

For the Patient: UGUNMPDAR

Treatment of Non-Metastatic Castration Resistant Prostate Cancer using Darolutamide

U = Undesignated (requires Compassionate Access Program (CAP) approval)
 GU = GenitoUrinary
 NM = Non-Metastatic
 P = Prostate
 DAR = DARolutamide

ABOUT THIS MEDICATION

What is this drug used for?

 Darolutamide (NUBEQA®) is used to treat prostate cancer that does not respond to other hormonal therapy.

How does this drug work?

 Darolutamide is an oral medication that blocks the effect of testosterone and reduces tumor size. Darolutamide is often used with another drug that lowers testosterone levels

TREATMENT SUMMARY

How is this drug given?

- Darolutamide is given as a tablet by mouth.
- The starting dose is 600 mg by mouth twice daily. A cycle of this medication is 30 days and you will go through multiple cycles depending on your response to treatment and/or the side effects you experience.
- Darolutamide must be taken WITH food. Take darolutamide exactly as directed by vour doctor.
- If you miss a dose, take it as soon as you can if it is within 6 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 double the dose to make up for the missed dose.

What will happen when I get my drugs?

- Blood tests and blood pressure measurements may be taken before the start of treatment and regularly during treatment. The dose of your medication may be changed based on your blood tests and/or other side effects.
- Monitor your blood pressure at home and keep a journal of the measurements to show to your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Your doctor will review the risks of treatment and possible side effects with you before starting treatment.

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

SIDE EFFECTS	MANAGEMENT
Nausea does not usually occur with darolutamide.	
Tiredness and lack of energy may sometimes occur.	Do not drive a car or operate machinery if you are feeling tired.
Diarrhea may rarely occur.	If diarrhea is a problem: Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods Note: 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.
Hair loss does not occur with darolutamide.	

INSTUCTIONS FOR THE PATIENT:

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.

If you experience symptoms or changes in your body that have not been
described above but worry you, or if any symptoms are severe, contact
at telephone number