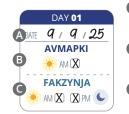
DOSING Calendar



 Write in the date you take your AVMAPKI FAKZYNJA CO-PACK.

- B Mark the box if you take AVMAPKI that day. Take each dose at the same time with food.
- C Mark the box each time you take FAKZYNJA that day. Take each dose with food.

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.



Please see Important Safety Information on the following pages and discuss any questions with your healthcare provider AVMAPKI[™] FAKZYNJA[™] CO-PACK (avutometinib capsules; defactinib tablets) 0.8mg 200mg

How should I take AVMAPKI FAKZYNJA CO-PACK?

AVMAPKI:

- On Weeks 1, 2, and 3, take 3.2 mg (4 capsules) on Day 1 and Day 4
- On Week 4, take a one-week break
- Take each dose at the same time with food
- Swallow capsules whole. Do not chew, break or open the capsules
- Keep refrigerated in original bottle



FAKZYNJA:

- On Weeks 1, 2, and 3, take 200 mg (1 tablet) two times a day
- On Week 4, take a one-week break
- Take with food
- Swallow tablets whole. Do not chew, break or crush the tablets
- Keep refrigerated in original bottle





Images shown are not actual size.



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Use the table below for monthly treatment guidance.



TAKE AVMAPKI FAKZYNJA CO-PACK exactly as your healthcare provider tells you to.

DO NOT change your dose, or stop taking AVMAPKI FAKZYNJA CO-PACK without talking to your healthcare provider.

IF YOU MISS A DOSE of AVMAPKI or FAKZYNJA, please see the Patient Information for instructions.

DISCARD any remaining medication at the end of the 3-week treatment period as instructed by your healthcare provider.

For additional safety information, please click here for full <u>Prescribing Information</u> and <u>Patient Information</u> and discuss with your doctor.



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- previously been treated with medicine for their cancer.

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IMPORTANT SAFETY INFORMATION

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) and 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.



IMPORTANT SAFETY INFORMATION (CONT'D)

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 healthcare 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
- dry skin
- itching
- blisters on your skin
- redness or swelling of your face, hands, or soles of your feet
- blisters or sores in your mouth
- peeling of your skin
- skin infection



IMPORTANT SAFETY INFORMATION (CONT'D)

- **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 and 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
- 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. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

For additional safety information, please click here for full <u>Prescribing Information</u> and <u>Patient Information</u> and discuss with your doctor.

