MOXCENT

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

Abbreviated Prescribing information for MOXCENT (Moxonidine Tablets B.P. 0.2 mg & 0.3 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: MOXCENT differs from other available centrally acting antihypertensives by exhibiting only low affinity to central α_2-adrenoceptors as compared to I1-imidazoline receptors; α_2-adrenoceptors are considered the molecular target via which sedation and dry mouth, the most common undesired side effects of centrally acting antihypertensives, are mediated. In humans, It leads to a reduction of systemic vascular resistance and consequently in arterial blood pressure.

INDICATIONS: It is indicated for hypertension.

DOSAGE AND ADMINISTRATION: *Adults (including the elderly)*: Treatment should be started with 200 µgs, which may be titrated after three weeks to 400 µgs, given as one dose or as divided doses (morning and evening) until a satisfactory response has been achieved. If the response is still unsatisfactory after a further three weeks' treatment, the dosage can be increased up to a maximum of 600 µgs in divided doses (morning and evening). A single dose of 400 µgs and a daily dose of 600 µgs in divided doses (morning and evening) should not be exceeded. In patients with moderate renal dysfunction (GFR above 30 ml/min, but below 60 ml/min), the single dose should not exceed 200 µgs and the daily dose should not exceed 400 µgs of moxonidine. The tablets should be taken with sufficient liquid. As the intake of food has no influence on the pharmacokinetic properties of moxonidine, the tablets may be taken before, during or after the meal. *Paediatric population*: MOXCENT is not recommended for use in children and adolescents below 18 years due to lack of data on safety and efficacy.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, Sick sinus syndrome or sino-atrial block, 2nd or 3rd degree atrioventricular block, Bradycardia (below 50 beats/minute at rest), Severe heart failure, Severe renal dysfunction (GFR <30 ml/min, serum creatinine concentration >160 µMol/l).

WARNINGS & PRECAUTIONS: Caution is recommended when treating patients with a possible predisposition to developing an AV block and in patients with 1st degree AV block. It must not be used in higher degree AV blocks. Special care should be exercised in patients with severe coronary artery disease or unstable angina pectoris because there is limited experience in this patient population. Caution is advised in the administration of moxonidine to patients with renal impairment as moxonidine is excreted primarily via the kidneys. In these patients, careful titration of the dose is recommended, especially at the start of therapy. If Moxonidine is used in combination with a beta-blocker and both treatments have to be discontinued, the beta-blocker should be discontinued first and then Moxonidine after a few days. An abrupt discontinuance of the moxonidine treatment is not advisable; instead, the dose should be reduced gradually over a period of two weeks. MOXCENT must be used with caution with in patients with co-existing moderate heart failure. Patients with rare hereditary problems of lactose intolerance should not take this medicine. Due to a lack of data on safety and efficacy, MOXCENT should not be used in children and adolescents below 18 years of age.

DRUG INTERACTIONS: Concurrent administration of other antihypertensive agents enhances the hypotensive effect of MOXCENT. Since tricyclic antidepressants may reduce the effectiveness of centrally acting antihypertensive agents, it is not recommended that tricyclic antidepressants be co-administered with moxonidine. Moxonidine can potentiate the sedative effect of tricyclic anti-depressants (avoid co-prescribing), tranquillisers, alcohol, sedatives and hypnotics. Moxonidine moderately augmented the impaired performance in cognitive functions in subjects receiving lorazepam. Moxonidine may enhance the sedative effect of benzodiazepines when administered concomitantly. Moxonidine is excreted

through tubular excretion. Interaction with other agents that are excreted through tubular excretion cannot be excluded.

ADVERSE REACTIONS: Dry mouth, Headache, Dizziness/Vertigo, Somnolence, Diarrhoea, Nausea/Vomiting/ Dyspepsia, Rash/ Pruritus, Asthenia, Back pain, Insomnia, Bradycardia, Tinnitus, Syncope, Hypotension (including orthostatic), Angioedema, Oedema, Neck pain and Nervousness.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/MOXCENT 0.2 mg, 0.3mg/JUL-25/02/ABPI

(Additional information is available on request)