Applicant : Eurolab (Pty) Ltd
Proprietary name : Pecaset 150 mg & 500 mg
Dosage form and strength : Tablet
: Capecitabine 150 mg & 500 mg
Date of submission : 12 December 2024
Approval date: : 22 April 2025

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NAME OF THE MEDICINE

Pecaset 150 film-coated tablet

Pecaset 500 film-coated tablet

Capecitabine

Contains sugar (anhydrous lactose)

Read all of this leaflet carefully before you start using Pecaset

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist.

Pecaset 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.

If any of the side effects gets serious, or if notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

What Pecaset is and what it is used for

What you need to know before you are take Pecaset

How to take Pecaset

Possible side effects

How to store Pecaset

Contents of the pack and other information

What Pecaset is and what it is used for

Pecaset belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Pecaset is used to treat colon, rectal, gastric or breast cancers.

Pecaset is used to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.

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

What you need to know before you take Pecaset

Do not take Pecaset:

If you are hypersensitive (allergic) to capecitabine or any of the other ingredients of Pecaset (see **WHAT** Pecaset **CONTAINS**).

If you previously have had severe reactions to fluoropyrimidine treatment (a group of anticancer medicines such as fluorouracil).

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 have severe low levels of certain white blood cells (leukopenia, neutropenia) or platelets (thrombocytopenia) in your body.

If you have a severe liver or kidney problem.

If you are being treated with sorivudine or brivudine (used to treat viral infections such as herpes zoster e.g. shingles or chicken pox).

Warnings and precautions

If you are taking warfarin or any other blood thinning medication. Your doctor will perform regular blood tests during your treatment with Pecaset and may adjust the dose of your medicine accordingly.

If you experience severe diarrhoea while you are taking Pecaset, inform your doctor immediately. You may become dehydrated and your doctor will closely monitor and treat your condition.

If you experience 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). Inform your doctor as soon as possible.

If you experience any heart problems or changes in the way your heart beats (abnormal heartbeat) while you take Pecaset.

If you have calcium imbalances (seen in blood tests).

If you experience any infection while you are taking Pecaset inform your doctor immediately. Pecaset lowers your immune system and the ability of your body to fight infections.

If you have any liver or kidney problems.

If you experience yellowing of your eyes or skin, inform your doctor immediately.

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 have diabetes mellitus (high blood sugar levels) or if your blood electrolyte levels (e.g sodium, potassium) are imbalanced.

If you have a history of eye problems as you may need extra monitoring of your eyes.

If you have a severe skin reaction.

If you are elderly.

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 Pecaset, 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

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

Other medicines and Pecaset

Taking other medicines with Pecaset:

Warfarin (used to thin your blood and prevent your blood from clotting).

Phenytoin (used to treat seizures or epilepsy).

Antacids (used to treat stomach ulcers or acid reflux).

Leucovorin/folinic acid (used with other medicine to treat cancer).

Sorivudine or brivudine (used to treat viral infections such as herpes zoster e.g. chicken pox or shingles).

Allopurinol (used to treat gout).

Interferon alpha (used to treat cancer).

Radiation therapy, oxaliplatin, bevacizumab or erlotinib (used to treat cancer).

Vaccines (used to improve your immune system to prevent certain diseases).

Taking Pecaset with food and drink

You should take Pecaset within 30 minutes after a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before taking Pecaset**.**

Do not take Pecaset if you are pregnant or suspect that you are pregnant. Pecaset can cause severe damage to your unborn baby and you should contact you doctor immediately.

Do not take Pecaset if you are breastfeeding your baby.

Male patients treated with Pecaset should use highly effective contraception, while being treated with Pecaset and for an additional 3 months after taking the last dose. Female patients and female sexual partners of male patients receiving Pecaset should use highly effective contraception, while being treated with Pecaset and for an additional 6 months after taking the last dose.

Driving and using machines

Pecaset may cause side effects, such as dizziness, fainting, confusion or problems with your eyesight. Do not drive a vehicle, operate machinery, or do anything else that requires your attention, until you know how Pecaset affects you.

