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## **NIRAPARIB FORT HE TREATMENT OF EPITHELIAL OVARIAN, FALLOPAIN TUBE OR PRIMARY PERITONEAL CANCER**

**RISHOTH P  
PHARM D II YEAR**



**Approved date:** September 27,2023

**Brand name:** Zejula

**Generic name:** Niraparib

**Class:** Poly ADP-ribose polymerase [PARP]  
inhibitors

**Manufacturing company:** Zai lab, Inc.

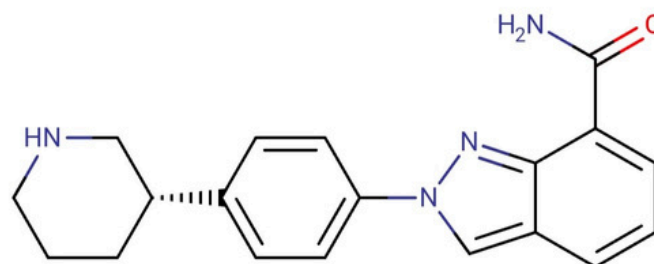
**Dosage form:** Tablets

**Molecular formulae:** C<sub>19</sub> H<sub>20</sub> N<sub>4</sub> O

**Molecular weight:** 320.39g/mol

**Storage:** Store in the original package to  
protect the tablets from absorption of water  
under high humidity conditions.

**Molecular structure:**



### **VISION**

To emerge as one of the premier pharmacy colleges in the country and produce pharmacy professional of global Standards.

### **MISSION**

- To deliver quality academic programs in Pharmacy and empower the students to meet industrial standards.
- To build student community with high ethical standards to undertake R&D in thrust areas of national and international standards.
- To extend viable outreach programs for the health care need of the society.
- To develop industry institute interaction and foster entrepreneurial spirit among the graduates

**Dosage:**

- The recommended dose for NIRAPARIB is 300mg taken once daily in the form of three capsules of 100mg each.
- Greater therapeutic uses in geriatric patients.

**Adult dosing:**

300mg orally once daily until disease progression if higher than 77kg or platelet count is higher than 1,50,000/mcl and then begin treatment within 8 weeks after most recent platinum-containing regimen.

**Dosage:**

- The recommended dose for NIRAPARIB is 300mg taken once daily in the form of three capsules of 100mg each.
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**Adult dosing:**

- 300mg orally once daily until disease progression if higher than 77kg or platelet count is higher than 1,50,000/mcl and then begin treatment within 8 weeks after most recent platinum-containing regimen.
- 200mg orally once daily until disease progression if lesser than 77kg or platelet count is lesser than 1,50,000/mcl and then begin treatment within 12 weeks after platinum-containing regimen.

**Pharmacokinetics:****1. ABSORPTION:**

Bioavailability is approximately 73% ▪ Effects of food:- No significant effect ▪ T<sub>max,oral</sub>:- 3hours

**2. DISTRIBUTION:**

It has high blood brain barrier • Protein binding , plasma proteins : 83% • V<sub>d</sub>:1074L

**3. METABOLISM:**

- Metabolism was primarily hepatic via carboxylesterases
- Inducer of CYP1A2[Cytochrome P450 family1 sub family A Polypeptide]
- Inhibitor of MATE1 and 2[Multi drug and toxin extrusion 1 and 2] and Weak inhibitor of BCRP[Breast cancer resistance protein]
- Substrate of P-GP[Permeability-glycoprotein1] and BCRP[Breast cancer resistance protein]

**4. EXCRETION:**

Fecal:33.8%;19% Unchanged • Renal:47.5%;11% Unchanged

**5. ELIMINATION HALF LIFE:** ▪ 36 Hours**ADVERSE DRUG REACTION:**

HYPERTENSION [17% - 21%] , DERMATOLOGIC RASH [10%], CONSTIPATION [31% - 38%] , DECREASE IN APPETITE [19% - 22%] , NAUSEA [53% - 77%] , VOMITING [17% - 40%] , ANEMIA [50% - 64%] , NEUTROPENIA [31% - 42%],THROMBOCYTOPENIA [54% - 71%] , HEADACHE [22% - 35%] , INSOMNIA[18% - 25%] , DYSPNEA [17% - 22%] , NASOPHARYNGITIS [13%]

**Contraindications:**

Myloid leukemia, Bone marrow suppression, Cardiovascular effects, Embryo-Fetal toxicity.

**Pregnancy and Lactation:**

Contraindicated to Pregnancy and Lactation mothers due to teratogenicity actions of drug in embryo.

**Precautions:**

1) Don't use two doses at a time. 2) Should not use if you are pregnant. 3) Should not breast feed while using Niraparib

**ANGIOEDEMA**  
**ASHITH SANJAY JADPATI**  
**PHARM D I year**

**Introduction :**

Angioedema is defined as " subcutaneous tissues and/or submucosal tissues circumscribed non-pitting edema affecting lips, face, neck, and extremities oral cavity, larynx, and gut." It becomes life-threatening when it involves the larynx, while intestinal angioedema is painful and mimics acute abdomen.

Angioedema was first described in 1882 by Quincke, then by Osler in 1888 (hereditary angioedema), and finally in 1963 by Donaldson et al (the role of C1 inhibitor).

**Classification of angioedema :****Acquired:**

- Allergic (histaminergic angioedema) associated with anaphylaxis
- Non-allergic (non-histaminergic angioedema), presenting isolated or in combination with urticaria
- Drug-induced, e.g., angiotensin-converting enzyme inhibitors and non-steroidal antiinflammatory drugs
- Complement-mediated secondary to acquired deficiency of C1-inhibitor
- Idiopathic which is subdivided into histaminergic and non-histaminergic

**Hereditary forms :**

- C1-Inhibitor deficiency divided into type 1 (lack of C1-inhibitor molecule) and typed 2 (dysfunctional C1-inhibitor molecule) with normal C1 inhibitor.

