

Specification of Leaflet :

60-75 GSM MAPLITHO PAPER

300 x 300 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

ACALABRUTINIB CAPSULES 100 MG

ACALAKAST™

Composition

Each hard gelatin capsule contains :

Acalabrutinib 100 mg

Excipients q.s.

Approved colour used in empty capsule shell.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

1. What ACALAKAST is

ACALAKAST is a medicine used to treat cancer.

- ACALAKAST contains the active substance acalabrutinib.
- It belongs to a group of medicines called Bruton tyrosine kinase (BTK) inhibitors.

What ACALAKAST is used for

ACALAKAST is used to treat adults with chronic lymphocytic leukaemia (CLL).

CLL is a cancer of white blood cells called B-lymphocytes (or B-cells). These cells are part of the immune system (the body's defences).

How ACALAKAST works

ACALAKAST works by blocking BTK, a protein in the body that helps these cancer cells grow and survive. By blocking BTK, ACALAKAST helps to kill and can reduce the number of cancer cells which can slow down the worsening of the disease.

If you have any questions about how ACALAKAST works or why this medicine has been prescribed for you, ask your doctor, pharmacist or nurse.

2. What you need to know before you take ACALAKAST

Do not take ACALAKAST if:

- you are allergic to acalabrutinib or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before taking ACALAKAST.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking ACALAKAST if you:

- have ever had unusual bruising or bleeding or are on any medicines that increase your risk of bleeding (see section 4 'Possible side effects').
- have an infection (see section 4 'Possible side effects')
- have recently had an operation or are about to have one. Your doctor may stop treatment with ACALAKAST before and after a medical, surgical or dental procedure.
- have ever had hepatitis B (a liver infection) – this is because ACALAKAST could cause hepatitis B to become active again and so that your doctor will look out for signs of this infection coming back (see section 4 'Possible side effects').
- have or ever had irregular heart beat (see section 4 'Possible side effects').

Talk to your doctor if you develop a new lesion or any change in the appearance of an area on the skin as you are at a high risk of developing skin cancer, see section 4. Use sun protection and make regular skin examination.

Your doctor will check your blood cell counts as needed during treatment.

Children and adolescents

Do not give this medicine to children or adolescents aged less than 18 years. This is because it has not been studied in this age group.

Other medicines and ACALAKAST

Tell your doctor, pharmacist or nurse if you are taking or have recently taken or might take any other medicines, especially if you take any of the following:

- antibiotics for bacterial infections – such as clarithromycin
- medicines for fungal infections – such as posaconazole, itraconazole, voriconazole
- ketoconazole – a medicine for Cushing's syndrome (a condition in which the body produces too much of the hormone cortisol)
- medicines for HIV infections – such as indinavir and ritonavir
- medicines for hepatitis C – such as telaprevir
- rifampicin – an antibiotic for bacterial infections (Tuberculosis)
- medicine for migraines – ergotamine
- medicine for low blood sodium – conivaptan
- medicine for high blood sugars – metformin
- medicine to prevent organ rejection – cyclosporine
- medicines for fits (seizures) or epilepsy – such as carbamazepine and phenytoin
- pimozone – a medicine used for Tourette (condition which causes uncontrolled movements and outbursts of words and sounds)
- St. John's wort – a herbal medicine for depression
- theophylline – medicine used for wheezing, shortness of breath, and chest tightness
- medicines for reducing Stomach acid :
 - antacids – such as calcium carbonate
 - Take ACALAKAST 2 hours before or 2 hours after you take these medicines
 - histamine-2 receptor blockers – such as ranitidine and famotidine
 - Take ACALAKAST 2 hours before or 10 hours after you take these medicines
 - proton pump inhibitors – such as omeprazole
 - Avoid taking these medicines while you are taking ACALAKAST
 - methotrexate – a medicine for diseases such as rheumatoid arthritis, psoriasis and ulcerative colitis, which are caused by the immune system working incorrectly.
 - This medicine should be taken at least 6 hours before or after ACALAKAST.

Medicines that increase your risk of bleeding

ACALAKAST may make you bleed more easily. Tell your doctor, pharmacist, or nurse if you take other medicines that increase your risk of bleeding:

- Antiplatelets (medicines that act against blood clotting) such as acetylsalicylic acid and clopidogrel.
- Anticoagulants (blood thinners) such as warfarin or enoxaparin.

