AVMAPKI™ FAKZYNJA™ CO-PACK
(avutometinib capsules; defactinib tablets) 0.8 mg; 200 mg

WHAT TO KNOW

When Starting Patients on Avmapki Fakzynja Co-Pack

INDICATION

Avmapki Fakzynja Co-Pack is indicated for the treatment of adult patients with *KRAS*-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Ocular Toxicities:** Ocular toxicities, including visual impairment and vitreoretinal disorders, occurred. Perform comprehensive ophthalmic evaluation at baseline, prior to cycle 2, every three cycles thereafter, and as clinically indicated. Withhold Avmapki Fakzynja Co-Pack for ocular toxicities until improvement at the same or reduced dose. Permanently discontinue Avmapki Fakzynja Co-Pack for any grade 4 toxicity.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

RECOMMENDATIONS STARTING AT BASELINE[1]

Ophthalmic Exams: Refer patients to a qualified eye care professional for a comprehensive ophthalmic exam at baseline, prior to cycle 2, and every 3 cycles thereafter, regardless of baseline exam findings, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs or symptoms.

Prophylactic Medications for Skin Reactions: Administer prophylactic medications for skin reactions with initiation of and during at least the first 2 cycles of Avmapki Fakzynja Co-Pack:

- Topical corticosteroid (applied to the face, scalp, neck, upper chest, and upper back)
- Systemic oral antibiotics

Liver Function Tests: Monitor liver-related laboratory values prior to the start of each cycle, on Day 15 of the first 4 cycles, and as clinically indicated.

CPK Evaluation: Monitor creatine phosphokinase (CPK) levels prior to the start of each cycle, on Day 15 of the first 4 cycles, and as clinically indicated.

Pregnancy Status: Verify the pregnancy status of females of reproductive potential prior to initiating treatment with Avmapki Fakzynja Co-Pack.

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TESTING AND MONITORING SCHEDULE

	Liver Function Tests	CPK Evaluation	Eye Exams	Pregnancy Status
BASELINE: Prior to cycle 1	X	X	X	X
Cycle 1 Day 15	X	X		
Prior to cycle 2	X	X	X	
Cycle 2 Day 15	X	X	Continue every 3 cycles and as clinically indicated	
Prior to cycle 3	X	X		
Cycle 3 Day 15	X	X		
Prior to cycle 4	X	X		
Cycle 4 Day 15	X	X		
Cycle 5 onward >>	Prior to each cycle (no Day 15) and as clinically indicated			

PROACTIVE MANAGEMENT FOR DRUG INTERACTIONS[1]

Strong and Moderate CYP3A4 Inhibitors or Inducers

- Avoid concomitant use of Avmapki Fakzynja Co-Pack with strong or moderate CYP3A4 inhibitors
- Avoid concomitant use of Avmapki Fakzynja Co-Pack with strong or moderate CYP3A4 inducers

Gastric Acid Reducing Agents

- Avoid concomitant use of Avmapki Fakzynja Co-Pack with proton pump inhibitors (PPIs) or H2 receptor antagonists
- If concomitant use of an acid-reducing agent cannot be avoided, administer Fakzynja 2 hours before or 2 hours after the administration of a locally acting antacid

Effect of Avmapki Fakzynja Co-Pack on Other Drugs

- Avoid concomitant use of Avmapki Fakzynja Co-Pack with warfarin. For patients requiring anticoagulation, an alternative to warfarin is recommended
- If concomitant use is unavoidable, monitor the international normalized ratio (INR) frequently during treatment
- Cases of bleeding and increased INR occurred in patients taking Fakzynja concomitantly with warfarin in clinical trials

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MONTHLY TREATMENT GUIDANCE

	Time	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Weeks 1, 2, & 3	Morning							
	Evening							
Week 4	One-week break. DO NOT take Avmapki Fakzynja Co-Pack during Week 4.							