**Complications :**

- Critical airway occlusion resulting in death
- Acute laryngeal, pharynx and tongue swelling
- Death from asphyxiation
- Hereditary angioedema associated pancreatitis

- Physicians should be mindful of cardiovascular instability including bradycardia after recombinant tissue plasminogen inhibitor in patients who take angiotensin-converting enzyme inhibitors

### **Deterrence and Patient Education :**

**Patient education for Hereditary angioedema:** Proper training will comfort a patient's intimidating feeling of self-administration of Subcutaneous injections.

### **For patients :**

- Individual training for each patient
- Teach them the strategy of planning and scheduling

### **Train parents/caregivers with the following skills :**

- C1-inhibitor subcutaneous injection site
- Aseptic technique
- Needle or syringe preparation
- Injection of C1 inhibitor through the subcutaneous route.

### **Follow-up care :**

It is important to follow-up closely during the first few months of treatment. Encourage patients to keep a logbook for treatment compliance which should include document and report a breakthrough attack of hereditary angioedema.

### **Enhancing Healthcare Team Outcomes :**

Hereditary angioedema: the latest studies indicate that interference RNA mediated knockdown of F12 mRNA ( ALN-F12) is an approach for the prophylactic treatment of hereditary angioedema. Gene therapy in hereditary angioedema may provide an option of durable treatment, but requires further studies for safety and tolerability. Functional polymorphism KLKB1-428G/A with or without functional F12-46C/T polymorphisms may be helpful as prognostic markers of disease. One may monitor 6-keto-prostaglandin F1 alpha as it may be a risk assessment blood marker in ACE inhibitor-induced angioedema. Angioedema is best managed by an interprofessional team as it has very high morbidity and mortality. Patients should be referred to the appropriate specialist as soon as possible. Patients admitted with respiratory distress need ICU monitoring, and the anaesthesia staff should be notified. A bedside tracheostomy set is highly recommended.

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# **UNDERSTANDING THE POTENTIAL RISKS OF PHTHALATES IN FAST FOOD AND THEIR IMPACT ON SEX HORMONE SYNTHESIS:**

**N.VIJAY VIGNESH , PHARM.D II YEAR**



The convenience of fast food has become an integral part of modern life, offering quick and easy meals for people on the go. However, recent concerns have arisen regarding the potential risks associated with certain chemicals found in these foods, particularly phthalates, and their impact on the human body, particularly on sex hormone synthesis and the endocrine system.

## **WHAT ARE PHTHALATES AND HOW DO THEY GET IN TO FAST FOOD?**

Phthalates are a group of chemicals commonly used in the manufacturing of plastics to enhance flexibility, durability, and transparency. They can be found in various consumer products such as packaging, toys, cosmetics, and even food packaging materials.<sup>1 2</sup> These chemicals can leach into food through direct contact or migration from packaging materials, especially when exposed to heat or acidic conditions, as commonly encountered in fast food preparation and storage. <sup>2</sup>

## **THE EFFECTS OF PHTHALATES ON THE ENDOCRINE SYSTEM AND SEX HORMONES:**

One significant concern regarding phthalate exposure is their potential to disrupt the endocrine system. These chemicals are known as endocrine disruptors, meaning they can interfere with the body's hormone regulation mechanisms. Phthalates can mimic or block hormones, potentially leading to imbalances in hormone levels, particularly affecting sex hormones like estrogen and testosterone.<sup>3 4</sup>

Research has shown that exposure to phthalates may lead to adverse effects on reproductive health, such as reduced fertility, altered sperm quality, and disrupted menstrual cycles. Additionally, these chemicals have been linked to developmental and behavioral issues in children and can pose risks during pregnancy. <sup>3 4</sup>

## **HEALTH RISKS ASSOCIATED WITH PHTHALATE EXPOSURE:**

Exposure to phthalates has been associated with several health risks beyond reproductive issues. Studies suggest a potential link between phthalate exposure and increased risk of conditions like diabetes, obesity, asthma, and certain types of cancer. These health implications have raised concerns and prompted calls for stricter regulations on the use of phthalates in consumer products.<sup>5</sup>



## Reducing Exposure to Phthalates from Fast Food:

While complete avoidance of phthalates may be challenging, there are steps individuals can take to minimize their exposure, especially when consuming fast food:

1. **Choose Fresh Options:** Opt for fresh, whole foods over processed or packaged fast food whenever possible. This reduces the likelihood of phthalate exposure from packaging materials.<sup>6</sup>
2. **Avoid Microwaving in Plastic Containers:** When reheating food, transfer it to glass or ceramic containers instead of plastic, as heat can cause phthalates to leach into the food.<sup>7</sup>
3. **Read Labels and Choose Wisely:** Check food labels for packaging materials known to contain phthalates and try to avoid those products.<sup>8</sup>
4. **Use Alternative Storage:** If storing leftovers, consider using glass or stainless-steel containers rather than plastic bags or wrap. <sup>8</sup>
5. **Practice Safe Handling:** Wash hands thoroughly after handling fast food packaging, especially before eating, to minimize potential exposure. <sup>8</sup>

## Conclusion:

Understanding the potential risks of phthalates in fast food is crucial for making informed choices about our dietary habits and overall health. While the complete elimination of phthalates from our environment may be challenging, taking proactive steps to reduce exposure, such as opting for fresh foods and avoiding certain packaging materials, can contribute to mitigating potential health risks associated with these chemicals.

By raising awareness and advocating for stricter regulations on phthalate use, individuals and policymakers can work together to promote healthier and safer food options for everyone.

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