

Dabrafenib-Trametinib

Tafinlar®-Mekinist®

Cancer-directed targeted therapy in capsules and tablets

Understanding your treatment

What is targeted therapy?

This treatment targets specific molecules, which are inside or on the surface of cancer cells. By targeting cancer cells, the targeted therapy limits damage to healthy cells. This type of treatment can be used alone or in combination with other treatments such as chemotherapy.

How can a targeted therapy help you?

Depending on your type of cancer and the stage of the disease, a targeted therapy can be used to :

- **Destroy** cancer cells
- **Stop** the cancer from spreading
- **Slow** the growth of cancer cells

How will you feel while on a targeted therapy?

Even though those treatments target cancer cells and limit damage to healthy cells, side effects can still arise.

Not everyone has side effects and each person's experience may differ. Side effects and their severity are not representative of the treatment's effect or lack thereof.

This document presents the most frequent side effects that your targeted therapy causes.

Medication

Dabrafenib

Capsules to take by mouth

Trametinib

Tablets to take by mouth

Administration

To be taken twice daily (approximately every 12 hours)

To be taken once daily

Take both of your medication on an empty stomach : 1 hour before or 2 hours after a meal

On a continuous basis

The trametinib tablets can be taken at the same time as the dabrafenib capsules in the morning or night.



A **blood test** will be done throughout your treatment cycle. Depending on the results and side effects of the previous treatment, the dose of the medication might be adjusted or the treatment might be interrupted.

How to take your medication?

Dabrafenib :

- Take your dabrafenib capsules as prescribed twice daily approximately every 12 hours. You may take your pills with a large glass of water on an empty stomach either 1 hour before or 2 hours after breakfast and supper.
- Capsules must be taken whole. Do not open the capsules.
- **If you forget a dose**, you may take it as soon as you remember if less than 6 hours have passed since the missed dose. Do not double your next dose. Try, however, to take your pills at the same time every day and in the same way (on an empty stomach).

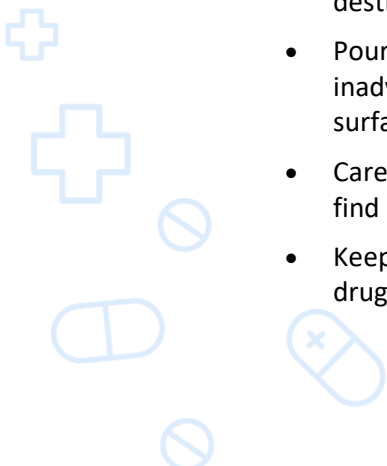
Trametinib :

- Take your trametinib tablets as prescribed once a day. You may take your pills with a large glass of water on an empty stomach either 1 hour before or 2 hours after breakfast and supper. You can take your trametinib tablets at the same time as your dabrafenib morning or evening capsules but make sure to take them at the same time everyday.
- Trametinib tablets must be taken whole. Do not chew, split or crush the tablets.
- **If you forget a dose**, you may take it as soon as you remember if less than 12 hours have passed since the missed dose. Do not double your next dose. Try, however, to take your pills at the same time every day and in the same way (on an empty stomach).

Storing and handling your medicines



- Wash your hands immediately after handling your capsules.
- Keep your **dabrafenib** capsules at room temperature, out of the reach of children and pets as well as protected from light, heat or moisture. Do not keep medicines in the bathroom.
- Keep your **trametinib** tablets **refrigerated**, out of the reach of children and pets as well as protected from light and moisture. Do not freeze the tablets. Do not remove the desiccant from the bottle. Once the bottle has been opened, the drug may be stored at room temperature (not more than 30°C) in the original bottle for 30 days.
- Don't throw away unused medication at home. Bring it back to your pharmacy to be destroyed safely. You may dispose of the empty containers in your home garbage can.
- Pour the pills from the container into the cap to avoid contact with other surfaces. If it inadvertently comes in contact with the surrounding surface, wash and rub the surface with water and soap.
- Caregivers should wear disposable gloves if they prepare medication for you. You can find disposable gloves at your local community pharmacy.
- Keep your medications in their original container and do not mix them with other drugs. The container should never be reused to put other objects or food.



How can this treatment affect your daily life?

Fatigue and appetite



- You may experience **fatigue** during your treatments. This is usually temporary and may be related to different reasons (medication, stress, the disease). Maintain a good level of activity but rest when you feel the need to.
- Your **appetite may diminish**. Eat more often, in smaller quantities.
- Your **sense of taste may be altered**. Enhance foods with *fines herbes* or lemon juice. Eating fruits and unsweetened candies, chewing non-sugared gums, etc., may mask the metallic taste.
- **Alcohol** in small quantities is allowed and will not affect the efficacy of the treatments.

