Ensartinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for lung cancer, but it may also be used for other uses.
- Your care team will perform a test for an abnormal anaplastic lymphoma kinase (ALK) gene to make sure treatment is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Ensartinib (en-SAR-tih-nib): Ensacove (EN-suh-kove)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Capsules taken by mouth.

Treatment Administration and Schedule

Your ensartinib dosing instructions:

_____

_____

_____

- Ensartinib comes in 2 capsule strengths: 25 mg and 100 mg. Your care team will tell you how much of each capsule to take.
- Your dose may differ, but ensartinib is usually taken as 225 mg (two 100 mg capsules and one 25 mg capsule) by mouth once daily.
- Take ensartinib 1 time a day, at the same time each day.
- Swallow ensartinib capsules whole. Do not crush or chew capsules. Do not open or dissolve the contents of the capsule.
- You may take ensartinib with or without food.
- If you miss a dose, take it as soon as you remember. If your next dose is due within 12 hours, skip the missed dose and take your next dose at your regular time. Do not take 2 doses on the same day to make up for the missed dose.
- If you vomit after taking a dose of ensartinib, do not take an extra dose. Take your next dose at your regular time.

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Storage and Handling of Ensartinib

- Store ensartinib at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- Keep ensartinib capsules in the original bottle.
- The bottle of ensartinib capsules contains a drying agent (desiccant) to help keep your medicine dry. Do not remove the desiccant from the bottle after opening. Do not open or eat the desiccant.
- Keep ensartinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused ensartinib.

Appointments: Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	
Other	

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Common Side Effects

Side Effect	Important Information
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale. Recommendations: • Get 7 to 8 hours of sleep each night. • Avoid operating heavy machinery when tired. • Balance work and rest, staying active but resting when needed. Talk to your care team if you have: • Shortness of breath • Dizziness • Fast or abnormal heartbeats • Severe headache
Skin Problems	Description: Treatment can cause symptoms of skin reactions, such as rash, itching, or skin swelling. Recommendations: • Take a warm (not hot) bath or shower every day with mild, unscented soap or body wash. • Pat skin dry (instead of rubbing) with a towel. • Use unscented lotion or moisturizing cream immediately after showering to prevent cracking. • Use lip balm for dry or chapped lips. • Avoid activities that put you at risk for cuts, injuries, or burns. • Use an electric shaver, not a razor, to prevent cuts. • Rinse cuts and scrapes immediately under running water and remove any debris from the wound. Wash the skin around the wound with soap. To avoid irritation, do not use soap on the wound. If you have a low platelet count and are at risk for bleeding issues, ask your doctor how to care for cuts. • Limit your time in the sun during treatment and for at least 1 week after your last dose. Ensartinib may make your skin sensitive to sunlight. When you are in the sun, wear a hat and protective clothing, and use a broad-spectrum sunscreen and lip balm with a Sun Protection Factor (SPF) of 30 or greater to protect against sunburn. • Use unscented, gentle laundry detergent. Some laundry detergents can irritate sensitive skin. • Your care team may recommend medicine for skin problems. Talk to your care team if you have: • Skin rash • Raised red pumps • Redness of the skin • Very dry skin that may affect the mucous membranes (such as mouth and eyes)

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<table>
<tr><td>Nausea and Vomiting</td><td>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.
Recommendations:
Eat smaller, more frequent meals.
Avoid fatty, fried, spicy, or highly sweet foods.
Eat bland foods at room temperature and drink clear liquids.
If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food.
Your care team may prescribe medicine for these symptoms.
Talk to your care team if you have:
Vomiting for more than 24 hours
Vomiting that’s nonstop
Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine)
Blood or coffee-ground-like appearance in your vomit
Bad stomach pain that doesn't go away after vomiting</td></tr>
<tr><td>High Blood Sugar</td><td>Description: Treatment can increase your blood sugar level.
Recommendations:
Eat a well-balanced diet.
Limit sugary drinks and foods.
Eat smaller, more frequent meals.
Be physically active for at least 30 minutes most days.
Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently.
Talk to your care team if you have:
Frequent urination
Drowsiness
Increased thirst
Loss of appetite
Blurred vision
Fruity smell on your breath
Confusion
Nausea, vomiting, or stomach pain
It becomes harder to control your blood sugar</td></tr>
<tr><td>Constipation</td><td>Description: Constipation means having a hard time passing stools or not going to the bathroom often. Your stools might feel hard and dry, which can make you uncomfortable or hurt.
Recommendations:
Keep track of how many times you move your bowels every day.
Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise.
Exercise regularly.
Eat high-fiber foods like raw fruits and vegetables.
Your care team may recommend medicine (such as polyethylene glycol 3350 or senna) for constipation.
Talk to your care team if you have:
Constipation that lasts 3 or more days
Constipation after 48 hours, even after using a laxative</td></tr>
</table>

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Liver Problems	Description: Treatment can harm your liver. This may cause nausea, stomach pain, and bleeding or bruising. It can also turn your skin and eyes yellow and make your urine dark. Lab tests may be performed to monitor liver function. Talk to your care team if you have: • Yellowing of your skin or the whites of your eyes • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark urine (tea colored) • Bleeding or bruising more easily than normal
Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Muscle and Joint Pain or Weakness	Description: Muscle pain feels like soreness, aches, cramps, or stiffness in one or more muscles. It may also include tenderness or weakness. Joint pain happens where two bones come together and can feel sharp, dull, throbbing, or burning. It often causes stiffness, swelling, and difficulty moving. Ensartinib can increase the level of an enzyme in your blood called creatine phosphokinase (CPK), which may be a sign of muscle damage. Recommendations: • Track your pain levels, areas of discomfort, and any activities that worsen or improve your symptoms. • Engage in gentle exercises like walking, stretching, or yoga to maintain mobility and strength, but consult your care team before starting any new exercise routine. • Apply a warm compress to relax stiff muscles or use cold packs to reduce swelling and numb pain in affected areas. • Your care team may prescribe or recommend medications, including over-the-counter pain relievers. Talk to your care team if you have: • Uncontrolled muscle or joint pain • Swelling, redness, or warmth in the joints • Weakness • Difficulty walking or moving

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Cough	Description: A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus. Recommendations: • Tell your care team what your cough feels like and when it happens. • Use a humidifier and drink plenty of water. • Keep your house clean by dusting and vacuuming regularly • Avoid exposure to smoke or strong chemicals. • Your care team may recommend medicine for cough. Talk to your care team if you have: • Trouble breathing • Chest pain or tightness • Coughing up blood

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Lung Problems	Treatment can cause severe or life-threatening swelling (inflammation) of the lungs. Symptoms may be similar to those from lung cancer. • Trouble breathing or shortness of breath • Chest pain • Cough with or without mucus • Fever of 100.4°F (38°C) or higher
Slow Heart Rate	• Dizziness or lightheadedness • Feeling faint
Vision Problems	Your care team may refer you to an eye specialist if you develop new or worsening vision problems during treatment. • Blurry vision • Double vision • Seeing flashes of light • Light hurting your eyes • New or increased floaters
Increased Uric Acid Level in Your Blood	• Red, hot, tender, or swollen joints, especially your big toe • Pain in your stomach-area or sides • Nausea or vomiting • Pink or brown urine
Allergic Reactions to FD&C Yellow No. 5 (tartrazine)	Ensartinib 100 mg capsules contain FD&C Yellow No. 5. FD&C Yellow No. 5 (tartrazine) that can cause allergic reactions in certain people, especially people who also have an allergy to aspirin. • Hives • Rash • Trouble breathing

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

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Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
  - If you are able to become pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment and for 1 week after your last dose.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment and for 1 week after your last dose.
- **Do NOT breastfeed** during treatment and for 1 week after your last dose.

Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Do not drink grapefruit juice or eat grapefruit.** Grapefruit may increase the amount of ensartinib in your blood.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.

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