- Previously had a severe and unexpected reaction to medicines belonging to the same class of anticancer medicines as capecitabine (fluoropyrimidine therapy) or if you are known to be hypersensitive or allergic to fluorouracil.
- Are known with dihydropyrimidine dehydrogenase (DPD) deficiency. Please speak to your doctor if you are unsure.
- Have low white blood cell and platelet counts. Please speak to your doctor if you are unsure.

- Have very poor liver function. Please speak to your doctor or pharmacist if you are unsure.
- Have very poor kidney function. Please speak to your doctor or pharmacist if you are unsure.
- Are also taking sorivudine or other medicines related to it for the treatment of viral infections. Please speak to your doctor or pharmacist if you are unsure.
- Are pregnant or breastfeeding (see **"Pregnancy and breastfeeding"**).
- Have a known condition where the body cannot break down the building blocks of DNA or RNA (DPD deficiency)

Take special care with CAPELODA:

Patients taking capecitabine, tegafur, 5-fluorouracil (a chemotherapy drug) or inactive medication that is broken down to 5-fluorouracil once broken down in the body, given either orally, by injection or infusion. These patients should be tested for DPD deficiency (a condition where the body cannot break down the building blocks if DNA or RNA) before they start treatment with CAPELODA.

A lower starting dose should be considered for patients with partial DPD deficiency, to reduce the possibility of experiencing a harmful effect (as they are at higher risk of experiencing life-threatening harmful effect). Following doses can be increased when there is no serious harmful effect experienced since the success of a lower dose has not been proven.

CAPELODA may cause diarrhoea (runny stomach), which can sometimes be severe (see **"POSSIBLE SIDE-EFFECTS"**). If you pass more than 4 to 6 stools per day or during the night, leak stools or if your stools are grossly bloody, you need to report to your doctor as a matter of urgency. Your doctor will interrupt treatment with CAPELODA until the diarrhoea

has cleared and may decide to lower your dosage of subsequent treatment sessions with CAPELODA. Doctor will also prescribe medicines to treat the diarrhoea.

Treatment with CAPELODA may cause hand-foot syndrome (see **"POSSIBLE SIDE-EFFECTS"**). Symptoms include numbness, pins and needles, redness, tingling, or disagreeable or atypical sensations in the hands and/or feet. This condition may progress to a painful red rash with swelling and discomfort severe enough to disrupt your activities of daily living. The most severe form of this adverse reaction present with moist peeling of the skin, ulceration, blistering or severe pain that renders you unable to work or perform everyday tasks. Please report any of these symptoms to your doctor as soon as possible. Your doctor may decide to stop treatment with CAPELODA until your symptoms have resolved and may also decide to decrease your dosage of CAPELODA.

CAPELODA may damage heart tissue leading to heart attack, angina (chest pain on exertion), abnormal heart rate or rhythm, palpitations, heart arrest, heart failure or abnormal electrical activity of the heart (as seen with an electrocardiogram or ECG) (see **"POSSIBLE SIDE EFFECTS"**). These events are more common in people with a history of heart disease. Your doctor will monitor you for any of these complications. If you develop chest pain that goes up to the chin or down the left arm, chest pain with nausea and/or vomiting, or if your chest feels tight, please consult your doctor as a matter of urgency.

CAPELODA may induce extremely serious allergic skin reaction (Stevens-Johnson syndrome and Toxic Epidermal Necrolysis) The reaction is characterised by early symptoms including high body temperature (fever) and flu-like symptoms. A few days later the skin begins to blister and peel forming painful raw areas. Complications may include dehydration (lack of water/fluid), sepsis (infection to an organ injury or damage that can lead to drop in blood pressure leading to respiratory or heart failure, stroke or even death), pneumonia (lung infection, characterised by a dry cough, chest pain, high body temperature difficulty in breathing), and multiple organ failure. CAPELODA should be permanently discontinued in patients who experience a severe skin reaction during treatment.

You should not take CAPELODA if you have been diagnosed with severely reduced kidney or liver function (see **"Do NOT take CAPELODA if you"**). If your kidney or liver function is mildly to moderately reduced, you will have to go for regular blood tests during treatment with CAPELODA to monitor their function.

If you develop chickenpox or shingles, please inform your doctor immediately, because it may be necessary to postpone treatment with CAPELODA for a short while.

Please tell your doctor if you have diabetes, because treatment with CAPELODA may influence your blood sugar levels (see **"POSSIBLE SIDE EFFECTS"**). Treatment with CAPELODA may also influence blood levels of various electrolytes, such as calcium, magnesium and potassium. You will have to go for regular blood tests to monitor your blood levels of these electrolytes.

Taking CAPELODA with food and drink:

CAPELODA tablets should be swallowed with water during or within 30 minutes after a meal.

