# PQIIN ACTION





OF NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER

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DAROLUTAMIDE IN COMBINATION
WITH DOCETAXEL FOR METASTATIC
HORMONE SENSITIVE PROSTATE CANCER



**NCODA'S** POSITIVE QUALITY INTERVENTION IN ACTION

### INTRODUCTION

In an effort to promote higher quality patient care, NCODA created the NCODA Positive Quality Intervention (PQI) as a precise and concise peer-reviewed clinical guidance resource for healthcare professionals. By providing Quality Standards and effective practices around specific aspects of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet simple resource for managing patients receiving oral or intravenous anti-cancer agents. This PQI in Action is a follow up to the NUBEQA® (darolutamide) PQIs. It explores how the medically integrated teams at Stockton Hematology Oncology Medical Group and The American Oncology Network (AON) incorporate PQIs as part of their daily workflow. It will discuss how utilizing the Darolutamide In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer and the Darolutamide in combination with Docetaxel for Metastatic Hormone Sensitive Prostate Cancer PQIs elevates patient care and experience.

Stockton Hematology Oncology Medical Group was established in 1991 to provide comprehensive care for patients diagnosed with cancer and blood disorders. With four locations in San Joaquin County, they offer a full spectrum of cancer care that focuses on prevention, screening, diagnosis and treatment of all cancers and blood diseases. Stockton Hematology Oncology Medical Group is proud to partner with Quality Cancer Care Alliance (QCCA), the first clinically Integrated Nationwide Network of Community Oncology Practices. https://www.shomg.net/

The American Oncology Network (AON) is an alliance of physicians and seasoned healthcare leaders partnering to ensure the long-term success of community oncology. Launched in 2018, their rapidly growing network represents physicians, nurse practitioners and physician assistants at multiple care sites across the country. The executive management team brings more than three decades of oncology practice management experience, enabling physicians to focus on what matters most – providing the highest quality care for patients. https://www.aoncology.com/

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#### THE PARTICIPANTS

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The American

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Patient Assistance Advocate

### PROSTATE CANCER AND DAROLUTAMIDE

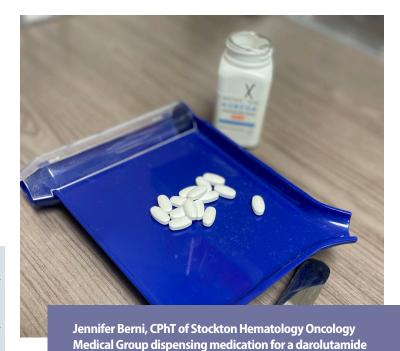
rostate cancer is the second most common cancer among men in the United States, following non-melanoma skin cancer. It is most frequently seen in those over the age of 65 years. Although prostate cancer can be seen in all races, African Amercian men have the highest rates of new diagnosis and are more than twice as likely to die of prostate cancer compared to other races/ethnicities. This tends to be a slow growing cancer, that has a 5-year survival rate of 97.1%. This means that out of every 100 men diagnosed with prostate cancer, 97.1% are still alive 5 years post-diagnosis (adjusted for death from other causes).

Initial risk stratification and staging workup are critical in determining active surveillance or if treatment is necessary. If a patient's prostate cancer recurs after primary treatment, androgen deprivation therapy becomes part of the standard of care. However, even with androgen deprivation treatment, many patients

CLICK HERE
TO VIEW DAROLUTAMIDE
(NUBEQA®) IN THE
TREATMENT OF NONMETASTATIC CASTRATION
RESISTANT PROSTATE
CANCER

will still have disease progression. For those patients classified as having non-metastatic castration-resistant prostate cancer (nmCRPC), delaying the development of metastases is a key therapeutic goal.<sup>3</sup> NUBEQA® (darolutamide) is a next-generation androgen receptor antagonist approved in 2019 for the treatment of nmCRPC.<sup>4</sup> Patients receiving NUBE-QA® should also receive a gonadotropin-releasing hormone (GnRH) analog (also referred to as Androgen Deprivation Therapy (ADT)) concurrently or have had a bilateral orchiectomy.

