Zykadia 150mg, Hard gelatin capsules: יקאדיה 150 מ"ג, כמוסות קלות קשיחות

A new formulation approved for use in countries, Zykadia 150mg, is now available at the pharmacy.

Zykadia 150mg capsules

Zykadia 150mg capsules contain Ceritinib 150mg, the active ingredient.

Ceritinib 150mg capsules contain the following ingredients:

- Microcrystalline cellulose, low-Substituted hydroxypropylcellulose, sodium starch glycolate, magnesium stearate, Colloidal Silicon Dioxide
- Gelatin, titanium dioxide (E171), indigotin – FD&C Blue 2 (E132), printing ink, black
- Shellac glaze 45%, iron oxide black (E172), propylene glycol, ammonium hydroxide 28%

ZYKADIA is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Lung cancer is the leading cause of cancer death in the world. Non-small cell lung cancer (NSCLC) accounts for more than 85% of all lung cancer cases. Systemic chemotherapy, with or without radiotherapy, is a cornerstone treatment for patients with locally advanced or metastatic NSCLC.

Anaplastic lymphoma kinase (ALK) is a receptor tyrosine kinase of the insulin receptor superfamily. In NSCLC, ALK rearrangement occurs in approximately 5% of cases. ALK-rearranged tumors depend on ALK for growth and survival and show marked sensitivity to ALK inhibitors such as crizotinib.

Despite initial responses to crizotinib, the majority of patients have a relapse within 12 months, owing to the development of resistance. Treatment options after the failure of crizotinib are limited. Furthermore, there are patients who do not tolerate or respond to crizotinib.

Ceritinib, the active ingredient of Zykadia 150mg, is an oral, small-molecule, ATP-competitive, tyrosine kinase inhibitor of ALK. Ceritinib inhibits autophosphorylation of ALK, ALK-mediated phosphorylation of downstream signaling proteins, and proliferation of ALK-dependent cancer cells both in vitro and in vivo.

The outstanding anti-tumor activity and resulting clinical benefit combined with the well characterized and manageable safety profile of ceritinib strongly support a positive benefit risk balance for ALK-positive NSCLC patients. This is an important new drug, filling a void for crizotinib-resistant disease.