

Midostaurin

Rydapt®

Cancer-directed targeted therapy in capsules



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 this treatment targets 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

Midostaurin

Capsules to take by mouth

Administration

To be taken twice every day (approximately every 12 hours)

Take with food

Induction (inpatient): Take from day 8 through day 21 (for a maximum of 2 cycles)

Consolidation (outpatient): Take from day 8 through day 21 of a 28-day cycle (for a maximum of 4 cycles)

****This medication is used with intravenous chemotherapy****



A **blood test** will be done prior to each treatment cycle and repeated regularly. Depending on the results and side effects of the previous treatment, the treatment might be delayed.

How to take your medication?

- Take your midostaurin capsules as prescribed twice a day at the same time each day. You must take your capsules with a meal and a large glass of water.
- Capsules must be taken whole. Do not open the capsules.
- **If you forget a dose**, skip the missed dose and go back to your usual dosing times. Do not take any doses to make up for the missed dose. Try, however, to take your pills at the same time every day and in the same way (with food).

Storing and handling your medicines



- Wash your hands immediately after handling your medication.
- Keep your medication 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.
- 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.
- If the pills inadvertently come 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.

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 for 4 months after the end of the treatment. Breast-feeding is contraindicated during treatment and for 4 months after the end of the 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 midostaurin.

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 and up to 48 hours after (or according to instructions from your cancer center).
- **Bodily fluids**
The treatment you're receiving stays in your body for a few days. During that period, it's possible that a certain quantity is found in some bodily fluids 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.
- **Drink plenty of fluids**
It is very important to drink plenty of fluids during your treatment, especially during the first few cycles. Furthermore, you could be prescribed a medication (allopurinol) to decrease the risk of problems related to the rapid destruction of abnormal cells and to protect your kidneys.

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.

****Midostaurin is given with intravenous chemotherapy. Some of the side effects listed below may be due to the chemotherapy treatment****

ADVERSE EFFECTS

MANAGEMENT

Decrease in white blood cells

A decrease in **white blood cells** will occur following your treatment. You may be at higher risk of infections during this period.

This decline is inevitable, will be important and extended (3 to 4 weeks). In order to prevent you from becoming infected, you will be isolated throughout this period (induction). The nursing staff will monitor your temperature and you will be administered antibiotics if required.

- Wash your hands often.
- During this period, avoid coming into contact with people who have contagious diseases.
- You may be prescribed a medication (**during the consolidation phase of treatment**) to stimulate your immune system (system that protects you from infections).
- You may be prescribed some medication (drugs that prevent bacterial, fungal or viral infections) to decrease the risk of infection.
- Inform a member of your healthcare team quickly if you notice any signs of infection (fever, chills, cough, sore throat, pain while urinating...).

➔ During the consolidation treatment phase (while you take your medication at home), go to the Emergency Room if :

- you have a fever of 38,3 °C (101°F) or above
or
- you have a fever of 38 °C (100,4 °F) twice an hour apart.

Fever

A majority of patients who receive this treatment will develop a **fever** during the induction treatment phase. You will undergo some medical exams and tests to check for bacteria. Having a fever does not necessarily mean that you have an infection, but you will nonetheless be given an antibiotic as a precautionary measure. Even with antibiotics, fever may last until your white blood cell level comes back normal. At that moment, antibiotics can be discontinued.

- Tell a member of your healthcare team if you notice any sign of infection (fever, chills, cough, sore throat, pain when urinating...).

ADVERSE EFFECTS

MANAGEMENT

Decrease in red blood cells

You will experience a decrease in red blood cells following your treatment. This is called anemia and is characterized by signs of fatigue, pale color, dizziness and shortness of breath.

- Keep active but respect signs of fatigue your body gives you; rest when you feel the need to.
- If you notice one or any of these effects, contact a member of your healthcare team.

Decrease in platelets

A decrease in platelets will occur during treatment. You may bruise or bleed more easily than you normally do.

