(avutometinib capsules; defactinib tablets) 0.8 mg; 200 mg

MONITORING AND MANAGING POSSIBLE SIDE EFFECTS DURING YOUR TREATMENT

You may experience side effects while taking AVMAPKI FAKZYNJA CO-PACK. Because of the way the treatment works in your body, certain types of side effects are more common than others.

Tell your care team about any side effects you experience and follow your healthcare provider's recommendations.

Here are some ways that may help you and your healthcare provider to monitor or manage some of these side effects.

Eye problems

Eye problems are common and can be severe.

 To help prevent, monitor, and manage these, your healthcare provider will send you to see an eye care professional before starting and during treatment, even if there are no initial findings



Be mindful of any changes in your vision and tell your healthcare provider about any new or worsening eye problems.

Severe skin reactions

Skin reactions are common and can be severe or life threatening. Treatment can make your skin sensitive to the sun and the light from sunlamps and tanning beds, which means you may burn more easily and get a severe sunburn.

Before and during treatment, your healthcare provider will give you:

- Medicines to apply to your face, scalp, neck, upper chest, and upper back
- Antibiotic medicines to take by mouth to help prevent skin reactions



? Take these steps:

- · Limit your time in the sun
- Apply daily sunscreen with a Sun Protection Factor (SPF) of 30 or greater
- Wear a hat and clothes that cover your skin to protect against sunburn
- Tell your healthcare provider if you get a sunburn

Liver problems

Liver problems are common and can be severe.

AVMAPKI FAKZYNJA CO-PACK can increase the level of aspartate aminotransferase, alanine aminotransferase, and bilirubin in your blood.

 Your healthcare provider will do blood tests before each treatment cycle and during treatment to check your liver function



Tell your healthcare provider if you have any signs or symptoms of liver damage such as jaundice, which is the yellowing of the skin or whites of the eyes.

Muscle problems (rhabdomyolysis)

AVMAPKI FAKZYNJA CO-PACK may cause muscle problems that can be severe. Treatment can increase the level of an enzyme in your blood called creatine phosphokinase (CPK), which can be a sign of muscle damage.

 Your healthcare provider will perform blood tests to check your levels of CPK before starting each treatment cycle and during treatment



Tell your healthcare provider if you get any signs or symptoms of increased CPK such as weakness or difficulty moving arms and legs, muscle or bone aches or pain that does not go away, dark red colored urine or decreased urine output.

Click to read full Prescribing Information and Patient Information.

AVMAPKITM FAKZYNJATMCO-PACK (avutometinib capsules; defactinib tablets) 0.8 mg; 200 mg

WHAT IS AVMAPKI FAKZYNJA CO-PACK?

AVMAPKI FAKZYNJA CO-PACK is a prescription medicine used to treat adults who have:

- low-grade serous ovarian cancer (LGSOC) that has come back (recurrent), and
- LGSOC with an abnormal KRAS gene, and
- previously been treated with medicine for their cancer.

It is not known if AVMAPKI FAKZYNJA CO-PACK is safe and effective in children.



THE MOST COMMON SIDE EFFECTS OF AVMAPKI FAKZYNJA CO-PACK INCLUDE:

- nausea
- tiredness
- increased aspartate aminotransferase
- diarrhea
- swelling in the body (edema)
- decreased hemoglobin
- increased alanine aminotransferase
- vomiting
- increased blood bilirubin
- increased triglycerides
- stomach-area pain

- acid reflux
- increased alkaline phosphatase
- decreased platelets
- constipation
- shortness of breath
- cough
- urinary tract infection
- decreased lymphocytes
- decreased neutrophils
- proteinuria

AVMAPKI FAKZYNJA CO-PACK may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of AVMAPKI FAKZYNJA CO-PACK; for additional safety information, click to read full <u>Prescribing Information</u> and <u>Patient Information</u> and discuss with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. <u>Please click to visit the website</u> or call 1-800-FDA-1088.

