ZYKADIA™
ceritinib 150 mg capsules

Lung Friendship

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NOVARTIS

Abbreviated Prescribing Information ZYKADIA® (ceritinib)

Presentation: Hard gelatin capsules containing 150 mg ceritinib; film-coated tablets containing 150 mg ceritinib. **Indications:** Zykadia is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung 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, rounded to the nearest multiple of the 150 mg dosage strength in patients with severe hepatic impairment. No dose 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 treatment and monthly thereafter. In patients who develop transaminase elevations, more frequent monitoring of 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 of ILD/pneumonitis, and permanently discontinue Zykadia in patients diagnosed with any grade treatment-related ILD/pneumonitis. • **QT interval prolongation:** Avoid use of Zykadia in patients with congenital long QT syndrome. Periodic monitoring with electrocardiograms (ECGs) and periodic monitoring of electrolytes (e.g., potassium) is recommended in patients with congestive heart failure, bradyarrhythmias, or electrolyte abnormalities and in patients who are taking medications that are known to prolong the QT interval. In case of vomiting, diarrhea, dehydration, or impaired renal function, correct electrolytes as clinically indicated. Permanently discontinue Zykadia in patients who develop QTc greater than 500 msec or greater than 60 msec change from baseline and Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia. Withhold Zykadia in patients who develop QTc greater than 500 msec on at least 2 separate ECGs until recovery to baseline or a QTc 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-dihydropyridine calcium channel blockers, clonidine, and digoxin) to the extent possible. Monitor heart rate and blood pressure regularly. In cases of symptomatic bradycardia that is not life-threatening, withhold Zykadia until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above, evaluate the use of concomitant medications, and adjust the dose of Zykadia if necessary. Permanently discontinue Zykadia for life-threatening bradycardia if no contributing concomitant medication is identified; however, if associated with concomitant medication known to cause bradycardia or hypotension, withhold Zykadia until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above, and if concomitant medication can be adjusted or discontinued, reinitiate Zykadia by reducing dose by 150 mg upon recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above, with frequent monitoring. • **Gastrointestinal adverse reactions:** Monitor and manage 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 treatment, 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 benefit 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 oesophageal disorder. **Common (≥1 to <10%):** Electrocardiogram QT prolonged, hyperglycaemia, amylase increased, vision disorder, pericarditis, hypophosphataemia, lipase increased, bradycardia, abnormal liver function tests, pneumonitis, renal failure, hepatotoxicity, and renal impairment. **Uncommon (≥0.1 to <1%):** Pancreatitis. **Interactions:** • **Strong CYP3A inhibitors:** Avoid concurrent use of strong CYP3A inhibitors. If concomitant use of strong CYP3A inhibitors is unavoidable, including but not limited to, ritonavir, saquinavir, telithromycin, ketoconazole, itraconazole, voriconazole, posaconazole, and nefazodone, reduce the Zykadia dose by approximately 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-gp inducers:** Avoid concomitant use of strong CYP3A inducers, including but not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, and St. John's Wort (Hypericum perforatum). Exercise caution with concomitant use of P-gp inducers. • **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, ergotamine, fentanyl, pimozide, quinidine, tacrolimus, alfentanil and sirolimus), and CYP2C9 substrates known to have narrow therapeutic indices (e.g., phenytoin and warfarin). If unavoidable, consider dose reduction for co-administered medicines that are CYP3A or CYP2C9 substrates with narrow therapeutic indices. Increase international normalized ratio (INR) monitoring frequency if warfarin co-administration is unavoidable. • **CYP2A6 and CYP2E1 substrates:** Exercise caution 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 increase the bioavailability of ceritinib. **Packs and prices:** Country-specific. **Legal classification:** Country-specific. **BSS :** version date Nov 2018

ต้อง ติดตาม

หมายเหตุ เป็นยาใหม่ใช้เฉพาะโรงพยาบาล
แพทย์ควรติดตามผลการใช้ยา

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