Darolutamide was designated as a Category 1 recommendation by NCCN for patients with nmCRPC and a prostate specific antigen doubling time of ≤ 10 months based on the results of the phase 3 ARAMIS trial.<sup>5</sup> This trial demonstrated that darolutamide 600 mg twice daily (typical starting dose) improved median metastasis-free survival vs placebo in this patient population (40.4 months vs 18.4 months; HR for metastasis or death 0.41; 95% confidence interval 0.34 to 0.50; P < 0.001).3 In addition, patients receiving darolutamide experienced clinical benefits compared to placebo including improved overall survival, reduced time to requirement for cytotoxic chemotherapy and skeletal related events, and increased time to pain progression. Darolutamide is also well tolerated with overall low rates of serious adverse events. In sharing his experience with darolutamide, Sunny K Philip Jr., MD of Stockton Hematology Oncology Medical Group



shared, "My experience with NUBEQA® has been overall positive. It is a well-tolerated medication, and it is my 'go-to' testosterone receptor inhibitor for patients with the appropriate indication due to the favorable adverse effect profile." The most common adverse events include fatigue, decreased neutrophil count, elevated liver function tests, pain in extremities, and rash. Darolutamide is also indicated in metastatic hormone sensitive prostate cancer (mHSPC) in combination with docetaxel plus ADT.

DAROLUTAMIDE (NUBEQA)
IN COMBINATION WITH
DOCETAXEL (TAXOTERE)
FOR METASTATIC HORMONE
SENSITIVE PROSTATE
CANCER

In the mHSPC combination, the patient recieves 6 cycles of docetaxel 75 mg/m², starting within 6 weeks of initiating darolutamide 600 mg by mouth twice daily (typical starting doses). ADT should also be initiated within 12 weeks of starting therapy unless the individual has

undergone bilateral orchiectomy.<sup>6</sup> Median overall survival in the darolutamide with food plus docetaxel plus ADT arm has not yet been determined, but showed a 32% reduced risk of death, while docetaxel-plus-placebo arm was 48%.<sup>9</sup> month median overall survival (HR=0.68, 95% confidence interval [CI], 0.57-0.80). Time to disease progression showed a 64% risk reduction compared to the control arm. Treatment with darolutamide and docetaxel resulted in a statistically significant delay in time to pain progression with time not yet being

reached vs. 27.5 months respectively (HR = 0.79, 95% CI = 0.66–0.95). It was also noted that the addition of darolutamide did not significantly increase toxicity when added to ADT and docetaxel. Darolutamide is a generally well-tolerated drug. Serious Grade 3/4 adverse effects have an incidence of less than 1% in patients treated with darolutamide plus ADT alone but this doubles with the addition of docetaxel. It is important to distinguish chemotherapy side effects from darolutamide side effects and make appropriate dose modifications. In preclinical studies, darolutamide does not appear to cross the blood-brain barrier, resulting in decreased neurological side effects, including seizures, which can be seen with other medications in this class. Stephanie Hodson, MD of

NON-METASTATIC CASTRATION RESISTENT PROSTATE CANCER

- » Darolutamide
- Androgen Deprivation Therapy

Gem State Cancer & Blood Specialists, a division of AON, shares that she has had a lot of experience with darolutamide in the metastatic hormone-sensitive prostate cancer space and goes on to say, "I find it easy to give to patients. NUBE-QA® is very well tolerated. I love the efficacy so I haven't had a lot of struggles." NCCN has designated darolutamide plus docetaxel plus ADT as Category 1 preferred regimen in mHSPC. Dr. Hodson goes on to share, "I actually don't find compliance a big issue and it is nice because it's a daily drug. It is less confusing than other dosing regimens and allows the patient to get into a routine."

#### METASTATIC HORMONE SENSITIVE PROSTATE CANCER

- » Darolutamide
- » Docetaxel
- » Androgen Deprivation Therapy

### **MEDICALLY INTEGRATED CARE: THE GOLD STANDARD**

n the complexity of cancer care, medically integrated dispensing is an integral way to promote and execute on the continuity of every patient's cancer care. NCO-DA defines Medically Integrated Pharmacy (MIP) as a dispensing pharmacy within an oncology center of excellence, that promotes a patient-centered, multidisciplinary team approach. The MIP is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the coordinated, quality care and therapies for cancer patients.8 The MIP model can improve the management of patients on therapies like darolutamide with ADT in nmCRPC or darolutamide in combination with docetaxel plus ADT. Hallmarks of MIPs include improved communication, adherence, management of side effects, coordination of regimen changes, speed to initiation, patient satisfaction, and financial assistance. Additonally, oncology community practices benefit from cost avoidance and producing less waste.9 NCODA offers multiple tools to aid the MIP practices in managing anti-cancer treatment. From the Oral Chemotherapy Education Sheets (OCE), to the Cost Avoidance/Waste Tracker; from the Financial Assistance tool, to the PQI. With injectable, oral, and combination regimens, cancer treatments continue to grow in complexity.



AON's Medically Integrated Team in Action.

The MIP offers a valuable option for improved patient care. This article will explore the benefits of PQI utilization as a core standard of the MIP and how adoption can benefit any practice.

The MIP staff has unparalleled access to patient information and means of direct communication with other members of the multidisciplinary team, making the MIP staff indispensable. This model greatly reduces fragmentation of care. The dedication of the MIP is exceptional. Maintaining a good relationship through great communication between the patient and the MIP team is important to ensure adherance. 10 Dr. Philip Jr. shares, "I am very fortunate to have a diligent staff that takes these extra steps in order to ensure a patient is able to get their medication. Once the medication is processed, our staff reviews when the patient gets the medication in their hand and sets up follow-up to monitor compliance, side effect monitoring, and appropriate timing of refills." This is a perfect example of how the MID model continually elevates care. The maintenance of open communication can help patients feel like they can be honest with their team about side effects, compliance, etc. This in turn allows the team to be able to better support the patient and improve outcomes. Dr. Hodson also shared that the best patient care comes when they are able to provide everything in-house.

Sally Solanki, MSN, RN, CNL, OCN, of Stockton Hematology Oncology Medical Group notes that at their practice, they focus on developing a relationship with the patient

as much as possible. She states, "Each patient is routinely followed by the same nurse. That really helps with identifying potential side effects that they may be having that they forgot to mention to the doctor because they are comfortable with the same nurse and they can share more." She goes on to share that at their practice they, "really focus on the continuity of care." This directly lines up with NCODA's mission and vision. Her teammate Jennifer Berni, CPhT shares, "The nurses are good about asking the patient, when they are getting their IV treatment 'how is the NUBEQA® going?' As well as 'are you having any side effects? How are the deliveries going, if they are getting it from a specialty, and if there are any issues... So it is a teamwork process! Especially when there are IV and oral combination regimens," such as darolutamide in combination with docetaxel plus ADT. Jennifer Berni, CPhT goes on to share that the relationship developed between the MIP staff and the patient is also very important. She states, "I think the other thing that I've seen too, is when we are following up with those patients, whether it be a phone call or when they come in for an appointment, we are asking about their oral chemo and how they are doing. I know they are really appreciative and this helps with compliance and with identifying side effects sooner."

# THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE SETTING QUALITY STANDARDS

hat is a PQI? A PQI is a precise and concise peer-reviewed clinical guidance resource. The PQI provides Quality Standards and best practices around a specific aspect of cancer care (medications, disease states, and supportive care). The MIP team is in a unique position to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. PQIs, an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. Alicia Barnes, CPhT from AON shares that to her PQIs are, "a one stop shop." Each document is laid out in a consistent format: description, background, PQI process, patient-centered activities, and references. This makes it fast and easy to find information when the reader is looking for a particular piece of information. Hayley Reed, PharmD, BCACP from AON shares that PQIs "provide real life clinical pearls that are just so helpful. You can read the drug monographs, you can read the package inserts, but how can you apply this to a live patient? How does this look in workflow? How can we make sure that we are delivering

the right dose, right medication, right counseling, and follow up? That's what I found particularly helpful are the PQIs."

On the idea of the value in this clinical guidance resource, Dr. Philip Jr. shares that, "I believe one of the most helpful parts of the PQI is that it provides a convenient standardized approach in both dispensing and monitoring patients on a certain therapy. This allows for less variability/discrepancies in monitoring parameters between the different providers, nursing, and MIP staff that are caring for the patient."

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Sunny K. Philip Jr., MD

### PATIENT-CENTERED ACTIVITIES: PATIENT EDUCATION

ral Chemotherapy Education (OCE) was conceived by NCODA as a resource to provide information about oral chemotherapy drugs and their side effects to both cancer patients and caregivers. This vital resource is developed in collaboration with the Oncology Nursing Society (ONS), the Hematology Oncology Pharmacy Association (HOPA), and the Association of Community Cancer Centers (ACCC). Working together we become stronger.

Both participating practices take patient education seriously and have it as a foundational element of their oral oncolytic programs. This is also an essential part of PQIs, being the first point in the Patient-Centered Activities section in both darolutamide PQIs.

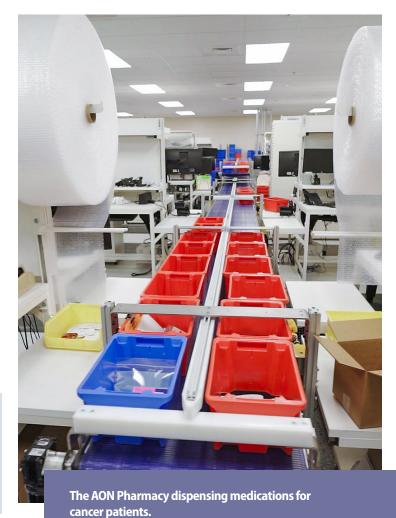
In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.<sup>8</sup> Standard 1.2 of the ASCO/NCODA Standards reads:

Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician assistant. The discussion should include drug name (generic and brand), drug dose,

CLICK HERE
TO VIEW
THIS OCE SHEET

schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.<sup>11</sup>

The darolutamide OCE sheet covers many important counseling points, including drug and food interactions, storage and handling, the handling of bodily fluids/waste, pregnancy/sexual activity considerations, and of course common adverse effects. The most common adverse events seen in clinical trials (≥2%) include fatigue, decreased neutrophil count, elevated liver function tests, pain in extremities and rash. The OCE sheet particularly calls attention to change in liver function and the potential for a decrease in white blood cells (WBC). With liver function, the OCE sheet advises patients to contact the care team if they notice yellowing of the skin or whites of the eyes, dark or brown urine, and/or bleeding or bruising. For decreased WBCs, the patient should contact



the care team if they experience signs or symptoms of an infection including a fever > 100.4°F/38°C, chills, sore throat, burning with urination, unusual tiredness, and/or develops sores that become red, draining, or does not heal. These are very important counseling points for the management of darolutamide. Hayley Reed, PharmD, BCACP expressed, "I just love the OCE sheets because they have the common management strategies." As the pharmacists complete a large component of the counseling around side effects and side effect management, she finds the OCE sheets to be a great patient-centered tool. Stockton Hematology Oncology Medical Group also uses the OCE and IVE sheet as part of their patient education. In their group, the nurse practitioner who is the lead on new start patient education.

## FINANCIAL ASSISTANCE: A VITAL PART OF PATIENT-CENTERED ACTIVITIES

inancial toxicity was brought up as a key consideration by many of the participants. With the cost of cancer care being so high, this is often a barrier for treatment inititation. If a patient is not able to afford their copay, they often will not fill the medication. Both practices have extensive experience with the Access Services by Bayer program, but still touch base with patients to keep the continuity of care in place, another touch point by the MIP. Access Services Patient Service Request form that can help patients receive a complimentary trial while waiting for prior authorization from insurance and assessing for tolerability. The Co-pay Assistance section gives the link for co-pay assistance for patients with private insurance. With prostate cancer being largely seen in those over the age of 65, the majority of patients on darolutamide will be of Medicare age. With this population, co-pay cards cannot be used due to federal regulations, and charitable foundations are the first step in securing assistance for the coverage of co-pays. Alicia Barnes, CPhT shares, "with NUBEQA® specifically being indicated for prostate cancer, that is definitely one of the diagnoses that funding is more limited because it is such a large population living with this diagnosis." She goes on to share that the Access Services by Bayer program (https://www.nubeqa-us.com/ patient-assistance-support) is, "one of the better programs. Their income guidelines are very generous. They will assist patients up to 500% of the federal poverty level, which for 2023 is \$98,600 for a household of two, so fairly generous!" Anissa Glover, CPhT of Stockton Hematology Oncology Medical Group, feels the same. She shares, "I like the new NUBEQA® patient assistance program. It is great in the sense of providing a month supply for initial starts. That is really

helpful while we are in the waiting period of the insurance, pending approvals and things like that. We also have quite a few patients on 'free drug', because prostate foundation grants are very rarely open throughout the year. So we do utilize the free drug program a lot and I would say they are pretty good."

Dr. Philip Jr. shares his thoughts on Stockton Hematology Oncology Medical Group's excellence on combating financial toxicity, "I believe our practice does extremely well in finding resources for our patients to help get medication covered. We have helped several patients get the therapy they desperately need by having a database of different grants, foundations, etc. to refer to when otherwise the cost would have been prohibitive." Annissa Glover, CPhT echoes these thoughts, "I feel our practice is really good about getting financial assistance for patients, by whatever means necessary. We work really closely with the patient and that is something they really praise us for. What we hear from patients is that they've never had faster service with somebody trying to get them assistance and making sure that they start therapy within a good timeframe. Once patients hear about their diagnosis or that they are progressing, they stress and want to start therapy as soon as possible. Of course there is insurance, out-of-pocket costs, and copays, so that is our big thing here - is really helping them out with financial assistance."

Alicia Barnes, CPhT reveals why she is so passionate about her job. She shares, "It is the most gratifying thing that you could do. There is absolutely no better feeling than calling the patient and telling them that they can get their medication for free. Just hearing this, the joy and relief from their voice. It is just the coolest thing."

### **NCODA MEMBERSHIP: VALUE FOR THE ENTIRE TEAM**

ver and over, it was shared how much value NCODA has brought to the medically integrated oncology care team. From the community to the initiatives, NCODA fills a void where there is a need. There really are resources and support for every member of the medically integrated team. Anissa Glover, CPhT shares that another NCODA member, "had helped me a lot, shared the templates that they used at their practice for doing chemo

teaches, and how they do seven day follow ups on patients who initiated therapy. She shared financial sheets and templates that we could use in our EMR system."

The Oncology Pharmacy Technician Association (OPTA) is another area of NCODA that provides a voice and resources for oncology pharmacy technicians worldwide. Alicia Barnes, CPhT wants everyone to know, "I use OPTA as a sounding board a lot. When things come up, changes with manufac-

turers, and all that sorts of other stuff. I rely on OPTA and NCODA CONNECT to network and find workarounds and ideas and solutions as to what other people have encountered. Finding out you know what worked for other OPTA members, you know, how are you getting these patients drugs?" She goes on to ask if you are not an NCODA member already, "Why are you hesitant? NCODA is the best networking tool you could possibly use. There are so many resources available, and you meet so many people."

