

Ixazomib-Lenalidomide-Dexamethasone

Ninlaro®-Revlimid®-Decadron®

Chemotherapy capsules

Understanding your treatment

What is chemotherapy?

Chemotherapy is a treatment against cancer that uses drugs to kill cancer cells. Chemotherapy can be used alone or in combination with other treatments such as radiotherapy.

How can chemotherapy help you?

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

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

How will you feel while on chemotherapy?

Chemotherapy is used to kill abnormal cells in your body. It can also damage healthy cells that divide quickly. Side effects occur when healthy cells are damaged.

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.

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

Medication

Ixazomib

Capsules to take by mouth

Lenalidomide

Capsules to take by mouth

Dexamethasone

Tablets to take by mouth

Administration

To be taken once daily on an empty stomach: 1 hour before or 2 hours after a meal

Take on days 1, 8, 15

Take once daily with or without food

Take for 21 days followed by a 7-day rest period

Take 10 tablets once a week, in the morning with food

Take on days 1, 8, 15 and 22 or in the following way:

Cycle : treatment repeated every 28 days

Treatment schedule*: Ixazomib-Lenalidomide-Dexamethasone (IRd)*

Day	1	2	3	4	5	6	7
Date							
Ixazomib (I)	I						
Lenalidomide (R)	R	R	R	R	R	R	R
Dexamethasone (d)	d						
____ 4-mg tablets	_____						
Day	8	9	10	11	12	13	14
Date							
Ixazomib (I)	I						
Lenalidomide (R)	R	R	R	R	R	R	R
Dexamethasone (d)	d						
____ 4-mg tablets	_____						
Day	15	16	17	18	19	20	21
Date							
Ixazomib (I)	I						
Lenalidomide (R)	R	R	R	R	R	R	R
Dexamethasone (d)	d						
____ 4-mg tablets	_____						
Day	22	23	24	25	26	27	28
Date							
Ixazomib (I)							
Lenalidomide (R)							
Dexamethasone (d)	d						
____ 4-mg tablets	_____						

* The schedule may be modified according to local practices.

Follow instructions given by your pharmacist about your medication schedule.



A **blood test** will be done regularly. If necessary, the dose of ixazomib and lenalidomide may be adjusted or the treatment may be delayed depending on the blood test results or on the side effects that you may have had with the previous treatment.

Pre-menopausal woman: a blood test will be required before the start of treatment to assess whether or not you are pregnant. The blood test will be mandatory every month thereafter.

How to take your medication?

Ixazomib :

- Take your ixazomib capsules as prescribed once a week, on the same day of the week, for 3 weeks in a row, followed by a 1-week rest. You may take your capsules with a big glass of water on an empty stomach, either 1 hour before or 2 hours after meal.
- Capsules must be taken whole. Do not break, chew or open the capsules.
- **If you forget a dose**, you may take it as soon as you remember as long as you have more than 72 hours until your next dose. Do not double your next dose. However, try to take your medication on the same day of the week and on an empty stomach.

Lenalidomide :

- Lenalidomide is dispensed through a specialty pharmacy that is different from your usual pharmacy.
- Take your lenalidomide capsules as prescribed once a day at the same time every day. You may take your medication before or during your meal with a large glass of water or juice. If you have difficulty tolerating it, for example, if it causes a stomach ache, take it while you eat. You must take your lenalidomide capsules on a continuous basis for 21 days followed by a 7-day rest.
- Capsules must be taken whole. Do not break, chew or open the capsules.
- **If you forget a dose**, you may take it as soon as you remember if it has been less than 12 hours since the missed dose but do not double your next dose. However, try to take your pills at the same time every day and in the same way (either with or without food).

Dexamethasone :

- Take your dexamethasone tablets, as prescribed once a week, preferably in the morning, with a meal.
- **If you forget a dose**, you may take it as soon as you remember but do not double the next dose. However, try to take your pills according to the regular schedule as much as possible.



Storing and handling your medicines



- Wash your hands immediately after handling your capsules.
- 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. The ixazomib and dexamethasone may be returned to your pharmacy. Bring the lenalidomide back to the specialty pharmacy that dispensed it to you or call this pharmacy to find out how to return it safely. You may dispose of the empty containers in your home garbage can.
- If the medication inadvertently comes in contact with a countertop or furniture, 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?

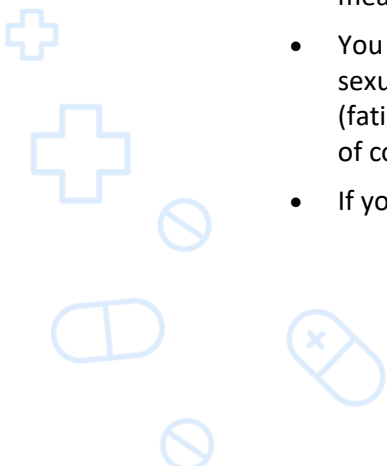
Appetite

- 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



- **Pre-menopausal women** must use **two different contraceptive methods**, starting at least 4 weeks prior to the beginning of treatment and until 90 days after the end of the treatment. Your treatment may cause **birth defects** or fetal death. Avoid taking if you are pregnant or trying to get pregnant. If you cannot use hormonal contraception (implants or injections), you must use 2 mechanical barriers (condom, diaphragm, cervical cap, contraceptive sponge). The contraceptive pill is not recommended with your treatment.
- **Men** must use a condom if they have sex with a pre-menopausal woman for the total duration of treatment and up to 90 days after the end of the treatment. This is a necessary measure even in men who have had a vasectomy.
- You can have an active sexual life during your treatment. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.). Furthermore, do not forget that you must use appropriate methods of contraception as lenalidomide may cause birth defects or fetal death.
- If you had unprotected sex or if your partner is pregnant: notify your doctor immediately.



