

## Ensartinib (Ensacove)

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### About This Medicine

ENSARTINIB (en SAR ti nib) treats lung cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Decrease in the number of white blood cells and red blood cells. This may raise your risk of infection and make you tired and weak.
- Decrease in a blood protein called albumin
- Increased uric acid in the blood
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Muscle and bone pain
- Swelling of the hands, feet, or any other part of the body
- Tiredness
- Fever
- Changes in your liver function
- Electrolyte changes
- Blood sugar levels may change
- Cough
- Rash
- Itching

**Note:** Each of the side effects above was reported in 20% or greater of people treated with ensartinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing.
- Severe changes in your liver function
- Severe allergic skin reactions. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. Sometimes, a serious and life-threatening reaction can happen that can cause a skin rash, along with problems with your organs, swollen lymph nodes, fever and higher than normal white blood cells.
- Sensitivity to sunlight/light. You may get a skin rash/reaction if you are in the sun or are exposed to sun lamps and tanning beds.
- Decreased heart rate
- Severe changes in blood sugar levels
- Blurred vision or other changes in eyesight
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Tell your care team before taking this medicine if you have an allergy to FDandC Yellow No.5 (tartrazine) or aspirin. (medicine) contains FDandC Yellow No.5 which may cause allergic-type reactions in certain people, especially people who also have an allergy to aspirin.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## How to Take Your Medicine

- Swallow the medicine whole with or without food. Take it at approximately the same time each day. Do not chew or crush it. Do not open or dissolve the contents of the capsules.
- **Missed dose:** If you miss a dose by less than 12 hours, take the missed dose right away and go back to your normal schedule. If you miss a dose by more than 12 hours, then skip the missed dose and go back to your normal schedule. Do not take 2 doses at the same time or extra doses.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove the desiccant. Do not open or eat the desiccant. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.



## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure during treatment and for at least 1 week after treatment.
- Use sunscreen and a lip balm with SPF 30 or higher when you are outdoors even for a short time. Cover up when you are out in the sun. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.

## Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with ensartinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurred vision or other changes in eyesight
- Sensitivity to light
- Flashes of light and/or floaters in your field of vision
- Feeling dizzy or lightheaded
- Tiredness or weakness that interferes with your daily activities
- Dry cough or a cough that is bothersome
- Wheezing and/or trouble breathing
- Pain in your chest
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Pain that does not go away, or is not relieved by prescribed medicines
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Warm, red, tender, or swollen joints, especially your big toe
- Swollen lymph nodes in your neck and/or armpits
- Urine that is pink or brownish in color
- Unexplained muscle pain, tenderness, or weakness
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Develop sensitivity to sunlight/light
- Abnormal blood sugar
- Sign of high blood sugar: unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 week after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 week after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.



- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may/can affect your ability to have children in the future. If you plan to have children, talk with your care team.

New January 2025