

Warning

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.

General information for patient Daratumumab, lenalidomide and dexamethasone (DRd)

Date: February 2019

Revision date:

Medication	Administration
Daratumumab	Intravenous infusion over a few hours <ul style="list-style-type: none">› Cycles 1* and 2: on days 1, 8, 15 and 22› Cycles 3 to 6: on days 1 and 15› Cycles 7 and subsequent: on day 1 * It is possible that daratumumab may be administered over 2 days, on days 1 and 2.
Lenalidomide (Revlimid®)	Capsule to be taken by mouth once daily during 21 days, with or without food, followed by 7 days off.
Dexamethasone	____ tablets of 4 mg (____ mg) to be taken with food OR Intravenous infusion Every week, over 1 or 2 days according to the following schedule: <ul style="list-style-type: none">› _____› _____
<i>Cycle repeated every 4 weeks (28 days)</i>	

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General Information associated with your treatment

- › These medications are used to prevent the multiplication of abnormal cells and destroy them.
- › A **blood test** will be done regularly. Depending on the results and side effects of the treatment, the dose of the medications might be adjusted or the treatment might be delayed. If you are a **pre-menopausal** woman, a blood test will be necessary before the start of lenalidomide and every month thereafter to assess whether or not you are pregnant.
- › Lenalidomide may cause **birth defects** or fetal death. **Women** of childbearing age must use **two different contraceptive methods**, starting at least 4 weeks prior to the beginning of lenalidomide until 3 months after the end of treatment. Avoid taking lenalidomide 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 contraindicated with your treatment.
- › **Men** must use a **condom if they have sex with a woman of childbearing age** for the total duration of treatment up to 4 weeks 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. Notify your doctor immediately if you had unprotected sex or if your partner is pregnant.
- › 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 non sugared candies, chewing non-sugared gums, etc., may mask the metallic taste.
- › **Alcohol** (in small quantities) is permitted and will not affect the efficacy of the treatments.
- › Consult your doctor or pharmacist before you take other medications (even over the counter medications available without a prescription) or **natural health products** or if you need to receive a **vaccine**. These may provoke an interaction with your treatment and diminish its efficacy or increase side effects.
- › Follow the instructions given by your cancer center about the right way to handle and dispose of biological fluids (for example urine, stools) in order to protect the environment and your relatives.
- › 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.

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Adverse effects and their management

Adverse effects	Management
Nausea , usually light, may occur during your treatment.	<ul style="list-style-type: none">› Medication to prevent nausea may be prescribed. At home, you may also have to take medication as needed.› Contact a member of your healthcare team if your medication does not relieve your nausea.
Usually there is no hair loss with this treatment.	
A decrease in the white blood cells will occur during your treatment. You will be at higher risk of infections.	<ul style="list-style-type: none">› Wash your hands often.› During this period, avoid coming into contact with people who have contagious diseases.› Consult your doctor or go immediately to the Emergency Room if you have a fever 38,3 °C (101°F) once or 38 °C (100,4 °F) twice an hour apart.› Contact a member of your healthcare team quickly if you notice any signs of infection (fever, chills, cough, sore throat, pain while urinating...).› Check with your pharmacist before taking medications with Aspirin® (acetylsalicylic acid), ibuprofen or other anti-inflammatory drugs (Ex : Motrin®, Advil®, Aleve®,...).› A medication against virus may be prescribed to decrease the risk of developing an infection.

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A decrease in platelets will occur during your treatment. You may bruise or bleed more easily than you normally do.	<ul style="list-style-type: none">› Use a tooth brush with soft bristles.› Check with your pharmacist before taking medications with Aspirin[®], Ibuprofen or other anti-inflammatory drugs (Ex : Motrin[®], Advil[®], Aleve[®],...).› 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.
You may experience infusion-related reactions with daratumumab, usually during the infusion and up to 4 hours after. Rarely, reactions can occur up to 48 hours after the infusion. The most common reactions are respiratory symptoms (tingling in the throat, nasal congestion, cough, difficulty breathing). Fever, chills, headache, hives, itching, nausea, vomiting and low blood pressure may also happen. These symptoms, usually mild to moderate, are more frequent during the first infusion and less common with subsequent infusions.	<ul style="list-style-type: none">› Medication to prevent allergic reactions will be prescribed prior to treatment and possibly after.› Notify the nurse if one of these symptoms occurs during the administration of the drug. Medication can be given to alleviate these symptoms.› If these symptoms occur at home after the infusion, contact rapidly a member of your healthcare team or go to Emergency Room.
You may sometimes experience diarrhea during your treatments.	<ul style="list-style-type: none">› Drink lots of liquids unless otherwise instructed by your doctor.› Contact a member of your healthcare team if you have significant diarrhea (more than 3 loose stools per day) for more than 24 hours.› If you have with diarrhea with fever, contact immediately a member of your healthcare team or go to Emergency Room.
Fatigue with or without dizziness and weakness may occur during your treatment. This may be related to different reasons (medication, stress, the disease).	<ul style="list-style-type: none">› Maintain a good level of activity but rest when you feel the need to.

