Aliqopa (copanlisib)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Aliqopa
- **Generic name:** Copanlisib
- **Pharmacological class:** Kinase inhibitor
- **Strength and Formulation:** 60mg; per vial; lyophilized powder for IV infusion after reconstitution and dilution
- **Manufacturer:** Bayer Healthcare
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

ALIQOPA


NDC 50419-385-01
Aliqopa™
(copanlisib) For Injection
60 mg*
*Equivalent to 69.1 mg copanlisib dihydrochloride
For intravenous infusion only.
Must be reconstituted and diluted.
Single dose vial - discard unused portion
Rx only
BAYER
60 mg/vial
One Vial
For Injection
NDC 50419-385-01
Aliqopa
(copanlisib) For Injection
LOT

Indications

- Treatment of adults with relapsed **follicular lymphoma (FL)** who have received at least two prior systemic therapies

Dosage & Administration

- Give 60mg as IV infusion over 1hr on Days 1, 8, and 15 of a 28-day cycle on an intermittent schedule (3 weeks on, 1 week off) until disease progression or unacceptable toxicity
- Concomitant strong CYP3A inhibitors: reduce to 45mg
- Dose modifications for toxicities: see full labeling

Considerations for Special Populations

- **Pregnancy:** Exclude status prior to initiation
- **Nursing mothers:** Not recommended during and for ≥1 month after last dose
- **Pediatric:** Not established
- **Elderly:** No clinically relevant differences in efficacy

Warnings/Precautions

- Monitor for signs/symptoms of **infection** (eg, pneumonia); withhold if Grade ≥3 infection develops
- Risk of serious pneumocystis jiroveci pneumonia (PJP); consider PJP prophylaxis for those at risks prior to initiation
- Diabetes

Warnings/Precautions

- Obtain optimal blood glucose and blood pressure (BP) control prior to each infusion; monitor closely
- **Discontinue** if blood glucose ≥500mg/dL is persistent at Copanlisib 30mg dose
- **Discontinue** if post-dose BP remains uncontrolled (>150/90mmHg) despite antihypertensives or elevated with life-threatening consequences

Warnings/Precautions

- Withhold and treat if non-infectious pneumonitis occurs; discontinue if Grade 2 recurs or if Grade ≥3 develops
- **Monitor ANC** at least weekly; withhold if ANC <0.5 x 10^3 cells/mm^3; reduce to 45mg if ANC ≤0.5 x 10^3 cells/mm^3 recurs
- Monitor for severe cutaneous reactions; withhold for Grade 3 reaction; discontinue if life-threatening

Warnings/Precautions

- Monitor for **thrombocytopenia**, other severe and non-life-threatening toxicities; see full labeling
- Embryo-fetal toxicity
- Females of reproductive potential and males (w. female partners) should use highly effective contraception during treatment and for ≥1 month after last dose

Interactions

- May be antagonized by strong **CYP3A inducers** (eg, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John’s wort); avoid

Interactions

- Potentiated by strong **CYP3A inhibitors** (eg, boceprevir, clarithromycin, cobicistat, conivaptan, danoprevir/ritonavir, diltiazem, elvitegravir/ritonavir, grapefruit juice, idelalisib, indinavir/ritonavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, others); if concomitant use unavoidable, reduce Copanlisib dose (see Adult)

Adverse Reactions

- Hyperglycemia
- Diarrhea
- Decreased general strength/energy
- Hypertension
- Leukopenia
- Neutropenia
- Nausea
- Lower respiratory tract infections
- Thrombocytopenia

Mechanism of Action

- Copanlisib is an inhibitor of phosphatidyl-inositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K-α and PI3K-δ isoforms expressed in malignant B cells
- Copanlisib has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines

Clinical Studies

- Aliqopa was evaluated in a Phase 2, multicenter, single-arm trial **CHRONOS-1** (n=142) in patients with follicular B-cell non-Hodgkin lymphoma who relapsed after at least 2 prior treatments
  - Patients must have received rituximab + an alkylating agent

Clinical Studies

- Of the total, 104 patients received **Aliqopa 60mg** (or 0.8mg/kg equivalent) as a 1hr IV infusion on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule until disease progression or unacceptable toxicity

Clinical Studies

- **Tumor response** was assessed via the International Working Group response criteria for malignant lymphoma
- **Efficacy** was based on overall response rate (ORR) as assessed by an Independent Review Committee

Clinical Studies

- Treatment with Aliqopa led to an **ORR of 59%** (95% CI: 49, 68)
  - Complete response was seen in 14%
  - Partial response was seen in 44%
- Median duration of response was 12.2 months (range: 0+, 22.6)
- Median time to response was 1.7 months (range: 1.3 to 9.7 months)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/aliqopa/drug/34755/