



Yonsa[®] (abiraterone) – New drug approval

- On May 23, 2018, [Sun Pharma announced](#) the FDA approval of [Yonsa \(abiraterone\)](#), for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with [methylprednisolone](#).
- Yonsa uses proprietary SoluMatrix Fine Particle Technology™ to create a micronized (smaller particle size) formulation of abiraterone tablets.
- Abiraterone is also available as the branded product, [Zytiga[®]](#) tablets.
 - Zytiga is approved in combination with [prednisone](#) for the treatment of patients with mCRPC and metastatic high-risk castration-sensitive prostate cancer.
- The efficacy of Yonsa was demonstrated by using the clinical studies conducted with Zytiga. In the first study, 1,195 patients who had received prior [docetaxel](#) therapy were randomized to abiraterone plus steroid vs. steroid alone. In the second study, 1,088 patients who had not received prior cytotoxic therapy were randomized to abiraterone plus steroid vs. steroid alone.
 - Both studies showed a statistically significant improvement in overall survival in patients treated with abiraterone plus steroid vs. steroid alone.
- Yonsa is contraindicated in pregnancy.
- Warnings and precautions of Yonsa include hypertension, hypokalemia and fluid retention due to mineralocorticoid excess; adrenocortical insufficiency, and hepatotoxicity.
- The most common adverse reactions (≥ 10%) with Yonsa use were fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.
- The most common laboratory abnormalities (> 20%) with Yonsa use were anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated aspartate aminotransferase, hypophosphatemia, elevated alanine aminotransferase, and hypokalemia.
- The recommended dosage of Yonsa is 500 mg (four 125 mg tablets) orally once daily in combination with methylprednisolone 4 mg orally twice daily.
 - To avoid medication errors and overdose, be aware that Yonsa tablets may have different dosing and food effects than other abiraterone products.
 - Yonsa should be swallowed whole with water. Do not crush or chew tablets.
- Sun Pharma's launch plans for Yonsa are pending. Yonsa will be available as 125 mg tablets.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.