

CALQUENCE® Tablets

Active ingredient(s): acalabrutinib maleate monohydrate

Consumer Medicine Information

This medicine has provisional registration in Australia for (CALQUENCE is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy). The decision to provisionally register this new use of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

This leaflet provides important information about using CALQUENCE tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CALQUENCE tablets.**

Where to find information in this leaflet:

1. Why am I using CALQUENCE tablets?
2. What should I know before I use CALQUENCE tablets?
3. What if I am taking other medicines?
4. How do I use CALQUENCE tablets?
5. What should I know while using CALQUENCE tablets?
6. Are there any side effects?
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1. Why am I using CALQUENCE?

CALQUENCE tablets contain the active ingredient acalabrutinib maleate monohydrate.

CALQUENCE belongs to a group of anti-cancer medicines called Bruton tyrosine kinase (BTK) inhibitors. BTK is a protein in the body that helps cancer cells to grow.

CALQUENCE works by blocking BTK which may help to reduce the number of cancer cells and may slow the spread of the cancer.

CALQUENCE tablets is used to treat:

Mantle Cell Lymphoma (MCL), a type of blood cancer that affects the lymph nodes (lymph glands). It is used in patients who have had at least one other treatment for their cancer.

Chronic Lymphocytic Leukaemia (CLL)/Small Lymphocytic Lymphoma (SLL), a type of blood cancer that affects lymphocytes (a certain type of white blood cell) and the lymph nodes.

2. What should I know before I use CALQUENCE?

Do not use CALQUENCE tablets if:

- you are pregnant or intend to become pregnant
- you are breastfeeding
- you are allergic to acalabrutinib, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.