

For the Patient: UGIAVPANEN

Other Names: Treatment of BRAF V600E - Mutated Metastatic Colorectal Cancer using Panitumumab and Encorafenib

U = **U**ndesignated **GI** = **G**astro**I**ntestinal AV = Advanced PAN = Panitumumab **EN** = **En**corafenib

ABOUT THESE MEDICATIONS

What are these drugs used for?

• Panitumumab and encorafenib is a drug combination given to treat cancer of the colon or rectum.

How do these drugs work?

- Panitumumab is a monoclonal antibody, a type of protein designed to target and interfere with the growth of cancer cells.
- Encorafenib is a targeted treatment that slows down or stops the growth of cancer cells.

INTENDED BENEFITS

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay the onset of new symptoms.
- It may take several treatments before your doctor can judge whether or not this treatment is helping.

TREATMENT SUMMARY

How are these drugs given?

- Panitumumab is given directly into the vein, intravenously (IV).
- Encorafenib is provided as capsules that you will take by mouth.
- You will receive panitumumab at the clinic by a chemotherapy nurse, for one day only. Your treatment will last about one and a half or two hours. Your first treatment will probably take longer, as the nurse will review information on the chemotherapy drug with you.
- Encorafenib is taken once daily continuously. This medication will be dispensed to you by a member of your cancer care team. You will receive enough medication to take at home

Developed: 1 Dec 2022

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The treatment is repeated every 2 weeks. This 2 week period of time is called a "cycle". The cycle is usually repeated as long as you are benefiting from treatment and not having too many side effects, as determined by your cancer care team.

The calendar shows how the medication is given each 2 week cycle. Cycle 1 and onwards:

С	DATE	TREATMENT PLAN
Y		► Week 1
С		→ Panitumumab IV on Day 1 only
L		→ Encorafenib once daily, every day
E		► Week 2
		→ No panitumumab
1		→ Encorafenib once daily, every day

Treatment is continued as long as you are benefiting from treatment and not having too many side effects.

What will happen when I get my drugs?

• A blood test is done each cycle, on or before the first day of each treatment cycle. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.

INSTRUCTIONS FOR THE PATIENT

Tell your cancer care team if you have ever had an unusual or allergic reaction to encorafenib or panitumumab or other antibody treatment before receiving treatment.

How should I store this drug?

Store encorafenib capsules in the original bottle. Do not remove desiccant. Keep out of the reach of children, at room temperature, away from heat, light, and moisture.

How should I take this drug?

- Encorafenib is taken once daily, at around the same time every day.
- You can take encorafenib with food or on an empty stomach.
- Do not chew, open or crush encorafenib capsules. Swallow whole with a full glass of water one at a time.
- If you miss a dose of encorafenib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times. Do NOT take a double dose to make up for the missed dose.
- If you vomit the dose of encorafenib, skip the dose and go back to your usual dosing times. Do NOT repeat the dose. Let your doctor know as a medication to prevent nausea may be required for future doses.

Developed: 1 Dec 2022 Revised:

What other drugs or foods can interact with panitumumab and encorafenib?

- Other drugs such as hormonal birth control, diltiazem, and posaconazole may interact with encorafenib. Tell your doctor or pharmacist if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with encorafenib.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of panitumumab or encorafenib.

Other important things to know:

Before you start taking encorafenib, talk to your doctor or pharmacist if you have any of the following:

Heart problems such as heart failure, valve problems or problems in the way your heart beats, including a condition called long QT syndrome.

Eye problems including blockage of the vein draining the eye or swelling in the eye which may be caused by fluid blockage.

Skin problems including rash or acne-like rash.

Lung or **breathing problems** including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue.

High blood pressure (hypertension)

Liver problems.

Bleeding problems.

Note:

- Treatment with encorafenib and panitumuab may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated and for 6 months after treatment. You must use reliable non-hormonal birth control as hormonal pills, patches or injections are not effective in pregnancy prevention as they do not work as well during treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for two months after your treatment ends.
- Tell doctors or dentists that you are being treated with encorafenib and panitumumab before you receive any treatment from them.

Developed: 1 Dec 2022

Revised:

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

You doctor will review the risks of treatment and possible side effects with you before starting treatment. The chemotherapy nurse will review possible side effects of the drug and how to manage those side effects with you on the day you receive your first treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Chills, fever, and shortness of breath may sometimes occur during the first panitumumab infusion. Reactions are less common with later treatments.	 Tell your nurse or doctor <i>immediately</i> if you have a reaction during your treatment. Your panitumumab may be temporarily stopped and then given more slowly. You may be given other drugs to treat the reaction

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Apply cool compresses or soak in cool water for 15 – 20 minutes several times a day.
Nausea and vomiting may occur after your treatment.	You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in Practical Tips to Manage Nausea.* Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Skin reactions such as acne, redness, rash, dryness or itchiness commonly occur.	 Avoid direct sunlight and tanning salons during treatment. Wear a hat, long sleeves, and long pants outside on sunny days. Wear a sunscreen that blocks both UVA and UVB and has a sun protection factor (SPF) of at least 30. Apply liberally, 30 minutes before exposure. Reapply every 2 hours and after swimming. Frequent moisturizing with alcohol-free emollient creams is recommended. Do not use over-the-counter acne preparations. Your doctor may prescribe a topical cream or oral antibiotic to manage the acne-like rash. Refer to Your Medication Sun Sensitivity and Sunscreens* or the BC Health Guide* for more information
Hand-foot skin reaction may sometimes occur. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain, or ulcers occur.	 Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. Avoid tight-fitting jewellery. Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. Apply sunscreen as above. Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) to hands and feet, liberally and often. Moisturize also as above. Tell your healthcare team at your next visit if you have any signs of hand-foot skin reaction as your dose may need to be changed.
Nail changes, including loosening or loss of the nail, and swelling, may occur.	If nails are painful, you may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity. Otherwise, be sure to mention it at your next visit.

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OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Minor bleeding, such as nosebleeds , may occur.	 Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat. Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes. After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes. Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped. Get emergency help if a nosebleed lasts longer than 20 minutes.
Abnormal heart rhythm (QT prolongation) rarely occurs.	Minimize your risk of abnormal heart rhythm by:
prolongation, rarely coodis.	 always checking with your pharmacist or doctor about drug interactions when starting a new medication, herbal product, or supplement. avoiding grapefruit and grapefruit juice. Get emergency help <i>immediately</i> if your heart is beating irregularly or fast OR if you feel faint, lightheaded, or dizzy.
Diarrhea may sometimes occur. If you	If diarrhea is a problem:
have diarrhea and it is not controlled, you can quickly become dehydrated.	 Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea* *Tell your healthcare team if you have diarrhea for more than 24 hours.
Constipation may sometimes occur.	 Exercise if you can. Drink plenty of fluids. Try ideas in Food Choices to Manage Constipation*
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Sugar control may sometimes be affected.	Tell your healthcare team if you are experiencing: Increased thirst. Changes in how often you pass urine (go pee). Check your blood sugar regularly if you have diabetes
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain continues or interferes with your activity.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem: Elevate your feet when sitting. Avoid tight clothing.
Taste alteration, loss of appetite, and weight loss may sometimes occur. Tiredness and lack of energy may occur.	 Try the ideas in Food Ideas to Cope with Taste and Smell Changes.* Do not drive a car of operate machinery if you are feeling tired. Try the ideas in the handout titled Fatigue/Tiredness – Patient Handout* OR Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.*
Hair loss sometimes occurs with encorafenib and is rare with panitumumab. If you lose hair, it will grow back once you stop treatment with panitumumab. Texture may change or unusual hair growth may occur.	If hair loss is a problem, refer to Resources for Hair Loss and Appearance Changes.*
Numbness or tingling of the fingers or toes may sometimes occur. This will slowly return to normal once your treatments are over. This may take several months	 Be careful when handling items that are sharp, hot, or cold. Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady. Tell your healthcare team at your next visit, especially if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.

^{*} Please ask your chemotherapy nurse, pharmacist or dietitian for a copy

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THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING ENCORAFENIB AND CHECK WITH YOUR HEALTHCARE TEAM OR **GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:**

- Signs of an allergic reaction (rare) soon after a treatment including fever, dizziness, fast heartbeat, face swelling, chills or breathing problems.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- Changes in eyesight such as blurred vision, loss of vision, seeing halos or coloured dots or you have eye pain
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Persistent loose watery stools, especially if thirst, fever, dizziness or decreased urine are present.
- Signs of **bleeding problems** such as black and/or tarry stools, blood in urine, pinpoint red spots on skin, or extensive bruising
- Signs of a blood clot such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain, or shortness of breath
- Face muscles that are weak, don't move, or appear to droop.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING **OFFICE HOURS) IF YOU HAVE:**

- Severe **skin reaction**, including the areas around the nails, that is painful, red, or swollen.
- Signs of anemia such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower
- Signs of **skin changes** such as a new wart, a sore or reddish bump that bleeds or does not heal, or a change in size, shape, or colour of a mole.
- Severe **abdominal pain** or tenderness.

If you experience symptoms or changes in your body that have not been
described above but worry you, or if any symptoms are severe, contact:
at telephone number:
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