RESET FORM

OCULAR ASSESSMENT GUIDE FOR AVMAPKI FAKZYNJA CO-PACK PATIENTS

This is an optional tool to help support patients prescribed AVMAPKI FAKZYNJA CO-PACK.

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

DATE OF EXAM: / /

WHY THIS ASSESSMENT IS IMPORTANT
Your patient is being referred by their oncologist for an ophthalmic exam as they have been prescribed AVMAPKI FAKZYNJA CO-PACK, which can cause ocular adverse reactions, including visual impairment and vitreoretinal disorders. Ocular baseline testing and follow-up visits help provide the information needed to monitor and manage these potential adverse reactions.

WHO THIS FORM IS FOR
This form is to be completed by the eye care provider performing the exam and submitted to the prescribing oncologist.

NOT A SUBSTITUTE FOR MEDICAL ADVICE
The information contained on this form is not intended to be medical advice, and both the eye care provider and oncologist should exercise their own professional judgment and expertise in making diagnoses, treatment decisions, and determining what information should be collected, shared, or relied upon.

PATIENT INFORMATION

Patient Name: _____ Patient ID: _____ DOB: _____

Oncologist Office Contact Information

Healthcare Provider: _____ Phone: _____
Other Office Contact: _____ Fax: _____
Email: _____

Eye Care Provider Contact Information

Healthcare Provider: _____ Phone: _____
Email: _____ Fax: _____

Visit Type

◯ Baseline exam ◯ Scheduled exam ◯ Follow-up due to patient-reported symptoms

BASELINE AND SCHEDULED EXAMS

Baseline Exam Only

Ocular conditions at baseline and best corrected visual acuity (Right and Left Eye)

Does the patient wear glasses or contact lenses for distance vision correction? ◯ Yes ◯ No

Visual Acuity

Best Corrected Distance Visual Acuity (if not baseline) **RIGHT EYE** 20 / _____ **LEFT EYE** 20 / _____

Slit Lamp Examination

RIGHT EYE		LEFT EYE	
Exam Result	**Describe Abnormality**	**Exam Result**	**Describe Abnormality**
◯ Normal		◯ Normal	
◯ Abnormal		◯ Abnormal	

Intraocular Pressure

RIGHT EYE _____ mmHg **LEFT EYE** _____ mmHg

Fundoscopy

RIGHT EYE		LEFT EYE	
Exam Result	**Describe Abnormality**	**Exam Result**	**Describe Abnormality**
◯ Normal		◯ Normal	
◯ Abnormal		◯ Abnormal	

Optical Coherence Tomography

Subretinal fluid foci
RIGHT EYE ◯ Present ◯ Absent

Subretinal fluid foci
LEFT EYE ◯ Present ◯ Absent

Please see additional Important Safety Information included in this guide and click here for full Prescribing Information.

OCULAR ASSESSMENT GUIDE FOR AVMAPKI FAKZYNJA CO-PACK PATIENTS

This is an optional tool to help support patients prescribed AVMAPKI FAKZYNJA CO-PACK.

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

Patient Name: _____ Patient ID: _____ DOB: _____

EXAM FINDINGS

Finding	Severity	Right Eye Check if Yes	Left Eye Check if Yes	AVMAPKI FAKZYNJA CO-PACK Prescriber Action	Eye Care Provider Action
Keratitis	Absent	◯	◯	No action	No action
	Present, mild in severity, not reaching threshold below	◯	◯	Observation/No dose change	Note observation
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected distance visual acuity	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolved to nonconfluent superficial keratitis, then resume at same dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
	Corneal ulcer or stromal opacity or best corrected distance visual acuity (BCVA) 20/200 or worse	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolved to nonconfluent superficial keratitis, then resume at reduced dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
	Corneal perforation	◯	◯	Permanently discontinue AVMAPKI FAKZYNJA CO-PACK.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
Blurred Vision	Absent	◯	◯	No action	No action
	Present, mild in severity, not reaching threshold below	◯	◯	Observation/No dose change	Note observation
	BCVA worse than baseline but no worse than 20/200	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolution to baseline or 20/40, whichever is worse, then resume treatment at same dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
	BCVA 20/200 or worse	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolution to baseline or 20/40, whichever is worse, then resume treatment at reduced dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
Conjunctivitis	Absent	◯	◯	No action	No action
	Present, mild in severity, not reaching threshold below	◯	◯	Observation/No dose change	Note observation
	Confluent superficial punctate staining, moderate to severe vasodilation	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolution to nonconfluent superficial keratitis, then resume treatment at same dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.
	Conjunctival ulcer or neovascularization	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK until resolution to nonconfluent superficial keratitis, then resume treatment at reduced dose.	If yes for either eye, notify prescribing oncologist for a dose adjustment.

Please see additional Important Safety Information included in this guide and click here for full Prescribing Information.

OCULAR ASSESSMENT GUIDE FOR AVMAPKI FAKZYNJA CO-PACK PATIENTS

This is an optional tool to help support patients prescribed AVMAPKI FAKZYNJA CO-PACK.

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

Patient Name: _____ Patient ID: _____ DOB: _____

EXAM FINDINGS (Cont'd)

Finding	Severity	Right Eye Check if Yes	Left Eye Check if Yes	AVMAPKI FAKZYNJA CO-PACK Prescriber Action	Eye Care Provider Action
Retinal Pigment Epithelial Detachment (RPE) and / or Subretinal Fluid Foci	Absent	◯	◯	No action	No action
	RPE present – first occurrence	◯	◯	Refer back to eye care provider for OCT in 2 weeks.	Repeat OCT examination in 2 weeks.
	First follow-up OCT exam and RPE present	◯	◯	Reduce dose of AVMAPKI FAKZYNJA CO-PACK.	Repeat OCT examination in 2 weeks.
	Second follow-up OCT exam and RPE present and/or loss of 1 line in BCVA	◯	◯	Withhold AVMAPKI FAKZYNJA CO-PACK.	Repeat OCT examination in 2 weeks.
	Third follow-up OCT examination	◯	◯	RPE resolving/resolved, resume at reduced dose. No resolution, permanently discontinue AVMAPKI FAKZYNJA CO-PACK.	Inform oncologist if resolved or not.

Please list any other observations here:

QUESTIONS

HAVE PATIENT QUESTIONS?

For questions about the patient or their treatment regimen, please reach out to the prescribing oncologist.

HAVE OTHER QUESTIONS?

For all other questions or to report an adverse event, please contact:
Verastem Medical Information
833-633-8786 | medinfo@verastem.com

Please see additional Important Safety Information included in this guide and click here for full Prescribing Information.

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.
- **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.

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.

Please click here for full Prescribing Information.

VERASTEM ONCOLOGY