INTRODUCING

THE NUBEQA®
30-DAY
FREE SAMPLE PROGRAM

Start your appropriate patients on treatment right in your office

The NUBEQA Free Sample Program may allow you to start your patients on NUBEQA quickly

Please read the following pages for important information for prescribers, patients, and pharmacies.

NUBEQA®
(darolutamide) 300 mg tablets

INDICATION

NUBEQA® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of adult patients with:

- Non-metastatic castration-resistant prostate cancer (nmCRPC)
- Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel

IMPORTANT SAFETY INFORMATION

Warnings & Precautions

Ischemic Heart Disease - In a study of patients with nmCRPC (ARAMIS), ischemic heart disease occurred in 3.2% of patients receiving NUBEQA versus 2.5% receiving placebo, including Grade 3-4 events in 1.7% vs. 0.4%, respectively. Ischemic events led to death in 0.3% of patients receiving NUBEQA vs. 0.2% receiving placebo. In a study of patients with mHSPC (ARASENS), ischemic heart disease occurred in 2.9% of patients receiving NUBEQA with docetaxel vs. 2% receiving placebo with docetaxel, including Grade 3-4 events in 1.3% vs. 1.1%, respectively.

Please see additional Important Safety Information throughout and full Prescribing Information.

START TREATMENT WITH THE NUBEQA®
30-DAY FREE SAMPLE PROGRAM

The NUBEQA Free Sample Program will give you the opportunity to

- Start your patients on NUBEQA right in your office
- Provide your patients with a 30-day supply of NUBEQA at no cost

Ordering a sample is simple

- Contact your sales representative, who will process your sample request
- Your order will be shipped within 24 to 48 hours

For illustrative purposes only.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings & Precautions (cont'd)

Ischemic Heart Disease (cont'd) - Ischemic events led to to death in 0.3% of patients receiving NUBEQA with docetaxel vs. 0.1% receiving placebo with docetaxel. Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue NUBEQA for Grade 3-4 ischemic heart disease.

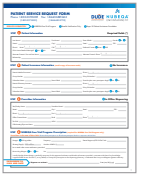
Seizure – In ARAMIS, Grade 1-2 seizure occurred in 0.2% of patients receiving NUBEQA vs. 0.2% receiving placebo. Seizure occurred 261 and 456 days after initiation of NUBEQA. In ARASENS, seizure occurred in 0.6% of patients receiving NUBEQA with docetaxel, including one Grade 3 event, vs. 0.2% receiving placebo with docetaxel. Seizure occurred 38 to 340 days after initiation of NUBEQA. It is unknown whether anti-epileptic medications will prevent seizures with NUBEQA. Advise patients of the risk of developing a seizure while receiving NUBEQA and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others. Consider discontinuation of NUBEQA in patients who develop a seizure during treatment.

How to dispense the sample

- Identify patients who are appropriate for NUBEQA
- Give the appropriate patients both the sample and the patient brochure
- Patient starter kits are also available from your sales representative

After dispensing the sample, initiate the prescription process for your patients

- Visit NUBEQAhcp.com to download the patient request form



- Use covermymeds.com
- Access Services by Bayer™ can help you with reimbursement, access, benefit verification, prior authorization assistance, and appeal support. Please call 1-800-288-8374 Monday-Friday, 9:00 AM - 6:00 PM (ET)

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings & Precautions (cont'd)

Embryo-Fetal Toxicity – Safety and efficacy of NUBEQA have not been established in females. NUBEQA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment with NUBEQA and for 1 week after the last dose.

Adverse Reactions

In ARAMIS, serious adverse reactions occurred in 25% of patients receiving NUBEQA vs. 20% of patients receiving placebo. Serious adverse reactions in ≥1% of patients who received NUBEQA included urinary retention, pneumonia, and hematuria. Fatal adverse reactions occurred in 3.9% of patients receiving NUBEQA vs. 3.2% of patients receiving placebo. Fatal adverse reactions in patients who received NUBEQA included death (0.4%), cardiac failure (0.3%), cardiac arrest (0.2%), general physical health deterioration (0.2%), and pulmonary embolism (0.2%).

Please see additional Important Safety Information throughout and full Prescribing Information.