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You may experience constipation .	<ul style="list-style-type: none">› Exercise if possible.› Drink lots of fluids (at least 8 glasses a day) unless otherwise instructed by your doctor.› Eat foods that are rich in fibre (cereals, fruits and vegetables).› Communicate with a member of your healthcare team who, if necessary, will prescribe the appropriate laxatives.
You may have shortness of breath with or without cough . These symptoms are rare and may be related to your treatment.	<ul style="list-style-type: none">› If these symptoms occur during treatment, talk to a member of your healthcare team as soon as possible.
You may experience cramps and spasms in your muscles during your treatment.	<ul style="list-style-type: none">› If this occurs, speak to a member of your healthcare team who will recommend analgesics.
Dexamethasone tablets may cause heartburn , increased appetite , nervousness and sleep disturbances .	<ul style="list-style-type: none">› 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.
A usually mild skin rash may occur during your treatment and might be associated with itchiness. This reaction could resolve after 2 to 3 weeks of treatment.	<ul style="list-style-type: none">› Consult a member of your healthcare team who will recommend appropriate measures.
A gradual fluid retention may occur with consecutive treatments and may present itself by swelling of hands, ankles and feet.	<ul style="list-style-type: none">› Raise your feet while sitting.› Avoid wearing tight clothes or shoes.› Notify your doctor if you are gaining weight rapidly, if you experience some swelling or if you are easily short of breath.

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Rare adverse effects that can be severe or serious to communicate quickly to your doctor

- | | |
|---|---|
| Rarely, you may experience pain in your calf or leg with a heat sensation, redness or you may suddenly experience difficulty breathing . | › A medication will be prescribed to prevent this reaction. |
| | › If you experience any of these symptoms, immediately consult your doctor or go to the Emergency Room. |

Special Considerations

- › Keep your medication at room temperature, out of reach of children and protected from light, heat or moisture.
- › You must avoid consuming **grapefruit**, Seville orange, starfruit, pomelo, pomegranate or foods containing them because of an interaction that could increase the side effects of your treatment.

For Lenalidomide:

- › If you forget a dose of lenalidomide, you may take it as soon as you remember but do not double your next dose. Try, however, to take your capsules in a regular, routine manner and in the same way (with or without food).
- › Capsules must be taken whole. Do not chew or open your capsules.
- › Wash your hands immediately after handling your capsules.
- › Don't throw away unused medication at home. Bring it back to the pharmacy that dispensed lenalidomide or call the pharmacy to check how to return the drug. This is to ensure the safe destruction of the drug.

For Dexamethasone:

- › Take your dexamethasone tablets, as prescribed once a week, preferably in the morning during your meal. If you forget a dose, you may take it as soon as you remember but do not double your next dose. Try, however, to take your pills in a regular, routine manner.

Pharmacist: _____

Phone: _____

from ____ h to ____ h (Monday to Friday)



Always keep this card on you.

If you need to receive a blood transfusion, show it to your doctors or other health care professionals.

NAME : _____

My blood group is:

☐ A ☐ B ☐ AB ☐ O ☐ Rh+ ☐ Rh-

The result of the indirect Coombs test was:

☐ negative ☐ positive for these antibodies:

More information can be found at: <https://www.geog.info> or in the Darzalex® prescribing information.

**WARNING: THIS PATIENT IS CURRENTLY
ON DARATUMUMAB**

Daratumumab binds to the CD38 protein present on red blood cells. This can cause a false-positive antibody detection test (indirect antiglobulin test).

It may persist for up to 6 months after the last dose of daratumumab.

There is no effect on the determination of ABO and Rh blood type.

If an urgent blood transfusion is necessary, ABO/RhD-compatible red blood-cells, can be administered without a crossmatch.