Balversa package insert pdf

From HemOnc.org - Hematology Oncology Vicky Klass/Mechanism: Tyrosine kinase inhibitor. Erdafitinib inhibits several tyrosine kinase receptors (RTKs), including fibroblast growth factor receptors (FGFR) FGFR1, FGFR2, FGFR3, FGFR4, FGFR4, as well as RET, CSF1R, PDGFRA, PDGRB, FLT4, KIT and VEGFR2. Erdafitinib inhibits FGFR-related phosphorylation and signal transduction, resulting in inhibition and death of tumor cells in FGFR-reexpression of tumor cells. Route: PO Extravasia: n/a Monitor for hyperphosphateemia; Dose adjustments may be necessary to insert packaging for brevity and simplicity, HemOnc.org will now focus on treatment regimens rather than listing information such as: renal/hepa dose adjustments, metabolism (including CYP450), selection, monitoring parameters (although this will be considered for checklists), or manufacturer. Instead, for the most current information, please refer to your preferred pharmacopeias such as Micromedex, Lexicomp, UpToDate (courtesy lexicomp), or package insert. Diseases for which it used Patient Information drug Erdafitinib (Balversa) package insert 1 History of changes in the FDA indication Also known as code name: JNJ-42756493 Brand: Balversa Synonym: Erda Links AdultPediatricDosage Forms Advanced or Metastatic Ursotetic Carcinoma, which has a growth factor receptor of fibroblast-2 (FGFR2) or FGFR3 genetic changes and progressed during or after at least 1 line of prior platinum-containing chemotherapy, including for 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy 8 mg PO qDay originally; increase to 9 mg PO qDay based on serum phosphate level (PO4) and tolerance in 14-21 days Continue until disease progression or unacceptable toxicity Increase dose to 9 mg qDay, If serum phosphate level first: 8 mg/day Second: 6 mg/day Third: 3 5 mg/day Fourth: 4 mg/day Fifth: Stop the drug if the fifth reduction is needed first: 6 mg/day Second: 5 mg/day Third: 4 mg/day Fourth: Stop the drug if the fourth reduction is necessary for all patients, limit the intake of phosphates to 600-800 mg/day; if the serum phosphate is 7 mg/dL, Think about adding an oral phosphate binder until serum phosphate levels return to 5.6-6.9 mg/dL (1.8-2.3 mmol/L): Continue at the current dose of 7-9 mg/dl (2.3-2.9 mmol/l): Revaluation weekly to phosphate 1 week of zgt;9 mg/dL (2.9 mmol/L): retention; revaluation weekly prior to phosphate of 10 mg/dL (3.2 mmol/L) or substantially altered underlying kidney function or Grade 3 hypercalcemia: retention; revaluation weekly to asymptomatic phosphate; Clinical or diagnostic Only hold the drug until the resolution If allowed for 4 weeks, resume at the next lower dose level; then, if there is no relapse within a month, consider reescalization If stable for 2 consecutive eye examinations, but not resolved, resume at the next lower dose of Visual acuity 20/40 or or or or or ≤3 lines of reduced vision from base retention to resolution If permitted within 4 weeks, may resume at the next lower dose visual acuity worse than 20/40 or qgt;3 lines of reduced vision from base retention to permission If permitted within 4 weeks, can resume 2 doses below If repeated, Consider the constant cessation of visual acuity 20/200 or worse in the affected eyes Constantly stop the 3rd grade: Hold the drug until it decides 1st grade or baseline, then can resume the dose 1 level below 4: Permanently stop mild or moderate (eG FR 30-89 ml/min/1.73 m2): Clinically significant trends in pharmacokinetics were not observed: Unknown Honey (TB ≤ULN and ACT zgt; ULN or TB qgt;) 1 to 1.5x ULN and any ACT) : No clinically significant trends in pharmacokinetics observed Moderate or severe: Unknown choice based on the presence of susceptible genetic changes FGFR in tumor samples, As discovered by FDA-approved companion diagnostic information on FDA-approved tests to detect genetic changes in FGFR in urotechelal cancer is available by: Assessment pho phosphate levels 14-21 days after initiation of monitor phosphate levels monthly For Hyperphosphateia Safety and Efficiency No Interactions Found Interaction Found FoundContraindicatedSerious - Use Of AlternativeSignificant - Monitor TsperminorAll Interactions Sort By: SeverityName Phosphate Increased (76%) Stomatitis (56%) Fatigue (54%) Creatinine increased (52%) Diarrhea (47%) Dry mouth (45%) ALT increased (41%) Alkaline phosphate increased (41%) Onyholis (41%) Reduced sodium (40%) Decrease in appetite (38%) Albumin decreased (37%) Dysgeusia (37%) Hemoglobin decreased (35%) Dry skin (34%) ACT increased (30%) Magnesium decreased (30%) Constipation (28%) Dry Eye (28%) Palmar-suscular erythrodicesesthesia (26%) Alopecia (26%) Phosphate decreased (24%) Abdominal pain (23%) Calcium increased (22%) Nausea (21%) Pain in the musculoskeletal and motor age (20%) Platelets decreased (19%) Leukocytes decreased (17%) Blurred vision (17%) Paronyemia (17%) Urinary tract infection (17%) Potassium increased (16%) Weight decreased (16%) Pyrexia (14%) Vomiting (13%) Nail discoloration (11%) Conjunctivitis (11%) Pain in orofaring (11%) Hematuria (11%) Artralgia (11%) Sodium decreased (16%) (grades 3-4) 1-10% (all varieties) Of Neutrophils decreased (10%) Fasting glucose increase (10%) Lacrimation increased (10%) Shortness of breath (10%) 1-10% (Classes 3-4) Fatigue (10%) Onyholis (10%) Phosphate decreased (9%) Stomatitis (9%) Palmar-suscular erythrodicesesthesia (6%) Urinary tract infection (6%) Dry Eye (6%) Creatinine increased (5%) Hemoglobin decreased (3%) Calcium increased (3%) Paroncia (3%) Neutrophils (2%) Diarrhea (2%) Abdominal pain (2%) Vomiting (2%) Shortness of breath (2%) Hematuria (2%) Platelets decreased (1%) Phosphate increased (1%) (1%) increased (1%) Increased alkaline phosphate (1%) Magnesium decreased (1%) Constipation (1%) Nausea (1%) Pyrexia (1%) Dysgeusia (1%) Pain in orofaring (1%) No warnings, based on the mechanism of action and research on animals, can cause harm to the fetus, if injected to pregnant women eye disorders can cause eye disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED), resulting in a field of vision defect perform monthly ophthalmological examinations during the first 4 months of treatment, and then every 3 months after that, and urgently at any time for visual symptoms all patients should receive dry eye prevention with eye suspensions as needed Increases in serum phosphate levels are pharmacodynamic effect as a consequence of FGFR inhibition The median start time for any hyperphosphateemia class event amounted to 20 days Monitor for hyperphosphateemia and subsequent dose modification if necessary patients may require phosphate binders during treatment Drug interaction review Coadministration increases concentration of erdafitinib , closely monitor adverse reactions and consider dose changes accordingly if a moderate CYP2C9 or strong CYP3A4 inhibitor stops, erdafitinib dose can be increased by the Co-administration can significantly reduce the concentration of erdafitinib plasma and the effectiveness of avoiding coad administration can significantly reduce the concentration of erdafibib plasma and efficacyIf a moderate indusor should be coadministered at the beginning of treatment, start with an 8-mg/daily dose, with the potential to increase to 9 mg/day based on serum phosphate levels on days 14-21 and tolerability If a moderate inductor should be coadministered after the initial dose increase period based on serum phosphate level and tolerability, increase the dose of erdafitinib to 9 mg When the moderate inductor is discontinued, continue erdafitinib at the same dose, in the absence of drug-related coadministration toxicity with other serum phosphate levels of altering agents may increase or decrease serum phosphate levels Avoid coad administration until the initial dose increase period (Days 14-21) Erdafiitib can change the concentration of plasticants that leads to either loss of activity or increased toxicityAdmination with sensitive substrates CYP3A4 with narrow therapeutic indices Erdafitinib can increase the concentration of plasma substrates OCT2 Consider alternative treatments Erdafitinib can increase the concentration of plasma P-gp substrates If co-administration is inevitable , separate introduction at least 6 hours before or after the introduction