Calcent™ 100

Acalabrutinib 100 mg

Presentation
Calcent™ 100: Each capsule contains Acalabrutinib INN 100 mg.

Description
Acalabrutinib is a small-molecule inhibitor of BTK. Acalabrutinib and its active metabolite, ACP-5862, form a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B cell antigen receptor (BCR) and cytokine receptor pathways. In B cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. In nonclinical studies, acalabrutinib inhibited BTK-mediated activation of downstream signaling proteins CD86 and CD69 and inhibited malignant B-cell proliferation and tumor growth in mouse xenograft models.

Indications and Uses
Acalabrutinib is a kinase inhibitor indicated for the treatment of adult patients with:
- Mantle cell lymphoma (MCL) who have received at least one prior therapy

This indication is approved under accelerated approval based on overall response rate Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

Dosage and Administrations
- Recommended dose is 100 mg orally approximately every 12 hours; swallow whole with water and with or without food
- Advise patients not to break, open, or chew capsules
- Manage toxicities using treatment interruption, dose reduction, or discontinuation
- Avoid Acalabrutinib in patients with severe hepatic impairment

Side-effects
Most common adverse reactions (incidence ≥ 30%) were: anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain.

Contraindications
None

Warnings & Precautions
- Serious and Opportunistic Infections: Monitor for signs and symptoms of infection and treat promptly
- Hemorrhage: Monitor for bleeding and manage appropriately
- Cytopenias: Monitor complete blood counts regularly
- Second Primary Malignancies: Other malignancies have occurred, including skin cancers and other solid tumors. Advise patients to use sun protection
- Atrial Fibrillation and Flutter: Monitor for symptoms of arrhythmias and manage

Use in specific population

Pregnancy and Lactation
Based on findings in animals, Acalabrutinib may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. No data are available regarding the presence of Acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production.

Pediatric Use
The safety and effectiveness of Acalabrutinib in pediatric patients have not been established.

Geriatric Use
No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

Hepatic Impairment
Avoid administration of Acalabrutinib in patients with severe hepatic impairment. The safety of Acalabrutinib has not been evaluated in patients with moderate or severe hepatic impairment.

Drug Interactions
- CYP3A Inhibitors: Avoid co-administration with strong CYP3A inhibitors. Dose adjustments may be recommended
- CYP3A Inducers: Avoid co-administration with strong CYP3A inducers. Dose adjustments may be recommended
- Gastric Acid Reducing Agents: Avoid co-administration with proton pump

Storage
Do not store above 30 ºC. Keep away from light and out of the reach of children.

Commercial Pack
Calcent™100: Each box contains 2 Alu-Alu blister strips of 6 capsules.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh