TUCATOR 150

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TUCATOR 150 [Tucatinib tablets 150 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tucatinib is a reversible, potent and selective tyrosine kinase inhibitor of HER2. In cellular signalling assays, tucatinib is >1000-fold more selective for HER2 compared to epidermal growth factor receptor. *In vitro*, tucatinib inhibits phosphorylation of HER2 and HER3, resulting in inhibition of downstream cell signalling and cell proliferation, and induces death in HER2 driven tumour cells. *In vivo*, tucatinib inhibits the growth of HER2 driven tumours and the combination of tucatinib and trastuzumab showed enhanced anti-tumour activity *in vitro* and *in vivo* compared to either medicinal product alone.

INDICATIONS: It is indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

DOSAGE AND ADMINISTRATION: The recommended dose is 300 mg tucatinib (two 150 mg tablets) taken twice daily continuously in combination with trastuzumab and capecitabine. TUCATOR is for oral use. The tablets should be swallowed whole and should not be chewed, crushed, or split prior to swallowing. It should be taken approximately 12 hours apart, at the same time every day, with or without a meal. TUCATOR may be taken at the same time with capecitabine.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Caution should be taken in Increased ALT, AST, and bilirubin, Increased creatinine without impaired renal function, Diarrhoea, Embryo-foetal toxicity, Sensitive CYP3A substrates, P-gp substrates, Strong CYP3A/moderate CYP2C8 inducers, Strong/moderate CYP2C8 inhibitors.

DRUG INTERACTIONS: A clinical drug interaction study found that co-administration of tucatinib with metformin (a MATE1/2-K substrate) resulted in an increase in metformin concentrations (1.1-fold Cmax (90% CI: 1.0, 1.2) and 1.4-fold AUC (90% CI: 1.2, 1.5)). Tucatinib reduced the renal clearance of metformin without any effect on glomerular filtration rate (GFR) as measured by iohexol clearance and serum cystatin C. No dose adjustment is required.

ADVERSE REACTIONS: Epistaxis, diarrhoea, nausea, vomiting, stomatitis, rash, arthralgia, AST increase, ALT increase, blood bilirubin increased, weight decrease**.**

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)