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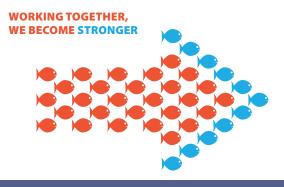
### OPTIMIZING PATIENT OUTCOMES THROUGH PATIENT-CENTERED INTEGRATED CARE

assion for patients is something that resounded loudly with each participant in this article. Sally Solanki, MSN, RN, CNL, OCN shares, "We strive to do the best we can for the patient, now more than ever." While Hayley Reed, PharmD, BCACP says, "My overwhelming message to any patient when they're starting therapy is that we are here to help manage this with you. You are not alone." All team members also agree that the MIP model and the PQI Clinical Resource are valuable to the oncology care team and to patients. It has been shown time and time again that fragmented care can lead to increased spending, but more troubling, worse clinical outcomes for the patient.<sup>12</sup> Both Stockton Hematology Oncology Medical Group and AON have made it their mission to combat fragmented care on a number of fronts; with a strong focus on the continuity of care and the relationship with the patient.

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The PQI fosters excellence in patient care through the identification of the appropriate patient, accurate selection, increased speed to therapy, reduced cost, and improved adherence techniques for the patient. Dr. Hodson states, "I just love having some sort of deep and rewarding interaction with patients. I love being able to help what is a potentially devastating situation, be a little bit less devastating. One of the things I love about my job is the science and how we are learning to take care of the cancer while still giving people hope and quality of life. I think NUBEQA® is an example of that, because it is a new drug that is built better than the previous drugs. Every time someone topples the king of the hill and has a new better product, it is just really exciting to see how that works." Darolutamide has shown proven efficacy in both nmCRPC and mHSPC and has shown a dedication to the patient through their support programs. These PQIs give the MIP and the oncology care team an easy-to-use, succinct clinical guidance resource for identification of the right patient and best practices for the treatment of a darolutamide patient. Pairing Medically Integrated Pharmacy with the darolutamide PQIs meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



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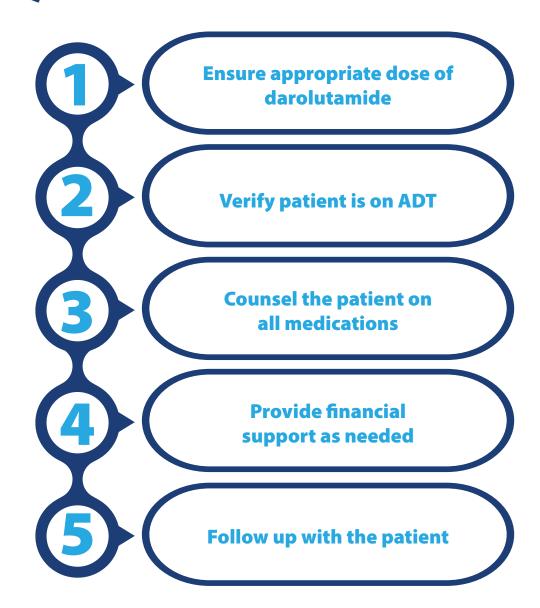
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### **Helpful Online Resources**

- NCODA Website
- Positive Quality Interventions
- Oral Chemotherapy Education Sheets
- Darolutamide (Nubeqa®) In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer
- Darolutamide (Nubeqa) in combination with Docetaxel
   (Taxotere) for Metastatic Hormone Sensitive Prostate
   Cancer PQI

### **PQI PRINCIPLES:**



#### **ON THE COVER:**

• Jennifer Berni, CPhT of Stockton Hematology Oncology Medical Group dispensing medication for a darolutamide patient.

NOTES

#### Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgement.

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