Pecaset contains

Pecaset contains anhydrous lactose (a sugar) as an excipient. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pecaset.

3. How to take Pecaset

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

Always take Pecaset exactly as your doctor has instructed you. You should check with your

doctor or pharmacist if you are unsure. Pecaset should only be prescribed by a doctor experienced in the use of anticancer medicines.

Pecaset should be swallowed whole with water and within 30 minutes of a meal.

Your doctor will determine the correct dose for you. Pecaset is 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. Your doctor will tell you how long your treatment with Pecaset will last.

Your doctor may prescribe Pecaset in combination with other medication.

If you have the impression that the effect of **Pecaset** is too strong or too weak, talk to your doctor or pharmacist.

If you take more Pecaset than you should:

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

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

If you forget to take Pecaset:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take Pecaset at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

Pecaset should be taken within 30 minutes after a meal.

4. Possible side effects

Pecaset can have side effects.

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

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

Swelling of your hands, feet, ankles, face, mouth or throat, which may cause difficulty in swallowing or breathing.

Rash or itching.

Fainting.

If you have diarrhoea or an increase of 4 or more bowel movements compared to your normal bowel movements each day or any diarrhoea at night.

If you have pain, swelling, redness or tingling on palms and/or soles of feet which affects your ability to perform daily tasks

Blisters or peeling of skin on hands or feet

If you experience chest pain especially if it occurs during exercise, or an irregular heartbeat.

If you have a fever or experience any signs of an infection.

If you take anti-coagulant medicines and your INR (international normalised ratio) is increased

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

chest infection, persistent cough, shortness of breath, flu-like symptoms,

skin infections, cold sores, mouth ulcers, tooth abscess,

feeling weak, unexplained bruising or bleeding (nose bleeds, bleeding gums or pinpoint bleeds on your skin),

loss of appetite, dehydration, thirst,

nausea, vomiting, abdominal pain, blood in the stools, constipation,

yellowing of your skin and eyes, also called jaundice,

dry or itchy skin, skin rash, nail changes,

pain in joints, limbs or back, swelling of joints,

bladder infection, blood in urine, increased night time urination, loss of bladder control,

tiredness, feeling unwell, swelling in the arms or legs,

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

Tell your doctor as soon as possible if you notice any of the following:

lumps under the skin,

high blood sugar levels, high cholesterol levels,

difficulty sleeping, depression, confusional state, panic attacks,

headache, dizziness, sensation of ‘pins and needles’, taste disturbances, difficulty speaking, impaired memory, difficulty balancing or walking, drowsiness,

excessive tearing or irritation of your eyes, blurred vision, light sensitivity,

ear pain, ringing in ears,

coldness in hands or feet, collapse, hot flushes, high or low blood pressure,

runny nose, sore throat,

indigestion, heartburn,

hair loss, skin discoloration, skin sensitivity to sunlight, increased sweating, nights sweats,

jaw pain, muscle spasms or muscle weakness,

decreased libido, vaginal bleeding.

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

If you are concerned about these or any other unexpected effect(s), talk to your doctor. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. 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 or to Eurolab (Pty) Ltd. by email: drug-safety@eurolab.co.za. By reporting side effects, you can help provide more information on the safety of Pecaset.

5. How to store Pecaset

Store at or below 25 °C. Keep blister strips in outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the label or 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 Pecaset contains

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

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

Croscarmellose sodium, ferric oxide red (colourant), ferric oxide yellow (colourant), hypromellose, magnesium stearate, microcrystalline cellulose, talcum, titanium oxide,

Contains sugar: lactose anhydrous.

What Pecaset looks like and contents of the pack

Clear transparent PVC/PVdC/aluminium blister strips containing 10 tablets.

Pack size: 30, 60 or 120 tablets are packed into an outer carton.

or

Aluminium/aluminium blister strips containing 10 tablets.

Pack size: 30, 60 or 120 tablets are packed into an outer carton

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

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Woodmead, 2144

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