Pregnancy and Breastfeeding:

Do not take CAPELODA if you are pregnant or breastfeeding your baby (see **"Do NOT take CAPELODA if you"**). CAPELODA may harm your baby. You should make use of adequate contraception to avoid becoming pregnant while taking CAPELODA. Please ask your doctor, pharmacist, or other healthcare professional for advice.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine

Driving and using machinery:

CAPELODA may cause dizziness, fatigue and nausea, which may make it difficult for you to drive a car or operate machinery. You should avoid driving a car or operating machinery until you know how CAPELODA affects you.

Important information about some of the ingredients in CAPELODA:

CAPELODA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you suffer from a rare hereditary conditions of galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, you should not take CAPELODA.

Taking other medicines with CAPELODA:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please speak to your doctor or pharmacist if you are taking any of the following medicines, because you may require a lower dosage or special precaution:

- Blood thinning medicines, such as warfarin (see initial boxed warning).
- Phenytoin for epilepsy.
- Antacids for heartburn or reflux.
- Leucovorin (folinic acid) for the treatment of cancer.
- Sorivudine or similar medicines (please see **"Do NOT take CAPELODA if you"**).
- Allopurinol for the treatment of gout.
- Other medicines that may lower your blood cell or platelet counts (please see **"Do NOT take CAPELODA if you"**).
- Interferon alpha for the treatment of cancer.

If you are scheduled for radiation therapy, your doctor may decide to alter your CAPELODA dose, as radiation therapy in combination with CAPELODA increases your risk of developing low white blood cell and platelet counts, thus increasing your risk of developing infections or bleeding complications.

Please speak to your doctor or pharmacist before you take any vaccination or immunisation, including flu vaccinations. CAPELODA may alter your body's immune response to both live virus and killed virus vaccines, either making the vaccination less effective or increasing your risk of developing side effects. If anyone in close contact with you, especially family members (mostly children), are scheduled for immunisation with oral poliovirus vaccine, it should be postponed. Please discuss this with your treating doctor.

HOW TO TAKE CAPELODA:

Always take CAPELODA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

CAPELODA tablets are usually taken twice daily (morning and evening) for 14 days followed by a 7-day rest period. Your doctor will calculate the most appropriate dosage for you. The tablets should be swallowed whole with water during or within 30 minutes after a meal.

You will be carefully monitored during therapy with CAPELODA. If you develop side effects (see **"POSSIBLE SIDE EFFECTS"**), your doctor may decide to alter your dosage or to interrupt treatment with CAPELODA depending on the nature and severity of the side-effects that you are experiencing. He/she will decide when to re-start therapy at a lower dose or whether treatment with CAPELODA should be stopped.

Your doctor will decide how long treatment with CAPELODA will last.

Safety of CAPELODA in children has not been established.

If you have the impression that the effect of CAPELODA is too strong or too weak, please speak to your doctor or pharmacist.

If you take more CAPELODA than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side -effects listed below.

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

If you forget to take CAPELODA:

Always take CAPELODA as prescribed. If you miss a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE EFFECTS:

CAPELODA can have side effects.

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

The most common side-effects following treatment with CAPELODA include gut disturbances, such as diarrhoea, nausea, vomiting, stomach pain, fatigue, and hand-foot syndrome

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

- Those that occur frequently:
    - Swelling of the face, lips, or tongue with skin rash, hives or itching accompanied by shortness of breath or difficult breathing, wheezing, and nausea or vomiting, since any combination of these symptoms may be due to an allergic reaction.
    - Coughing with yellow- or green-coloured phlegm accompanied by fever or shortness of breath since this may indicate a lung infection.
    - Fever, ulcers that will not heal, blood in the urine, flank, pain, coughing with sputum production or any other symptoms you think may be due to an infection.
    - Pin-point red spots on the skin, easy bruising, blood in the urine or bleeding from the gums, since this may be due to low platelet counts.
    - Bleeding from any site.
    - Diarrhoea or runny stomach

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

- Sudden collapse.
- High fever with nausea, vomiting, loss of appetite, coughing, generally feeling unwell, neck stiffness, and lack of energy as this may indicate a serious or blood-borne infection.
- Chest pain with exertion, chest pain going up the chin or down the left arm, or chest pain accompanied by difficult breathing, nausea, vomiting or anxiety.