RECOMMENDED DOSING AND ADMINISTRATION[1]

Avmapki Capsules 

- The recommended dosage of Avmapki capsules is 3.2 mg (four 0.8 mg capsules) taken orally twice weekly (Day 1 and Day 4) for the first 3 weeks of each 4-week cycle until disease progression or unacceptable toxicity
- Take Avmapki at the same time with each dose. Avmapki should be taken with food. Swallow capsules whole. Do not chew, break, or open the capsules
- If a dose of Avmapki is missed by more than 24 hours, skip the missed dose and take the next scheduled dose as prescribed. Do not take 2 doses at the same time to make up for a missed dose
- If vomiting occurs after taking Avmapki, do not take an additional dose. Take the next scheduled dose as prescribed

Fakzynja Tablets 

- The recommended dosage of Fakzynja tablets is 200 mg (one tablet) taken orally twice daily for the first 3 weeks of each 4-week cycle until disease progression or unacceptable toxicity
- Take each dose of Fakzynja with food. Swallow tablets whole. Do not chew, break, or crush the tablets
- If a dose of Fakzynja is missed by more than 6 hours, skip the missed dose and take the next scheduled dose as prescribed. Do not take 2 tablets at the same time to make up for a missed dose
- If vomiting occurs after taking Fakzynja, do not take an additional dose. Take the next scheduled dose as prescribed

Images shown are not actual size.

Scan to view the dosing calendar

For additional information on dosing, please visit AvmapkiFakzynjaCo-Pack-HCP.com and see full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions (cont'd)

- **Serious Skin Toxicities:** Skin toxicities, including photosensitivity and severe cutaneous adverse reactions (SCARs), occurred. Adhere to concomitant medications. Monitor for skin toxicities and interrupt, reduce or permanently discontinue Avmapki Fakzynja Co-Pack based on severity, tolerability and duration.
- **Hepatotoxicity:** Monitor liver function tests prior to each cycle, on day 15 of the first 4 cycles, and as clinically indicated. Withhold, reduce or discontinue Avmapki Fakzynja Co-Pack based on severity and persistence of abnormality.
- **Rhabdomyolysis:** Monitor creatine phosphokinase prior to the start of each cycle, on day 15 of the first four cycles, and as clinically indicated. If increased CPK occurs, evaluate patients for rhabdomyolysis or other causes. Withhold, reduce or permanently discontinue Avmapki Fakzynja Co-Pack based on severity and duration of the adverse reaction.
- **Embryo-Fetal Toxicity:** Avmapki Fakzynja Co-Pack can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Adverse Reactions

The most common (≥ 25%) adverse reactions, including laboratory abnormalities, were increased creatine phosphokinase, nausea, fatigue, increased aspartate aminotransferase, rash, diarrhea, musculoskeletal pain, edema, decreased hemoglobin, increased alanine aminotransferase, vomiting, increased blood bilirubin, increased triglycerides, decreased lymphocyte count, abdominal pain, dyspepsia, dermatitis acneiform, vitreoretinal disorders, increased alkaline phosphatase, stomatitis, pruritus, visual impairment, decreased platelet count, constipation, dry skin, dyspnea, cough, urinary tract infection, and decreased neutrophil count.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Drug Interactions

- **Strong and moderate CYP3A4 inhibitors:** Avoid concomitant use with Avmapki Fakzynja Co-Pack.
- **Strong and moderate CYP3A4 inducers:** Avoid concomitant use with Avmapki Fakzynja Co-Pack.
- **Warfarin:** Avoid concomitant use of Avmapki Fakzynja Co-Pack with warfarin and use an alternative to warfarin.
- **Gastric acid reducing agents:** Avoid concomitant use of Avmapki Fakzynja Co-Pack with proton pump inhibitors (PPIs) or H2 receptor antagonists. If use of an acid-reducing agent cannot be avoided, administer Fakzynja 2 hours before or 2 hours after the administration of a locally acting antacid.

Use in Specific Populations

- **Lactation:** Advise not to breastfeed.
- **Fertility:** May impair fertility in males and females.

For medical information about Avmapki Fakzynja Co-Pack, **call 833-MED-VSTM (833-633-8786)**.

REFERENCE: 1. Avmapki Fakzynja Co-Pack. Prescribing information. Verastem, Inc; 2025.

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VERASTEM ONCOLOGY

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