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NUBEQA® Free Sample Program Requirements

- The NUBEQA Free Sample Program provides NUBEQA at no cost for up to 30 days to eligible patients
- The NUBEQA Free Sample Program is only valid in the United States and Puerto Rico and is void where restricted or prohibited by law
- Qualifying prescriptions for the NUBEQA Free Sample Program must be for an on-label use of NUBEQA
- Participation in the NUBEQA Free Sample Program is not contingent on any past, present, or future prescriptions for, or purchase of, NUBEQA or any other Bayer product. No purchase or refills are required
- If applicable, patient is responsible for any taxes or costs associated with shipment of product
- The program is available to all patients, irrespective of drug coverage
- Bayer reserves the right to rescind, revoke, or amend the NUBEQA Free Sample Program at any time for any reason without prior notice
- By enrolling in the NUBEQA Free Sample Program, the prescribing physician agrees to these requirements
- Bayer cannot ensure continuity of care after the initial sample is dispensed for Medicare Part D patients who may experience co-pay and/or reimbursement challenge with their federally funded insurance program

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

The most common adverse reactions (>2% with a ≥2% increase over placebo), including laboratory test abnormalities, were increased AST, decreased neutrophil count, fatigue, increased bilirubin, pain in extremity, and rash. Clinically relevant adverse reactions occurring in ≥2% of patients treated with NUBEQA included ischemic heart disease and heart failure.

In ARASENS, serious adverse reactions occurred in 45% of patients receiving NUBEQA with docetaxel vs. 42% of patients receiving placebo with docetaxel. Serious adverse reactions in ≥2% of patients who received NUBEQA with docetaxel included febrile neutropenia (6%), decreased neutrophil count (2.8%), musculoskeletal pain (2.6%), and pneumonia (2.6%). Fatal adverse reactions occurred in 4% of patients receiving NUBEQA with docetaxel vs. 4% of patients receiving placebo with docetaxel. Fatal adverse reactions in patients who received NUBEQA included COVID-19/COVID-19 pneumonia (0.8%), myocardial infarction (0.3%), and sudden death (0.3%). The most common adverse reactions (≥10% with a ≥2% increase over placebo with docetaxel) were constipation, decreased appetite, rash, hemorrhage, increased weight, and hypertension. The most common laboratory test abnormalities (≥30%) were anemia, hyperglycemia, decreased lymphocyte count, decreased neutrophil count, increased AST, increased ALT, and hypocalcemia.

No-cost Supply of NUBEQA Requirements

- The no-cost supply of NUBEQA is not insurance
- The no-cost supply of NUBEQA may not be billed in whole or part to any patient or insurer
- The no-cost supply of NUBEQA may not be sold, purchased, or traded
- By accepting the no-cost product, the patient agrees to these requirements

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

Clinically relevant adverse reactions in <10% of patients who received NUBEQA with docetaxel included fractures, ischemic heart disease, seizures, and drug-induced liver injury.

Drug Interactions

Effect of Other Drugs on NUBEQA – Combined P-gp and strong or moderate CYP3A4 inducers decrease NUBEQA exposure, which may decrease NUBEQA activity. Avoid concomitant use.

Combined P-gp and strong CYP3A4 inhibitors increase NUBEQA exposure, which may increase the risk of NUBEQA adverse reactions. Monitor more frequently and modify NUBEQA dose as needed.

Effects of NUBEQA on Other Drugs – NUBEQA inhibits breast cancer resistance protein (BCRP) transporter. Concomitant use increases exposure (AUC) and maximal concentration of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use where possible. If used together, monitor more frequently for adverse reactions, and consider dose reduction of the BCRP substrate.

NUBEQA inhibits breast cancer resistance protein (BCRP) transporter. Concomitant use increases exposure (AUC) and maximal concentration of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use where possible. If used together, monitor more frequently for adverse reactions, and consider dose reduction of the BCRP substrate.

NUBEQA inhibits OATP1B1 and OATP1B3 transporters. Concomitant use may increase plasma concentrations of OATP1B1 or OATP1B3 substrates. Monitor more frequently for adverse reactions and consider dose reduction of these substrates.

Review the Prescribing Information of drugs that are BCRP, OATP1B1, and OATP1B3 substrates when used concomitantly with NUBEQA.

Please see additional Important Safety Information throughout and full Prescribing Information.

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CONSIDER NUBEQA® AS A 1ST option for nmCRPC or mHSPC

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