- Swelling of the feet, ankles, legs, hands or arms or inability to lie down due to shortness of breath, or coughing with the production of pink sputum, since any of these symptoms may be due to heart failure.
- Severe headache accompanied by altered or loss of consciousness, loss of function of a limb or paralysis of one side of the body, since any combination of these symptoms may be due to a stroke.
- Palpitations or abnormal heart rate or rhythm.
- Altered consciousness, including confusion, with or without neck stiffness, nausea or vomiting.
- Severe pain in the eye with redness, tearing and reduced vision.
- Reduced vision or double vision.
- Coughing of blood.
- Chest pain made worse by breathing or coughing accompanied by shortness of breath, difficult breathing or tightness of the chest.
- Vomiting blood or a substance resembling coffee grounds, blood in the stool or passing black, tarry, foul-smelling stools.
- Intractable vomiting accompanied by severe stomach pain.
- Distension of the stomach, loss of appetite, nausea and vomiting, fever, and inability to pass stool.
- Nausea, vomiting, listlessness and lack of energy, swelling of the hands or feet and legs, palpitations, seizures (convulsions), muscle cramps, fainting spells and at a later stage, loss of consciousness since, a combination of these symptoms may be due to tumour lysis syndrome.
- Severe thirst accompanied by cold, clammy skin, tiredness or weakness, reduced urine production and sometimes confusion, as these symptoms may be due to dehydration.
- Hand-foot syndrome.

- Pins and needles (including pins and needles around the lips or inside the mouth).
- Impaired sense of touch.
- Red, teary eyes or eye irritation.
- Shortness of breath.
- Nose bleeds.
- Coughing.
- Ulcers in or around the mouth.
- Vomiting that does not respond to treatment.
- Pain the upper stomach accompanied by heartburn.
- Any skin rash or painful cracks in the skin.
- Fever or chills.
- Swelling of feet, ankles or legs.
- Pain in a calve or leg muscle accompanied by swelling of the leg, since this may be due to a blood clot.
- Yellow discolouration of the whites of the eyes or skin with or without pain over the liver area, nausea, vomiting, loss of appetite or fever.
- Pain over the kidneys with increased or decreased frequency of urination, difficulty passing urine, blood in the urine, leaking urine or frequent night-time urination.
- Painful urination.
- High blood pressure.
- Tightness of the chest or wheezing.
- Swelling of the stomach.
- Fainting spells.
- Lack of muscle coordination, impaired balance, abnormal walking, or speech abnormalities.
- Memory impairment.

- Difficulty swallowing.
- Any skin rash in a sun-exposed area (e.g. face, hands, or feet).
- Skin discolouration, rash, redness, pain or swelling in an area on the skin previously exposed to radiation therapy.
- Tremors.
- Excessive hunger, excessive thirst and frequent urination accompanied by tiredness since, these symptoms may be due to high blood sugar (glucose) levels.
- Vaginal bleeding.
- Thrush.
- Soft tissue swelling or lump under the skin.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Loss of appetite or reduced appetite.
- Cold sores.
- Runny or blocked nose and/or sore throat.
- Weight loss.
- Sleeplessness, depression.
- Anxiety.
- Taste disturbances, dizziness, headache.
- Vertigo.
- Nausea, stomach pain, constipation, poor digestion, flatulence, dry mouth, or pain in the mouth.
- Dry skin, discolouration or darkening of the skin, nail disorders, peeling of the skin, itching, hair loss or other skin problems.
- Pain in a limb, back pain, pain in a joint, or muscle pain.

- Fatigue, loss of energy or listlessness, extreme tiredness or weakness, generally feeling unwell.
- Hiccups
- Night sweats.
- Thirst.
- Irritability, sleepiness, panic attacks, depressed mood, and decreased libido.
- Increased weight.
- Ear pain.
- Hot flushes or coldness in the hands or feet.
- Dizziness when standing up as this may be due to low blood pressure.
- Hoarseness.
- Pain in the rectum.
- Brittle nails, loosening of nails, nail discolouration, abnormal nails, nail ulcers.
- Increased sweating.
- Pain or swelling in a joint, bone pain, facial pain, stiffness or muscle weakness, pain in the jaw or muscle spasms.
- A single glistening, red node on the skin that bleeds easily.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CAPELODA:

Store at or below 25 °C.

Keep the tablets in the blister pack and the blisters in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CAPELODA:

CAPELODA 150:	Carton containing 60 film-coated tablets packed in clear PVC/ PVdC film and plain aluminium foil blister strips of 10 tablets each.
CAPELODA 500**:**	Carton containing 120 film-coated tablets packed in clear PVC/ PVdC film and plain aluminium foil blister strips of 10 tablets each.

IDENTIFICATION OF CAPELODA:

CAPELODA 150:	Pink-coloured, capsule-shaped, biconvex, film-coated tablet with 150 debossed on one side and plain on the other side.
CAPELODA 500:	Pink-coloured, capsule-shaped, biconvex, film-coated tablet with 500 debossed on one side and plain on the other side.

REGISTRATION NUMBERS:

CAPELODA 150: 47/26/0363

CAPELODA 500: 47/26/0364

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

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