Sex life and birth control



- You can have an **active sexual** life during your treatments. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.).
- It's safe to kiss, to touch, to hold hands, to sleep in the same bed and to cuddle.
- The effect of the drug on male or female fertility is unknown. This medication may have an effect on the menstrual cycle as well as spermatozoid production. However, this does not prevent erection or sexual activity and as such, you can have an active sexual life during your treatments. Pregnancy is possible and this medication could be harmful to the fetus. The use of an effective method of contraception is highly recommended for both men and women while on treatment and up to 4 months after the end of the treatment. Breast-feeding is contraindicated during treatment.

Foods and medicines to avoid



- **Grapefruit**
You must avoid consuming grapefruit, Seville orange, starfruit, pomelo, pomegranate or foods containing them. The consumption of those foods could increase the side effects of your treatment.

Tips and precautions



- **Sit down to urinate and fold down the toilet lid**
Women as well as men should sit down to urinate and fold down the toilet lid before flushing in order to avoid splashing. Flush twice to make sure everything has been flushed away. Follow these precautions during your treatments (or according to instructions from your cancer center).
- **Bodily fluids**
During the course of your treatment, your medicine may be found in certain liquids or secretions that you produce such as urine, stools, vomit, sperm and vaginal discharge. In order to protect the environment and those living with you, follow the instructions given by your cancer center about the right way to handle and dispose of the bodily fluids.





- **Over the counter medicines, natural health products and vaccines**

Consult your healthcare team:

- if you intend to take any other medication (with or without a prescription) or natural health products.
- if you need to receive a vaccine.

This could decrease your treatment's efficacy or increase its side effects.

- **Always have on hand the complete list of your medications**

Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to your doctor and your pharmacist. It is important to make them aware of any change.



What are the side effects of your treatment?

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

ADVERSE EFFECTS

MANAGEMENT

Fever and chills

Fever and chills may occur during your treatment. It may be a reaction to the treatment instead of a sign of infection. It usually occurs within the first 6 months of treatment but it remains possible at any time.

A decrease in **white blood cells** is unlikely during treatment.

- If recommended by your doctor and if you don't have an infection, a medication like acetaminophen (ex: Tylenol®, Atasol®) can be used to treat your symptoms.

✔ **Continue your treatment if:** your temperature is below 38,5°C or 101,3°F.

Stop your treatment and contact your healthcare team as soon as possible if: your temperature is above 38,5°C or 101,3°F.

- ✖ **Stop your treatment and go to the Emergency Room as soon as possible if:** the fever is accompanied by signs of infection (cough, sore throat, pain when you urinate) or a blood pressure drop, weakness and dizziness.

Nausea

Nausea and vomiting, usually light, may occur during your treatment.

- You will be prescribed medication to be taken as needed if you have nausea.

✔ **Continue your treatment if:** you have light nausea that does not prevent you entirely from eating. Make sure to continue your medication prescribed for your nausea.

⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have significant nausea, experience vomiting that is partially preventing you from eating. Make sure to continue your medication prescribed for your nausea.

- ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe nausea or repeated vomiting that prevents you completely from eating.



Skin rash

A skin rash, usually mild, may occur during your treatment. It generally involves the trunk, the arms and legs and can be associated with itchiness.

To help prevent or decrease these reactions:

- Use fragrance-free, alcohol-free mild soap or cleaning products. Also use bath or shower oils to avoid skin dryness.
- Moisturize your skin 2 to 3 times a day with fragrance-free, thick, emollient-based creams like Aveeno®, Neutrogena® or Vaseline Intensive Care® lotion.
- Use non-perfumed creams and cosmetics without alcohol or dye.
- Avoid sun exposure. In case of unavoidable sun exposure, wear a hat and clothes with long sleeves.
- Use a broad-spectrum sunscreen (SPF of 30 or more) which contains zinc oxide or titanium dioxide.

If despite all these measures, skin reactions appear:

- ✓ **Continue your treatment but contact your healthcare team if:** you develop skin problems such as pimples or redness, scattered on your skin but that are not itchy or tender. Continue to apply moisturizing cream.
- ⚠ **Continue your treatment and contact your healthcare team as soon as possible if:** you develop skin problems such as pimples or redness, scattered on your skin and they itch or are tender. Continue to apply moisturizing cream.
- ✗ **Stop your treatment and contact your healthcare team without delay or head to the Emergency Room:** if you develop skin problems, such as pimples or redness all over your body, pain or swelling.

Diarrhea

Diarrhea can sometimes occur with your treatment.

- Drink lots of liquids (8 to 10 glasses a day) unless otherwise instructed by your doctor.
- Eat and drink often but in small quantities.
- ✓ **Continue your treatment if:** you have light diarrhea (2 to 3 additional loose stools per day compared to usual before starting your treatment). Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24 hours period. Contact a member of your healthcare team if the diarrhea does not improve after taking loperamide for 24 hours.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you experience more than 4 to 6 additional loose stools per day compared to usual before starting your treatment. Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose

stool for a maximum of 8 tablets per 24 hours period.

