ICLUSIG®
(ponatinib) tablets
45 mg, 15 mg

Working to take the "NO" out of "NO RESPONSE"

ICLUSIG® (ponatinib) gives appropriate patients a chance to achieve a response.[1]

For patients with CML or Ph+ ALL when no other TKI# is indicated, or who have the T315I mutation[2]

Abbreviated Prescribing Information

ICLUSIG® (ponatinib) 15 mg/45 mg tablets. **Indication:** In adult patients with (1) chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation; and (2) Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. **Dosage:** Recommended starting dose: 45 mg once daily. Assess the patient's cardiovascular status before treatment initiation. Refer to the package insert for dose modification for management of toxicities. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and precautions:** Risk of myelosuppression; a complete blood count should be performed every 2 weeks for the first 3 months and then monthly or as clinically indicated. Monitoring for evidence of arterial occlusion and thromboembolism; interrupt treatment in such events. If decreased vision or blurred vision occurs, perform an ophthalmic examination (including fundoscopy). Reports of treatment-emergent hypertension; urgent clinical intervention required for hypertension associated with confusion, headache, chest pain, or shortness of breath. Discontinue treatment in patients developing serious heart failure. Caution recommended in patients with a history of pancreatitis or alcohol abuse. Patients with severe hypertriglyceridemia should be appropriately managed to avoid pancreatitis. Liver function tests should be performed prior to treatment initiation and monitored periodically, as clinically indicated. Interrupt treatment and evaluate patients for serious or severe haemorrhage. Monitor for active HBV infection in HBV carriers throughout therapy and for several months after treatment. Interrupt treatment in the event of posterior reversible encephalopathy syndrome. Caution recommended in patients with hepatic/renal impairment. Not advised in pregnancy; only used when clearly necessary. Stop breastfeeding during treatment & use effective contraception during treatment. **Drug interactions:** Caution in concomitant use with CYP3A inhibitors/inducers, transporter substrates (e.g. P-gp and BCRP) & anti-clotting agents in patients who may be at risk of bleeding events. **Adverse reactions:** Pneumonia, pancreatitis, abdominal pain, atrial fibrillation, pyrexia, myocardial infarction, peripheral arterial occlusive disease, anaemia, angina pectoris, decreased platelet count, febrile neutropenia, hypertension, coronary artery disease, congestive cardiac failure, cerebrovascular accident, sepsis, cellulitis, acute kidney injury, UTI and increased lipase. **Please see full Prescribing information for details. Full prescribing information is available upon request.**

Abbreviations:
CML: chronic myeloid leukemia; Ph+ ALL: Philadelphia chromosome-positive acute lymphoblastic leukemia; TKI: tyrosine kinase inhibitor

References:
1. Cortes JE, et al. Blood. 2018; 132(4): 393-404.
2. Iclusig® (Ponatinib) Hong Kong Prescribing Information revised Jan 2019.

#: Imatinib, Nilotinib, Dasatinib

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