- Use a toothbrush with soft bristles.
 - Consult your pharmacist before taking over the counter medications containing Aspirin® or other anti-inflammatory medication (e.g. Advil®, Motrin®, Aleve®, etc.).
 - Tell your healthcare team if you notice any type of bleeding (blood in urine, stools, mouth, nose, etc.)
 - You may need platelet transfusions.
 - During the **consolidation** treatment phase when you will take midostaurin at home :
- ➔ **Go to the Emergency Room if:** you experience prolonged bleeding (over 20 minutes), or bleeding that will not stop, if you have blood in your stools or urine or if you are spitting/coughing up blood.

Nausea

Significant **nausea** and vomiting may occur while you are taking your treatment.

- You will be prescribed medication to be taken as needed if you have nausea.
 - During the **induction** phase of treatment, tell a member of your healthcare team if you have nausea.
 - During the **consolidation** phase of treatment while you take midostaurin at home :
- ✔ **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.



ADVERSE EFFECTS

MANAGEMENT

Diarrhea

You may sometimes experience diarrhea, which may start after the start of 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.
- During the **induction** phase of treatment, tell a member of your healthcare team if you have diarrhea.
- During the **consolidation** phase of treatment while you take midostaurin at home:
 - ✔ **Continue your treatment if:** you have light diarrhea (2 to 3 additional loose stools per day compared to usual before starting your treatment). Contact a member of your healthcare team if the diarrhea does not improve after 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.
 - ✖ **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.

Skin rash

A skin rash (pimples, redness), usually mild, may occur following your treatment. It generally involves the trunk, the arms and legs and might be associated with itchiness.

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

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.

Abdominal pain

Abdominal pain may occur sometimes.

- If this bothering you, talk to a member of your healthcare team.

Ulcers in the mouth

Ulcers in the mouth may appear after your treatment. These ulcers can also appear in the throat.

- Gently and regularly brush your teeth after each meal and at bedtime.
- To prevent this effect, rinse your mouth with a solution of water and salt with or without baking soda or mouthwashes **without** alcohol found in stores. Gargle 4

times a day – after every meal and at bedtime. Do not drink or eat for one hour after you gargle.

- During the **induction** phase of treatment, tell a member of your healthcare team if you have ulcers in your mouth.
- During the **consolidation** phase of treatment while you take midostaurin at home:
 - ✔ **Continue your treatment if:** you have mild discomfort (ulcer, sensitivity, redness, irritation) that does not prevent you from eating. Continue your mouthwash.
 - ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have moderate discomfort (redness and painful lesions) that prevents you from eating, but not completely. Continue your mouthwash.
 - ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe discomfort and pain that is bothersome enough that it prevents you almost completely from eating.

Hair loss

Usually there is **no hair loss** with this treatment alone.

However, **total hair loss** will occur with the intravenous chemotherapy given with midostaurin. This may happen 2 to 3 weeks after the start of the treatment. However, don't worry; your hair will grow back after treatments have ended.



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:

- Persistent cough and/or fever and suddenly have trouble breathing
- Feeling out of breath
- Fast or irregular heartbeat
- Shortness of breath, swelling of the ankles

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 **DECEMBER 2019**



Treatment Diary | Midostaurin 28 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 (***except for a decrease in white blood cells or bleeding: continue your treatment and go to the Emergency Room**).

Refer to the information sheet for more details.





CYCLE DAYS

(Record the number of 25mg capsules taken)

morning
evening

Date (dd-mm)

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

	DECREASE IN WHITE BLOOD CELLS							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
	You have a fever of 38,3°C (101°F) or above or you have a fever of 38°C (100,4°F) twice an hour apart with or without symptoms of infection.																																		
	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
	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.																																		

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
✔	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).																												
ULCERS IN THE MOUTH		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
✔	Mild discomfort (ulcer, sensitivity, redness, irritation) that does not prevent you from eating.																												
⚠	Moderate discomfort (redness and painful lesions) that prevents you from eating, but not completely.																												
⛔	Severe discomfort and pain that is bothersome enough that it prevents you almost completely from eating.																												
BLEEDING		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
⛔	Prolonged bleeding (more than 20 minutes), or if it's not possible to stop it, or blood in the stools or urine or cough up blood.																												