



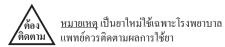


## **U**NOVARTIS

Abbreviated Prescribing Information ZYKADIA® (ceritinib)

Presentation: Hard gelatin capsules containing 150 mg certitinib; film-coated tablets containing 150 mg certitinib. Indications: Zykadia is indicated for the treatment of patients with locally advanced or metastatic non-small cell hung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive. Dosage and administration: Adults: Recommended dose is 450 mg taken orally once daily with food at the same time each day. Maximum recommended dose is 450 mg taken orally once daily with food. • Temporary dose interruption and/or dose reduction of Zykadia therapy may be required based on individual safety and tolerability. • Zykadia should be discontinued in patients unable to tolerate 150 mg taken once daily with food. Children (below the age of 18 years): The safety and efficacy of Zykadia have not been established in pediatric patients. Special populations: • No dose adjustment necessary in patients with mild to moderate renal impairment. Use caution in

patients with severe renal impairment. . Reduce the dose by approximately one-third adjustment necessary in patients with mild or moderate hepatic impairment. Contraindications: None. Warnings and precautions: • Hepatotoxicity: Monitor with liver laboratory tests prior to the start of treat or liver transaminases and total bilirubin should be done as clinically indicated. • Interstitial lung disease (ILD) / Pneumonitis: Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis. Exclude other potential causes Periodic monitoring with electrocardiograms (ECGs) and periodic monitoring of electrolytes (e.g., potas with any-grade treatment-related ILD/pneumonitis. • QT interval prolongation: Avoid use of Zykadia in patients with congenital long QT syndrome. iss, or electrolyte abnormalities and in patients who are taking medications that are known to prolong the QT interval. In case of vomiting, diarrhea, eumonitis, and permanently discontinue Zykadia in patients diagnosed wit ecommended in patients with congestive heart failure, bradyar dehydration, or impaired renal function, correct electrolytes as clinically indicated. Permanently discontinue Zy dia in patients who develop QTc greater than 500 msec greater than 60 msec change from baseline and Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia. Withhold less than 481 msec; then reinitiate Zykadia by reducing dose by 150 mg. • Bradycardia: Avoid use of Zykadia in combination with other agents known to cause bradycardia (e.g., beta-blockers, non-dihydropy-Zykadia in patients who develop QTc greater than 500 msec on at least 2 separate ECGs until recovery to baseline or a QT Trading calculation in the object of the state of the sta patients using standards of care, including anti-diarrheals, anti-emetics, or fluid replacement, as indicated. Dose interruption and dose reduction may be employed as necessary. If vomiting occurs during the course of freatment, the patient should not take an additional dose, but should continue with the next scheduled dose. Hyperglycemia: Monitor fasting serum glucose prior to the start of Zykadia treatment and periodically thereafter as clinically indicated. Initiate or optimize anti-hyperglycemic medications as indicated. • Elevations of lipase and/or amylase: Monitor lipase and amylase prior to the start of Zykadia treatment and periodically thereafter as clinically indicated. Pregnancy, lactation, females and males of reproductive potential: Pregnancy: Should not be given to pregnant women unless the potential enefit outweighs the potential risk to the fetus. Lactation: A decision should be made whether to discontinue breast-feeding or discontinue Zykadia taking into account the importance of Zykadia to the mother. Females and males of reproductive potential: Females of reproductive potential to be advised to use effective contraception (methods that result in less than 1% pregnancy rates) while on treatment and for up to 3 months after discontinuation. Infertility: The potential for Zykadia to cause infertility in male and female patients is unknown. Adverse drug reactions: Very common (>10%): Liver laboratory test abnormalities, diarrhoea, fatigue, abdominal pain, nausea, decreased appetite, vomiting, weight decreased, constipation, blood creatinine increased. rash. anaemia. and oesophaceal disorder. Common (>1 do 1%): Electrocardiogram (T prolonged, hyperglycaemia, anylase increased, vision disorder, cericarditis, hypophosphataemia, lipase increased, vision disorder, cericarditis, hypophosphataem one-third, rounded to the nearest multiple of the 150 mg dosage strength. After discontinuation of a strong CYP3A inhibitor, resume the Zykadia dose that was taken prior to initiating the strong CYP3A inhibitor. • P-gp inhibitors: Exercise caution with concomitant use of P-gp inhibitors and carefully monitor adverse drug reactions. • Strong CYP3A and P-op inducers: Avoid concomitant use of strong CYP3A inducers, including but not limited to, carbamazepine, phenobarbital, phenvtoin, rifabutin, rifampin, and St. John's Wort (Hypericum perforatum), Exercise caution with concomitant use of P-op inducers, or CYP3A and CYP2C9 substrates: Avoid co-administration of Zykadia with substrates primarily metabolized by CYP3A or CYP2C9, CYP3A substrates known to have narrow therapeutic indices (e.g., ciclosporin, dihydroergotamine, fentanyl, pimozide, quinidine, tacrolimus, alfentanil and sirolimus), and CYP2C9 substrates known to have narrow therapeutic indices (e.g., bhenvtoin and warfarin). If unavoidable, consider dose reduction for co-administered medicines that are CYP2A6 and CYP2E1 substrates: ion with concomitant use of CYP2A6 and CYP2E1 substrates and carefully monitor adverse drug reactions. • Drug-food/drink interactions: Zykadia should be taken with food. Patients should be instructed to avoid grapefruit or grapefruit juice as they may inhibit CYP3A in the gut wall and increased of the state of the s of ceritinib. Packs and prices: Country-specific. Legal classification: Country-specific. BSS : version date Nov 2018



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โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา ใบอนุญาตโฆษณาเลขที่ มศ. 121/2560