Foods and medicines to avoid



- **Grapefruit**

You must avoid consuming grapefruit, Seville oranges, starfruit, pomelo, pomegranate or foods containing them. The consumption of those foods could increase the side effects of dexamethasone.

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 for up to 48 hours after your treatment (or according to instructions from your cancer center).

- **Bodily fluids**

During the treatment period, it's possible that a certain quantity of the medication 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 the complete list of your medications on hand**

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

Diarrhea

You may sometimes experience diarrhea.

- 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-hour 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-hour 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.

Constipation

You may experience constipation.

- Exercise if possible.
- Drink lots of liquids (at least 8 glasses a day) (unless otherwise instructed by your doctor).
- Eat foods that are rich in fiber (cereals, fruits and vegetables).
- Communicate with a member of your healthcare team who, if necessary, will recommend appropriate laxatives.



Decrease in white blood cells

A decrease in the white blood cells will occur during your treatment. You could be at higher risk to contract infections.

- Wash your hands often.
- During this period, avoid coming in contact with people who have contagious diseases.
- Contact a member of your healthcare team quickly if you notice any signs of infection (chills, cough, sore throat, pain while you urinate, etc.).
- In case of fever, do not take acetaminophen (Ex: Tylenol®, Atasol®) and anti-inflammatory medication (Ex: Motrin®, Advil®, Aleve®).
- You could be prescribed a medication against viruses to decrease the risk of developing an infection.
- ➔ **Stop your treatment and 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.

Decrease in platelets

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

- Use a tooth brush 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.).
- Contact a member of your healthcare team if you bruise more easily than you normally do or if you have a tendency to bleed easily from the nose or the gums.

Fatigue

You may experience fatigue and dizziness during your treatment. This is usually temporary and may be related to different reasons (medication, stress, the disease, dehydration, ...).

- Maintain a good level of activity but rest when you feel the need to.

Numbness or tingling of the hands and feet

You may experience numbness or tingling of the hands and feet. This phenomenon usually increases with the number of treatments received.

- ✔ **Continue your treatment but contact your healthcare team if:** you have light loss of sensitivity or light tingling sensation at your fingertips and feet that do not prevent you from doing your daily activities.
- ⚠ **Stop your treatment and call your healthcare team as soon as possible if:** you have moderate loss of sensitivity or moderate tingling sensation at your fingertips and feet that partially prevent you from doing your daily activities.
- ➔ **Stop your treatment and call your healthcare team as quickly as possible if:** you have severe loss of sensitivity or severe tingling sensation at your fingertips and feet that almost completely prevent you from doing your daily activities.

Nausea

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

- You will be prescribed medication to take as needed to relieve 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.

Fluid retention

A gradual fluid retention may occur with your treatment and may present itself by swelling of the hands, ankles and feet.

- Raise your feet while sitting.
- Avoid wearing tight clothes or shoes.
- Notify a member of your healthcare team if you are gaining weight rapidly, if you experience some swelling or if you are easily short of breath.

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.

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. The rash may go away after the first 2 to 3 weeks of treatment.

- ✔ **Continue your treatment, but contact your healthcare team if:** you develop a skin rash, such as pimples or redness **without** any itchiness or tenderness.
- ⚠ **Stop your treatment and call your healthcare team as soon as possible:** you develop a skin rash, such as pimples or redness **with** itchiness or tenderness.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you develop a skin rash, such as pimples or redness all over your body with pain and your skin feels hot to the touch.

Heartburn, increased appetite, nervousness and sleep disturbances

Dexamethasone tablets may cause heartburn, increased appetite, nervousness and sleep disturbances.

- To minimize these side effects, take the tablets with food in the morning.
- Notify a member of your healthcare team if these symptoms occur and affect your daily activities. Some measures can be recommended.

ADVERSE EFFECTS

MANAGEMENT

Blood sugar

If you are diabetic, your blood sugar may increase with dexamethasone.

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

Hair loss

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

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:

- Pain, warmth and redness on the calves or the legs
- Sudden difficulty breathing with cough and/or persistent fever

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 NOVEMBER 2019



LEGEND

-  Continue your treatment.
-  **Continue** your treatment and contact your healthcare team as soon as possible (**diarrhea, nausea**).
-  **Stop** your treatment and contact your healthcare team as soon as possible (**numbness or tingling of the hands and feet, skin problems**).
-  Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.

Refer to the information sheet for more details

TREATMENT

(Record the dose taken)

Ixazomib :

mg

Lenalidomide :

mg









Dexamethasone :

mg

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

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).																												
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.																												

NUMBNESS OR TINGLING OF THE HANDS AND FEET		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 loss of sensitivity or light tingling sensation at your fingertips and feet that do not prevent you from doing your daily activities.																												
	Moderate loss of sensitivity or moderate tingling sensation at your fingertips and feet that partially prevent you from doing your daily activities.																												
	Severe loss of sensitivity or severe tingling sensation at your fingertips and feet that almost completely prevent you from doing your daily activities.																												
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.																												
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
	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.																												