

DACLACRUZ

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

Abbreviated Prescribing information for DACLACRUZ (Daclatasvir Tablets 60 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Daclatasvir is an inhibitor of nonstructural protein 5A (NS5A), a multifunctional protein that is an essential component of the HCV replication complex. **INDICATIONS:** For use with sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV) genotype 3 infection.

DOSAGE AND ADMINISTRATION: The recommended dose of Daclacruza is 60 mg once daily, to be taken orally with or without meals. Daclacruza must be administered in combination with other medicinal products.

CONTRAINDICATIONS: cytochrome P450 3A4 (CYP3A4) and P-glycoprotein transporter (P-gp), phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort (*Hypericum perforatum*).

PRECAUTIONS Daclacruza must not be administered as monotherapy. Cases of severe bradycardia and heart block have been observed when Daclacruza is used in combination with sofosbuvir and concomitant amiodarone, Daclacruza should not be used during pregnancy.

DRUG INTERACTIONS: Daclacruza is contraindicated in combination with medicinal products that strongly induce CYP3A4 and P-gp, e.g. phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort (*Hypericum perforatum*), and thus may lead to lower exposure and loss of efficacy of Daclacruza.

ADVERSE REACTIONS: Anaemia, decreased appetite, insomnia, irritability, headache, dizziness, migraine, hot flush, cough, dyspnoea, dyspnoea exertional, nasal congestion, nausea, diarrhoea, vomiting, abdominal pain, gastroesophageal reflux disease, constipation, dry mouth, flatulence, pruritis, rash, alopecia, dry skin, arthralgia, myalgias and fatigue.

MARKETED BY:



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IN/ DACLACRUZ 60mg /JAN-2016/01/ABPI
(Additional information is available on request)