- ➔ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have 7 or more additional loose stools per day compared to usual before starting your treatment, if you are not able to hold it in (incontinence) or if you have diarrhea with a fever.

Headaches

You may experience headaches.

- If this happens and is bothering you, talk to a member of your healthcare team who will recommend a medication for pain.

High blood pressure

High blood pressure might occur.

- Your blood pressure might be checked during your visit with your doctor.
- A member of your healthcare team might ask you to measure your blood pressure regularly and record it in a diary.
- If you experience high blood pressure, medication can be prescribed to control it.
- ✓ **Continue your treatment if:** your resting blood pressure is below 140/90 mmHg.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** your blood pressure is above 140/90 mmHg over a short period of time or less than 24 hours.
- ➔ **Stop your treatment and call your healthcare team as quickly as possible if:** your blood pressure is above 160/100 mmHg all or most of the time over a period of 24 hours. **Head to the Emergency Room** if your blood pressure is above 200/120 mmHg or if you have a headache or are confused.

Muscle and bone pain

You may experience muscle, bone and joint pain and cramps that may occur during your treatment.

- If you present with bone or muscle pain, speak with a member of your healthcare team who will recommend an appropriate pain reliever.

Hair loss

Depending on the individual, **thinning of the hair** may occur. In general, this happens 2 to 3 weeks after the start of the treatment.

- Use gentle shampoo.
- In order to slow hair loss, avoid brushing hair vigorously.
- Avoid hair spray, dyes and perms.

You may notice **discoloration of your hair**, which may become grey, or a **change of texture** (more curly). However, don't worry, the hair will grow back and the situation will return to normal at the end of the treatment.

Blood sugar

Your blood sugar may increase during your treatment.

- If you are diabetic, check your blood sugar levels more often. If the values are higher than usual, communicate with a member of your healthcare team.
- For everyone, if you feel very thirsty and if you urinate in greater amounts and more often, communicate with a member of your healthcare team quickly.

Skin lesions

Skin lesions, that may or may not be cancerous, sometimes appear 6 to 24 weeks after the start of treatment.

- Tell a member of your healthcare team about any change on your skin like a wound, wart or red bump that is bleeding and does not heal.

RARE ADVERSE EFFECTS THAT CAN BE SEVERE OR SERIOUS

If the following side effects occur, stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room:

- Fast or irregular heartbeats
- Shortness of breath and swelling of the ankles
- Pain in your calf or leg with local skin warmth and redness or sudden difficulty breathing
- Eye problems such as pain, redness, blurred or decreased vision

PHARMACIST: _____

PHONE: _____

FROM ____ H ____ TO ____ H ____ (MONDAY TO FRIDAY)

This fact sheet has been prepared by a sub-committee of the Comité national de l'évolution de la pratique des soins pharmaceutiques of the Programme québécois de cancérologie of the Ministry of Health and Social Services in consultation with the Comité de l'évolution de la pratique en oncologie of the Institut national d'excellence en santé et en services sociaux.

DEVELOPED OCTOBER 2018 | REVISED FEBRUARY 2020

Treatment Diary | Dabrafenib-Trametinib 30 days

CYCLE START DATE :

LEGEND

- ✔ Continue your treatment.
- ⚠ Continue your treatment and contact your healthcare team as soon as possible.
- ✘ Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.

Refer to the information sheet for more details

CYCLE DAYS

(Record the dose taken)

Dabrafenib :
mg (am)
mg (pm)










1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30

Trametinib : mg

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Date (dd-mm)

FEVER AND CHILLS		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
✔	Your temperature is below 38,5°C or 101,3°F.																														
✖	Your temperature is above 38,5°C or 101,3°F.																														
✖	Your fever is accompanied by signs of infection (cough, sore throat, pain when you urinate) or a blood pressure drop, weakness and dizziness.																														
NAUSEA AND VOMITING		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
✔	Light nausea that does not prevent you entirely from eating.																														
⚠	Significant nausea or if you experience vomiting that is partially preventing you from eating.																														
✖	Severe nausea or repeated vomiting that prevents you completely from eating.																														

SKIN PROBLEMS		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Skin problems that you did not have before such as pimples or redness, scattered on your skin but that are not itchy or tender.																														
	Skin problems that you did not have before such as pimples or redness, scattered on your skin and they itch or are tender.																														
	Skin problems that you did not have before such as pimples or redness all over your body, pain or swelling.																														
DIARRHEA		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Light diarrhea: you have 2 to 3 additional loose stools per day compared to usual.																														
	Moderate diarrhea: you have 4 to 6 additional loose stools per day compared to usual.																														
	Severe diarrhea: you have 7 or more additional loose stools per day compared to usual before starting your treatment or you are not able to hold it in (incontinence).																														
HIGH BLOOD PRESSURE		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
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