For the Patient: Darolutamide
Other names: NUBEQA®

- **Darolutamide** (dar" oh loo’ ta mide) is a drug that is used to treat prostate cancer. It blocks the effect of testosterone which is a male sex hormone that may stimulate the growth of prostate cancer. Darolutamide is often used with another drug that lowers testosterone levels. It is a tablet that you take by mouth. The tablet contains lactose.

- Tell your doctor if you have ever had an unusual or **allergic reaction** to darolutamide before taking darolutamide.

- **Blood tests** may be taken regularly during treatment.

- It is important to **take** darolutamide exactly as directed by your doctor. Make sure you understand the directions.

- **Take** darolutamide with food.

- If you **miss a dose** of darolutamide, take it as soon as you can if it is within six hours of the missed dose. If it is more than six hours since your missed dose, skip the missed dose and go back to your usual dosing times. Do NOT take a double dose to make up for the missed dose.

- Other drugs such as rifampin (RIFADIN®), rosuvastatin (CRESTOR®), and itraconazole (SPORANOX®) may **interact** with darolutamide. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.

- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of darolutamide.

- Darolutamide may affect **fertility** in men. If you plan to have children, discuss this with your doctor before being treated with darolutamide.

- Darolutamide may damage sperm and may harm the baby if used during pregnancy. It is best for male patients to use a **condom** during sexual activity with a pregnant woman, and a condom plus one other effective **birth control** method during sexual activity with a woman who may become pregnant. Ask your doctor how long you should continue using birth control after your treatment has ended. Tell your doctor right away if your partner becomes pregnant.
• **Do not donate semen** while you are taking darolutamide and for three months after the last dose.

• **Store** darolutamide tablets out of the reach of children, at room temperature, away from heat, light, and moisture.

• **Tell** doctors, dentists, and other health professionals that you are being treated with darolutamide before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

<table>
<thead>
<tr>
<th>SIDE EFFECTS</th>
<th>MANAGEMENT</th>
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<tbody>
<tr>
<td><strong>Nausea</strong> does not usually occur with darolutamide.</td>
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<tr>
<td><strong>Tiredness</strong> and lack of energy may sometimes occur.</td>
<td>• Do not drive a car or operate machinery if you are feeling tired.</td>
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<td></td>
<td>• Try the ideas in <em>Fatigue/Tiredness – Patient Handout.</em></td>
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<tr>
<td><strong>Diarrhea</strong> may rarely occur.</td>
<td>If diarrhea is a problem:</td>
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<td>• Drink plenty of fluids.</td>
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<td>• Eat and drink often in small amounts.</td>
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<td>• Avoid high fibre foods as outlined in <em>Food Choices to Help Manage Diarrhea.</em></td>
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<td></td>
<td>• <strong>Note:</strong> If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your darolutamide dose.</td>
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<tr>
<td><strong>Hair loss</strong> does not occur with darolutamide.</td>
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</table>

*Please ask your chemotherapy nurse or pharmacist for a copy.

**STOP TAKING DAROLUTAMIDE AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:**

• Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, sudden onset of cough, or fainting.
SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:
- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of **bladder problems** such as changes in urination or presence of blood.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:
- Constipation.
- Hot flashes.
- Skin rash.
- Weight loss.
- Memory loss or confusion.
- Dizziness.
- Pain in arms or legs, hands or feet.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR