Balversa (erdafitinib)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Balversa
- **Generic name:** Erdafitinib
- **Pharmacological class:** Kinase inhibitor
- **Strength and Formulation:** 3mg, 4mg, 5mg; tablets
- **Manufacturer:** Janssen
- **How supplied:** Tabs 3mg—56, 84; 4mg—14, 28, 56; 5mg—28
- **Legal Classification:** Rx

Balversa


Balversa™
(erdafitinib) table
4 mg
Product of Switzerland
Manufactured for:
Janssen Products, LP
Horsham, PA 19044
© 2019 Janssen
janssen
NDC 59676-040-56
Balversa™
(erdafitinib) tablets
4 mg
Each film-coated tablet contains 4 mg of erdafitinib.
Rx only
56 film-coated tablets
janssen

Indication

- Locally advanced or metastatic **urothelial carcinoma** that has susceptible FGFR3 or FGFR2 genetic alterations, and has progressed during or following at least 1 line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
  - Indication is approved under **accelerated approval** based on tumor response rate

Dosage & Administration

- **Confirm** presence of FGFR genetic alterations by an FDA-approved test
- Swallow whole
- Initially 8mg once daily; increase to 9mg once daily at 14–21 days if serum phosphate level <5.5mg/L with no ocular disorders or Grade ≥2 adverse reactions; treat until disease progression or unacceptable toxicity
- Dose modifications for adverse reactions: see full labeling

Considerations for Special Populations

- **Pregnancy:** can cause fetal harm; exclude status prior to initiation
- **Nursing mothers:** not recommended (during and for 1 month after the last dose)
- **Pediatric:** not established
- **Elderly:** no overall difference in safety or efficacy observed between patients ≥65 years and younger patients
- **CYP2C9 poor metabolizers:** monitor for increased adverse reactions in patients who are known or suspected to have CYP2C9*3/*3 genotype

Warnings/Precautions

- Perform **ophthalmic exam** (include visual acuity, slit lamp, fundoscopy, optical coherence tomography) monthly for the first 4 months then every 3 months thereafter, and as needed; withhold if central serous retinopathy occurs; permanently discontinue if not resolved within 4 weeks or if Grade 4 severity

- Monitor **phosphate levels** monthly

Warnings/Precautions

- Known or suspected **CYP2C9*3/*3 genotype**: monitor
- Embryo-fetal toxicity
- Advise females of reproductive potential and males (w. female partners) to use effective **contraception** during and for 1 month after the last dose

Interactions

- Potentiated by **strong CYP2C9 or CYP3A4 inhibitors**: consider alternatives, if use unavoidable, monitor closely and adjust dose accordingly
- May be antagonized by **strong CYP2C9 or CYP3A4 inducers**: avoid
- May be antagonized by **moderate CYP2C9 or CYP3A4 inducers**: if use necessary after initial dose increase period, based on serum phosphate levels and tolerability, increase dose up to 9mg

Interactions

- Concomitant other **serum phosphate level-altering agents** may affect serum phosphate levels: avoid before initial dose increase period
- Avoid concomitant sensitive CYP3A4 substrates with **narrow therapeutic index**

Interactions

- May potentiate **OCT2 substrates**; consider alternatives or reducing the dose of substrates
- May potentiate **P-gp substrates**; if use unavoidable, separate dosing by ≥6hrs before or after substrates

Adverse Reactions

- **Most common** (≥20%): increased phosphate, stomatitis, fatigue, increased creatinine, diarrhea, dry mouth, onycholysis, increased alanine aminotransferase, increased alkaline phosphatase, decreased sodium, decreased appetite, decreased albumin, dysgeusia, decreased hemoglobin, dry skin, increased aspartate aminotransferase, decreased magnesium, dry eye, alopecia, palmarplantar erythrodysesthesia syndrome, constipation, decreased phosphate, abdominal pain, increased calcium, nausea, and musculoskeletal pain

- **Also:** ocular disorders (eg, central serous retinopathy/retinal pigment epithelial detachment)

Mechanism of Action

- Erdafitinib is a kinase inhibitor that binds to and inhibits enzymatic activity of FGFR1, FGFR2, FGFR3 and FGFR4 based on *in vitro* data
- It inhibits FGFR phosphorylation and signaling and decreases cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions
- Erdafitinib demonstrated antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer

Clinical Studies

- The safety and efficacy of Balversa were evaluated in an open label, single-arm study in patients with locally advanced or metastatic urothelial carcinoma whose disease progressed on or after at least 1 prior chemotherapy and that had at least 1 of the following genetic alterations: **FGFR3 gene mutations** (R248C, S249C, G370C, Y373C) or **FGFR gene fusions** (FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7)

Clinical Studies

- Patients (N=87) received a starting dose of Balversa 8mg once daily with a dose increase to 9mg once daily in those whose serum phosphate levels were below the target of 5.5mg/dL between days 14 and 17; a dose increase occurred in 41% of patients
- Treatment was administered until disease progression or unacceptable toxicity
- The primary efficacy outcome measures were objective response rate (ORR) and duration of response (DoR)

Clinical Studies

- Results showed an ORR of 32.2% (95% CI, 22.4, 42.0) with a complete response seen in 2.3% of patients and a partial response observed in 29.9% of patients
- The median DoR was 5.4 months (95% CI, 4.2, 6.9)
- See full labeling for more clinical trial data

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/balversa/