



Information for the patient

Acaluni100 mg hard capsules

Acalabrutinib

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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, 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 signs of illness 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.

What is in this leaflet:

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

1. What Acaluni is and what it is used for

What Acaluni is

Acaluni is a medicine used to treat cancer.

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

What Acaluni is used for

Acaluni 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 Acaluni works

Acaluni works by blocking BTK, a protein in the body that helps these cancer cells grow and survive. By blocking BTK, Acaluni 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 Acaluni 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 Acaluni

Do not take Acaluni 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 Acaluni.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acaluni 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 Acaluni before and after a medical, surgical or dental procedure.
- have ever had hepatitis B (a liver infection) – this is because Acaluni 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 Acaluni

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
- pimozide – 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 Acaluni 2 hours before or 2 hours after you take these medicines
 - histamine-2 receptor blockers – such as ranitidine and famotidine
 - Take Acaluni 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 Acaluni
- 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 Acaluni.

Medicines that increase your risk of bleeding

Acaluni 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 Acaluni if you are pregnant, think you may be pregnant, or are planning on having a baby. This is because Acaluni may harm your unborn baby.

Breast-feeding

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

Driving and using machines

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

Acaluni 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 Acaluni

Acaluni will only be prescribed to you by a doctor with experience in the use of medicines for cancer. Always take Acaluni 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 Acaluni with food or between meals.
- You can check when you last took a capsule of Acaluni 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 Acaluni than you should

If you have taken more Acaluni 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 Acaluni 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 Acaluni 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).
- 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 Acaluni (see Section 2 'What you need to know before you take Acaluni')

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Acaluni

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

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

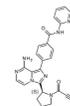
This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Acaluni contains

The active substance is acalabrutinib, an inhibitor of Bruton tyrosine kinase (BTK). The molecular formula for acalabrutinib is $C_{26}H_{23}N_3O_2$, and the molecular weight is 465.51. The chemical name is 4-{8-amino-3-[(2S)-1-(but-2-ynyl)pyrrolidin-2-yl]imidazo[1,5-a]pyrazin-1-yl}-N-(pyridin-2-yl)benzamide. The chemical structure of acalabrutinib is shown below:



Each hard capsule contains 100 mg of acalabrutinib.

The other ingredients are:

- Capsule content: microcrystalline cellulose, colloidal anhydrous silica, partially pregelatinised maize starch, magnesium stearate and sodium starch glycolate (see section 2 "Acaluni contains sodium").
- Capsule shell: gelatine, titanium dioxide

What Acaluni looks like and contents of the pack

Acaluni is a 20mm hard gelatine capsule.

Acaluni is supplied in bottle. Each bottle contains either 56 or 60 hard capsules.

Not all pack sizes may be marketed.

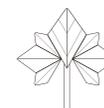
Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical **and Food** Co., Ltd
Rd13 South, 31km, Ban Naphasuk, Saithany District
Vientiane
Lao PDR

Manufacturer

Tongmeng(Lao) Pharmaceutical **and Food** Co., Ltd
Rd13 South, 31km, Ban Naphasuk, Saithany District
Vientiane
Lao PDR

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:



TLPH