

ACABRUNAT (Acalabrutinib 100mg hard capsules)

(Acalabrutinib 100mg)

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What ACABRUNAT is used for

ACABRUNAT 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 ACABRUNAT works

ACABRUNAT works by blocking BTK, a protein in the body that helps these cancer cells grow and survive. By blocking BTK, ACABRUNAT 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 ACABRUNAT works or why this medicine has been prescribed for you, ask your doctor, pharmacist or nurse.

Before you use ACABRUNAT

- When you must not use it

Do not take Acabrunat if:

- you are allergic to acalabrutinib or any of the other ingredients of this medicine.

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

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.

Before you start to take it

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

- have ever had unusual bruising or bleeding or are on any medicine that increase your risk of bleeding

- have an infection
- have recently had an operation or are about to have one. Your doctor may stop treatment with ACABRUNAT before and after a medical, surgical or dental procedure
- have ever had hepatitis B (a liver infection) – this is because Acabrunat could cause hepatitis B to become active again and so that your doctor will look out for signs of this infection coming back
- have or ever had irregular heart beat

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. Use sun protection and make regular skin examination.

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

- Taking other medicines

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

How to use ACABRUNAT

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

- How much to use

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

- When to use it

- 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 ACABRUNAT with food or between meals

- How long to use it

Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking ACABRUNAT if you develop certain side effects.

- If you forget to use it

- 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.

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- 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 Acabrunat 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.

- *If you use too much (overdose)*

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

While you are using it

- *Things you must do*

Stop taking ACABRUNAT 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)].

- *Things you must not do*

Do not change your dose or stop taking ACABRUNAT unless your healthcare provider tells you to.

- *Things to be careful of*

- ACABRUNAT 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 ACABRUNAT if you are pregnant, think you may be pregnant or are planning on having a baby. This is

because ACABRUNAT may harm your unborn baby.

Breast-feeding

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

Driving and using machines

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

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

Side effects

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

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 ACABRUNAT

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)

Consult your doctor or pharmacist for more information if you experience any side effects after using this medicine

You may report any side effects or adverse 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 & Disposal of ACABRUNAT

- *Storage*

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 blister foil and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

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- 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

ACABRUNAT is a hard gelatin capsule size '1' with dark blue opaque color cap and yellow opaque body and printed with "NAT 100 mg" on body in black ink.

ACABRUNAT is supplied in aluminium blisters containing 10 capsules. Each carton contains 60 capsules.

- Ingredients

Active ingredient:

The active substance is acalabrutinib. Each capsule contains 100 mg of acalabrutinib.

Inactive ingredients:

The other ingredients are:

- Capsule content: mannitol, croscarmellose sodium, colloidal silicon dioxide, and sodium stearyl fumarate
- Capsule shell: gelatine, purified water, titanium dioxide, FD & C Blue 2 and iron oxide yellow.
- Printing ink: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide and purified water

- MAL number

MALxxxxx

Manufacturer

Natco Pharma limited,
Rangareddy District,
Kothur, 509228, India.

Product Registration Holder

Unimed Sdn Bhd,
No. 53, Jalan Tembaga SD 5/2B, Bandar
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Malaysia.

Date of revision of text

04/02/2026

Serial Number

NPRA (R2) 25/114