substrates with a narrow therapeutic index Based on the mechanism of action and conclusions in animal reproduction studies, can cause harm to the fetus when introduced Women's Animal Research: Administration of pregnant rats during organogenesis caused malformations and embryonic death in maternal effects that were less than human exposure to the maximum recommended human dose based on AUC Pregnancy testing recommended for women's reproductive potential prior to erdafitinib infertility: Based on findings in animal studies, May worsen fertility in women's reproductive potential contraception women: Advise women of reproductive capacity to use effective contraception during treatment and within 1 month after the last dose Men: Advising male patients with female partners of reproductive potential to use effective contraception during treatment and within 1 month after the last dose of Lactation No data on the presence in human milk, the effect on breast-feeding children, or on the production of milk Due to potential adverse reactions , advise breastfeeding women not to breastfeed during treatment and for 1 month after the last dose Of Category A: Generally acceptable. Controlled studies in pregnant women do not show any evidence of fetal risk. B: Could be acceptable. Either animal studies do not show any risk, but human studies are not available or animal studies have shown minor risks and human studies have been conducted and have shown no risk. C: Use with caution if the benefits outweigh the risks. Animal studies show risk and human research is not available or neither animals nor human studies are done. D: Use LIFE-THREATENING in emergencies when there are no safer drugs. Positive evidence of the risk of human fetus development. X: Do not use during pregnancy. The risks involved outweigh the potential benefits. There are safer alternatives. NA: Information is not available. Fibroblast growth factor inhibitor (FGFR); FGFRs are a family of receptors tyrosine kinase in vitro, erdafitinib inhibits FGFR phosphorylation and signaling and reduces cell vitality in cell lines, Expressing FGFR genetic changes including point mutations, amplification and fusion Absorption Peak Plasma Time: 2.5 h Peak plasma concentrations: 1399 ng/ml AUC: 29,268 ng'hr/mL Vd Distribution: 29 L Protein bound: 99.8%; primarily alpha-1-acid glycoprotein Metabolism primarily metabolized by CYP2C9 and CYP3A4 Contribution CYP2C9 and CYP3A4 in the total purification of erdafitinib estimated at 39% and 20%, respectively unchanged erdtinafiib was the main medicinal moiety in plasma; There were no circulating metabolites Elimination half-life: 59 hours Full clearance: 0.362 L/hr Selection: 69% feces Unchanged); 19% urine (19% unchanged) Pharmacogenomics CYP2C9 poor metabolizers CYP2C9'3 / No. 3 genotype: Erdafitinib systemic impact is projected to be 50% higher, estimated to be present in 0.4-3% of the population among different ethnic groups may take with or without food Swallow pills overall; Do not chew or crush vomiting dose: If vomiting occurs at any time after taking erdafitinib, erdafitinib, Dose should be taken the next day Missed dose Take the missed dose as soon as possible on the same day Resume the regular daily dose schedule the next day Additional tablets should not be taken to make a missed dose of Storage at 20-25oC (68-77oF); Excursions are allowed to 15-30oC (59-86oF) FormularyPatient DiscountsAdding plans allows you to compare the status of the formula with other drugs in the same class. To see the formula information, first create a list of plans. Your list will be saved and can be edited at any time. Adding plans allows you to view formulas and any limitations for each plan. Manage and view all your plans together - even plans in different states.Compare formula status of other drugs in the same class. Access to the plan list on any device - mobile or desktop. Monographs of Medscape prescription drugs are based on FDA-approved labeling information, unless otherwise stated, combined with additional data from primary medical literature. Literature. balversa package insert pdf. balversa fda package insert