Indications[2]

Hypertension, where monotherapy with candesartan cilexetil or hydrochlorothiazide is not sufficient.

Posology and method of administration[2]

Dose in Hypertension

The recommended dose of CANDESARTAN HCT SANDOZ TABLET is one tablet once daily.

The dose of candesartan cilexetil should be titrated before switching to CANDESARTAN HCT SANDOZ TABLET.

Most of the antihypertensive effect is usually attained within 4 weeks of initiation of treatment.

When clinically appropriate a direct change from monotherapy to CANDESARTAN HCT SANDOZ TABLET may be considered. Dose titration of candesartan cilexetil is recommended when switching from hydrochlorothiazide monotherapy.

Candesartan HCT Sandoz Film Coated Tablet 16mg/12.5mg Basic Succinct Statement

Composition: CANDESARTAN HCT SANDOZ TABLET 16mg/12.5mg **Indications:** Hypertension, where monotherapy with candesartan cilexetil or hydrochlorothiazide is not sufficient. **Dose and Method of Administration:** Oral use. CANDESARTAN HCT SANDOZ TABLET should be taken once daily with or without food. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients or to sulfonamide derived active substances. Hydrochlorothiazide is a sulfonamide derived active substance. Pregnancy and lactation. Severe renal impairment (creatinine clearance <30 ml/min/1.73 m2 BSA). Severe hepatic impairment and/or cholestasis. Refractory hypokalaemia and hypercalcaemia. Gout. The concomitant use of CANDESARTAN HCT SANDOZ TABLET with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m2 BSA). **Special warnings and precautions for use:** Renal impairment. Kidney transplantation. Dual blockade of the renin-angiotensin-aldosterone system (RAAS). Renal artery stenosis. Intravascular volume depletion. Non-melanoma skin cancer. Hepatic impairment. Aortic and mitral valve stenosis (obstructive hypertrophic cardiomyopathy). Primary hyperaldosteronism. Electrolyte imbalance. Metabolic and endocrine effects. **Interactions with other medicinal products and other forms of interaction:** Clinical trial data has shown that dual blockade of the RAAS through the combined use of ACE- inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (including acute renal failure) compared to the use of a single RAAS-acting agent (see section Contraindications and Special warnings and precautions for use). **FERTILITY, PREGNANCY AND LACTATION:** The use of CANDESARTAN HCT SANDOZ TABLET is contraindicated during pregnancy (see section Contraindications). Patients receiving CANDESARTAN HCT SANDOZ TABLET should be made aware of that before contemplating a possibility of becoming pregnant so that they can discuss appropriate options with their treating physician. When pregnancy is diagnosed, treatment with CANDESARTAN HCT SANDOZ TABLET must be stopped immediately and if appropriate, alternative therapy should be started. When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause foetal and neonatal injury and death. Exposure to angiotensin II receptor antagonist therapy is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia) (see section Preclinical safety data). There is limited experience with hydrochlorothiazide during pregnancy, especially during the first trimester. Animal studies are insufficient. Hydrochlorothiazide crosses the placenta. Based on the pharmacological mechanism of action of hydrochlorothiazide, its use during pregnancy may compromise foeto-placental perfusion and may cause foetal and neonatal effects like icterus, disturbance of electrolyte balance and thrombocytopenia. It is not known whether candesartan is excreted in human milk. However, candesartan is excreted in the milk of lactating rats. Hydrochlorothiazide passes into mother's milk. Because of the potential for adverse effects on the nursing infant, CANDESARTAN HCT SANDOZ TABLET should not be given during breast-feeding (see section Contraindications). **Effects on ability to drive and use machines:** No studies on the effects on the ability to drive and use machines have been performed, but based on its pharmacodynamic properties CANDESARTAN HCT SANDOZ TABLET is unlikely to affect this ability. When driving vehicles or operating machines, it should be taken into account that occasionally dizziness or weariness may occur during treatment of hypertension. **Undesirable effects:** Blood and lymphatic system disorders, Metabolism and nutrition disorders, Respiratory, thoracic and mediastinal disorders, Nervous system disorders, Gastrointestinal disorders, Hepato-biliary disorders, Skin and subcutaneous tissue disorders , Musculoskeletal, connective tissue and bone disorders , Renal and urinary disorders

Important note: For Healthcare Professionals Only. Before prescribing, consult full prescribing information. Based on Candesartan HCT Sandoz Film Coated Tablet PI Aug 2019.

Reference 1: A Single-Dose, Comparative Bioavailability Study of Two Formulations of Candesartan Cilexetil/Hydrochlorothiazide 16mg/12.5mg Tablets Under Fasting Conditions, Xueyu (Eric) Chen, Andrea S. Gershon, Tomislav Buconjic, Robert C. Wu (2008). **2:** Candesartan HCT Sandoz Tablet 16mg/12.5mg Package Insert (Aug 2019).

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