

### 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, bortezomib and dexamethasone (DVd)

**Date:** January 2020

**Revision date:**

| Medication                                     | Administration   |
|--|--|
| For cycles 1 to 8: cycles of 3 weeks (21 days) |  |
| Daratumumab                                    | Intravenous infusion over a few hours <ul style="list-style-type: none"><li>› Cycles 1 to 3: on days 1, 8 and 15</li><li>› Cycles 4 to 8: on day 1</li></ul> * It is possible that daratumumab may be administered over 2 days on days 1 and 2 |
| Bortezomib                                     | Subcutaneous injection on days 1, 4, 8 and 11<br>Or  |
| Dexamethasone                                  | Tablets or by intravenous infusion<br>On days _____ : administered by the nurse before daratumumab<br>On days _____ : _____ tablets of 4 mg<br>( _____ mg) to be taken with food at home   |
| From cycle 9 and on: 4 weeks (28 days) cycles  |  |
| Daratumumab                                    | Intravenous infusion over a few hours on day 1   |

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## General Information associated with your treatment

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- › 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.
- › 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.
- › 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.).
- › For **male patients**, the sperm count may be affected and negative effects on the embryo may occur. In fact, the production of spermatozooids may be reduced or completely absent during treatments. In certain patients, this reduction of fertility may be permanent, may get better or return to normal after the treatments have stopped. This reduction of **fertility** does not prevent erection or sexual activity. A pregnancy remains possible. If you have sex with a woman of childbearing age it is strongly recommended to use a method of contraception during the treatment.
- › In **pre-menopausal female patients** chemotherapy may cause irregularities or cessation of the menstrual cycle during treatments. The menstrual cycle may restart or return to normal after the end of treatments. The menstrual cycle may also stop permanently. However, a pregnancy remains possible and chemotherapy administered during pregnancy may harm the embryo. A birth control method is strongly recommended during treatments. Breast-feeding is contra-indicated during 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  |
|--|---|
| <b>Nausea</b> , usually light, may occur during your treatment.  | <ul style="list-style-type: none"><li>› At home, you may have to take medication as needed.</li><li>› Contact a member of your healthcare team if your medication does not relieve your nausea.</li></ul>   |
| Usually there is <b>no hair loss</b> with this treatment.  |   |
| A decrease in the <b>white blood cells</b> will occur during your treatment. You will be at higher risk of infections.     | <ul style="list-style-type: none"><li>› Wash your hands often.</li><li>› During this period, avoid coming into contact with people who have contagious diseases.</li><li>› 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.</li><li>› Contact a member of your healthcare team quickly if you notice any signs of infection (fever, chills, cough, sore throat, pain while urinating...).</li><li>› In case of fever, do not take acetaminophen (Ex: Tylenol®, Atasol®) and anti-inflammatory medication (Ex : Motrin®, Advil®, Aleve®..).</li><li>› A medication against viruses may be prescribed to decrease the risk of developing an infection.</li></ul> |
| A decrease in <b>platelets</b> will occur during your treatment. You may bruise or bleed more easily than you normally do. | <ul style="list-style-type: none"><li>› Use a toothbrush with soft bristles.</li><li>› Check with your pharmacist before taking medications with Aspirin®, ibuprofen or other anti-inflammatory drugs (Ex : Motrin®, Advil®, Aleve®,..).</li><li>› Contact a member of your healthcare team if you bruise more than you normally do or if you have a tendency to bleed from the nose or the gums.</li></ul>   |

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|---|---|
| <p>You may experience <b>infusion-related reactions</b> with daratumumab, usually during the infusion and up to 4 hours after. Rarely, reactions can occur up to 48 hours after the infusion.</p> <p>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.</p> | <ul style="list-style-type: none"><li>› Medication to prevent allergic reactions will be prescribed prior to treatment and possibly after.</li><li>› Notify the nurse if one of these symptoms occurs during the administration of the drug. Medication can be given to alleviate these symptoms.</li><li>› If these symptoms occur at home after the infusion, contact rapidly a member of your healthcare team or go to Emergency Room.</li></ul> |
| <p>You may have <b>shortness of breath</b> with or without <b>cough</b>. These symptoms are rare and may be related to your treatment.</p>  | <ul style="list-style-type: none"><li>› If these symptoms occur, speak to a member of your healthcare team as soon as possible.</li></ul>   |
| <p><b>Fever and chills</b> may occur a few hours following your treatment.</p>  | <ul style="list-style-type: none"><li>› Consult a member of your healthcare team who will recommend appropriate measures.</li></ul>   |
| <p>You may experience <b>numbness or tingling of the hands and feet</b>. This phenomenon usually increases with the number of treatments received.</p>  | <ul style="list-style-type: none"><li>› If you experience these symptoms, notify a member of your healthcare team at your next visit.</li></ul>   |
| <p>You may sometimes experience <b>diarrhea</b> during your treatments.</p>   | <ul style="list-style-type: none"><li>› Drink lots of liquids unless otherwise instructed by your doctor.</li><li>› Contact a member of your healthcare team if you have significant diarrhea (more than 3 loose stools per day) for more than 24 hours.</li><li>› If you have with diarrhea with fever, contact immediately a member of your healthcare team or go to Emergency Room.</li></ul>  |
| <p><b>Fatigue</b> or weakness may occur during your treatment. This may be related to different reasons (medication, stress, the disease).</p>  | <ul style="list-style-type: none"><li>› Maintain a good level of activity but rest when you feel the need to.</li></ul>   |

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|--|---|
| You may experience <b>constipation</b> .   | <ul style="list-style-type: none"><li>› Exercise if possible.</li><li>› Drink lots of fluids (at least 8 glasses a day) unless otherwise instructed by your doctor.</li><li>› Eat foods that are rich in fibre (cereals, fruits and vegetables).</li><li>› Communicate with a member of your healthcare team who, if necessary, will prescribe the appropriate laxatives.</li></ul> |
| Dexamethasone tablets may cause <b>heartburn, increased appetite, nervousness and sleep disturbances</b> .                           | <ul style="list-style-type: none"><li>› To minimize these side effects, take the tablets with food in the morning.</li><li>› Notify a member of your healthcare team if these symptoms occur and affect your daily activities. Some measures can be recommended.</li></ul>  |
| A gradual <b>fluid retention</b> may occur with consecutive treatments and may present itself by swelling of hands, ankles and feet. | <ul style="list-style-type: none"><li>› Raise your feet while sitting.</li><li>› Avoid wearing tight clothes or shoes.</li><li>› Notify your doctor if you are gaining weight rapidly, if you experience some swelling or if you are easily short of breath.</li></ul>  |

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## Special Considerations

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- › Bortezomib might cause low blood pressure that may lead to fatigue, dizziness, fainting, or blurred vision. Do not drive or operate any dangerous tools or machines if you experience such side effects.
- › Green tea and vitamin C modify bortezomib's activity. Avoid green tea and drinks or food that contain green tea or vitamin C supplements for the whole duration of your treatment with bortezomib.
- › Take your dexamethasone tablets, as prescribed, 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.
- › If you need to receive a blood transfusion, inform your doctor or nurse that you are receiving daratumumab. Show them the pocket card (following page).

**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.**