Pregnancy

Talk to your doctor before taking ACALAKAST if you are pregnant, think you may be pregnant, or are planning on having a baby. This is because ACALAKAST may harm your unborn baby.

Breast-feeding

Do not breast-feed during treatment with ACALAKAST and for 2 days after your last dose of ACALAKAST. It is not known if ACALAKAST passes into your breast milk.

Driving and using machines

ACALAKAST is unlikely to affect the ability to drive and use machines. However, if you feel dizzy, weak or tired while taking ACALAKAST, you must not drive or use machines.

ACALAKAST contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take ACALAKAST

ACALAKAST will only be prescribed to you by a doctor with experience in the use of medicines for cancer. Always take ACALAKAST exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to take

- The usual dose is one capsule (100 mg) twice a day. Take doses about 12 hours apart.

How to take

- Swallow the capsule whole with water at about the same time each day.
- Do not chew, dissolve or open the capsules as this may change how quickly the medicine gets into your body.
- You can take ACALAKAST with food or between meals.
- You can check when you last took a capsule of ACALAKAST by looking on the blister. Pictures on the blister will help you to take your dose at the right time — the sun for the morning dose and the moon for the evening dose.

If you take more ACALAKAST than you should

If you have taken more ACALAKAST than you should, see a doctor or go to the nearest hospital straight away. Take the capsules and this leaflet with you. If you forget to take a dose

- If less than 3 hours have passed after your usual time for taking a dose, take the missed dose right away. Take the next dose at your usual time.
- If more than 3 hours have passed after your usual time for taking a dose, skip the missed dose. Take the next dose at your usual time.
- Do not take a double dose of ACALAKAST to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking ACALAKAST and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

- Bleeding. Symptoms may be black stools or stools with blood, pink or brown urine, nosebleeds, bruising, unexpected bleeding, vomiting or coughing up blood, dizziness, weakness, confusion.
- Infections. Signs may include fever, chills, feeling weak or confused, cough, shortness of breath [Pneumonia, a very common side effect (may affect more than 1 in 10 people) or Aspergillus infections, an uncommon side effect (may affect up to 1 in 100 people)].

Common serious side effects (may affect up to 1 in 10 people)

- fast heart rate, missed heart beats, weak or uneven pulse, dizziness, feeling faint, chest discomfort or shortness of breath (signs of heart rhythm problems known as atrial fibrillation and atrial flutter).

Uncommon serious side effects (may affect up to 1 in 100 people)

- fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain. This can be symptoms of tumor lysis syndrome (TLS) – a condition caused by the fast breakdown of cancer cells.

Other side effects:

Very common (may affect more than 1 in 10 people):

- muscle or joint pain
 - headache
 - rash
 - feeling tired (fatigue), weakness or lack of energy
 - feeling sick to your stomach (nausea), vomiting, stomach pain, constipation (infrequent or hard to pass stool), diarrhoea (frequent or loose stools)
 - decreased number of red blood cells, decreased number of neutrophils (a type of white blood cells) or decreased number of cells that help blood clot (platelets)
 - high blood pressure
 - dizziness
 - headache, pressure in the eyes, nose or cheek area (sinusitis)
 - sore throat and runny nose (nasopharyngitis)
 - upper respiratory tract infection
 - urinary tract infection (pain or burning feeling when passing urine).
 - new cancers, including cancers of the skin, may happen during treatment with ACALAKAST (see Section 2 'What you need to know before you take ACALAKAST')
- Common (may affect up to 1 in 10 people):
- bronchitis (does not require immediate action)
 - herpes

Uncommon side effects (may affect up to 1 in 100 people)

- memory loss, trouble thinking, difficulty walking or sight loss – these may be signs of a serious brain infection (Progressive Multifocal Leukoencephalopathy or PML)
- fever, chills, weakness, confusion, being sick and yellowing of the skin or eyeballs (jaundice) – these may be signs of hepatitis B (a liver infection) becoming active again.
- lymphocytosis (a higher than normal amount of lymphocytes, a type of white blood cells, in the blood).

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ACALAKAST

Storage: Store below 30° C

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Keep container tightly closed, Do not use if seal is broken or integrity is compromised.

6. Contents of the pack

Presentation: 30 capsules are supplied in HDPE bottles.

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Made in India By:

APRAZER

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