

PATIENT INFORMATION

AVMAPKI™ FAKZYNJA™ CO-PACK (ave-MAP-kee Fak-zin-jah koh-pak) (avutometinib capsules; defactinib tablets) co-packaged for oral use

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.

Before taking AVMAPKI FAKZYNJA CO-PACK, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of eye or vision problems
- have had severe skin reactions
- have liver problems
- are pregnant or plan to become pregnant. AVMAPKI FAKZYNJA CO-PACK can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with AVMAPKI FAKZYNJA CO-PACK.
- You should use effective birth control (contraception) during treatment and for 1 month after the last dose of AVMAPKI FAKZYNJA CO-PACK.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with AVMAPKI FAKZYNJA CO-PACK.

Males with a female partner who is able to become pregnant:

- You should use effective birth control (contraception) during treatment and for 4 months after the last dose of AVMAPKI FAKZYNJA CO-PACK.
- are breastfeeding or plan to breastfeed. It is not known if AVMAPKI FAKZYNJA CO-PACK passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after the last dose of AVMAPKI FAKZYNJA CO-PACK.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. AVMAPKI FAKZYNJA CO-PACK may affect the way other medicines work, and other medicines may affect how AVMAPKI FAKZYNJA CO-PACK works.

Especially tell your healthcare provider if you take:

- proton pump inhibitors (PPIs) or H2 receptor antagonists
- a blood thinner called warfarin

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take AVMAPKI FAKZYNJA CO-PACK?

- Take AVMAPKI FAKZYNJA CO-PACK exactly as directed by your healthcare provider.
- Do not change your dose or stop taking AVMAPKI FAKZYNJA CO-PACK without talking to your healthcare provider.
- If you develop certain side effects your healthcare provider may change your dose, temporarily stop, or completely stop your treatment with AVMAPKI FAKZYNJA CO-PACK.

Take AVMAPKI capsules and FAKZYNJA tablets with food.

- If you vomit after taking AVMAPKI capsules or FAKZYNJA tablets, do not take an additional dose. Take the next scheduled dose as prescribed by your healthcare provider.

AVMAPKI capsules:

- Take each dose at the same time.
- Swallow the capsules whole. Do not chew, break, or open the capsules.
- If you miss a dose of AVMAPKI by more than 24 hours, skip the missed dose and take the next scheduled dose as prescribed by your healthcare provider. Do not take two doses at the same time to make up for a missed dose.

FAKZYNJA tablets:

- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- If you take antacids, take FAKZYNJA tablets 2 hours before or 2 hours after taking the antacid.
- If you miss a dose of FAKZYNJA by more than 6 hours, skip the missed dose and take the next scheduled dose as prescribed by your healthcare provider. Do not take two doses at the same time to make up for a missed dose.

Before and during treatment with AVMAPKI FAKZYNJA CO-PACK, your health care provider will give you medicines to apply to your face, scalp, neck, upper chest and upper back, and antibiotic medicines to take by mouth to help prevent skin reactions.

What should I avoid while taking AVMAPKI FAKZYNJA CO-PACK?

- Limit your time in the sun. AVMAPKI FAKZYNJA CO-PACK can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You may burn more easily and get a severe sunburn. Apply daily sunscreen with a Sun Protection Factor (SPF) of 30 or greater and wear a hat and clothes that cover your skin to protect against sunburn. Talk to your healthcare provider if you get a sunburn.

What are the possible side effects of AVMAPKI FAKZYNJA CO-PACK?**AVMAPKI FAKZYNJA CO-PACK may cause serious side effects, including:**

- **eye problems.** Eye problems are common with AVMAPKI FAKZYNJA CO-PACK and can be severe. Your healthcare provider will send you to see an eye care professional before starting treatment, during treatment, and for any new or worsening eye problems. Tell your healthcare provider if you get any new or worsening eye problems including:
 - changes in vision, such as blurred vision, double vision, or vision loss
 - dry eye(s)
 - eye and eyelid inflammation, including redness, swelling, and itching
 - eye pain
 - new or increased floaters (small dark spots or squiggly lines that float across your vision)
 - light hurting eyes or seeing flashes of light
- **severe skin reactions.** Skin reactions are common with AVMAPKI FAKZYNJA CO-PACK and can be severe or life threatening. Tell your healthcare provider if you develop any new or worsening skin reactions including:
 - skin rash or acne
 - blisters on your skin
 - blisters or sores in your mouth
 - dry skin
 - redness or swelling of your face, hands, or soles of your feet
 - peeling of your skin
 - skin infection
 - itching
- **liver problems.** Liver problems are common with AVMAPKI FAKZYNJA CO-PACK and can be severe. Treatment with 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 starting each treatment cycle and during treatment to check your liver function. Tell your healthcare provider if you get any signs or symptoms of severe liver problems including:
 - yellowing of your skin or the white part of your eyes
 - itchy skin
 - feeling very tired
 - flu-like symptoms
 - nausea or vomiting
 - upper right side stomach pain
 - dark or tea colored urine
 - bleeding or bruising more easily than normal

- **muscle problems (rhabdomyolysis).** AVMAPKI FAKZYNJA CO-PACK may cause muscle problems that can be severe. Treatment with AVMAPKI FAKZYNJA CO-PACK can increase the level of an enzyme in your blood called creatine phosphokinase (CPK) and 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 including:
 - 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

The most common side effects of AVMAPKI FAKZYNJA CO-PACK include:

- nausea
- decreased hemoglobin
- stomach-area pain
- cough
- tiredness
- increased alanine aminotransferase
- acid reflux
- urinary tract infection
- increased aspartate aminotransferase
- vomiting
- increased alkaline phosphatase
- decreased lymphocytes
- decreased neutrophils
- diarrhea
- increased blood bilirubin
- decreased platelets
- proteinuria
- swelling in the body (edema)
- increased triglycerides
- constipation
- shortness of breath

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. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AVMAPKI FAKZYNJA CO-PACK?

- Store AVMAPKI capsules and FAKZYNJA tablets in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original bottles.
- The AVMAPKI capsules and FAKZYNJA tablets come in child-resistant bottles.

Keep AVMAPKI FAKZYNJA CO-PACK and all medicines out of the reach of children.

General information about the safe and effective use of AVMAPKI FAKZYNJA CO-PACK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AVMAPKI FAKZYNJA CO-PACK for a condition for which it was not prescribed. Do not give AVMAPKI FAKZYNJA CO-PACK to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AVMAPKI FAKZYNJA CO-PACK that is written for health professionals.

What are the ingredients in AVMAPKI FAKZYNJA CO-PACK?

AVMAPKI (avutometinib) capsules:

Active ingredient: avutometinib

Inactive ingredients: magnesium stearate, mannitol, black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, and strong ammonia solution. The capsule shell contains carrageenan, hypromellose, potassium chloride, purified water, and titanium oxide.

FAKZYNJA (defactinib) tablets:

Active ingredient: defactinib

Inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

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 For more information, go to www.AvmapiFakzynjaCo-Pack.com or call 1-877-878-6662.