

Only for the use of Medical Professionals

Tizadin[®] Tizanidine

Description

Tizadin[®] is the preparation of Tizanidine Hydrochloride which is a centrally acting skeletal muscle relaxant. It acts as an agonist of α_2 -adrenergic receptor sites and presumably reduces spasticity by increasing presynaptic inhibition of motor neurons.

Indications

Tizadin[®] is indicated in:

Painful muscle spasms

- associated with static and functional disorders of the spine (cervical and lumbar syndromes)
- following surgery e.g. for herniated intervertebral disc or osteoarthritis of the hip.

Spasticity due to neurological disorders

- multiple sclerosis
- chronic myelopathy
- degenerative spinal cord disease
- cerebrovascular accident and cerebral palsy.

Dosage and administration

Adult over 18 years of age:

Initially 2 mg daily as a single dose increased according to response at intervals of at least 3-4 days in steps of 2 mg daily (and given in divided doses) usually up to 24 mg daily in 3-4 divided doses. The daily dose of 36 mg should not be exceeded.

Use in patients with renal impairment

In patient with renal insufficiency (creatinine clearance <25 ml/min), it is recommended to start treatment at 2 mg once daily. Dosage increases should be done in small steps according to tolerability and efficacy. If efficacy has to be improved, it is advisable to increase first the once daily dose before increasing the frequency of administration.

Use in Elderly

Experience with the use of Tizanidine in the elderly is limited. Caution is therefore indicated when using Tizanidine in elderly patients.

Use in children

Experience in children is limited and the use of Tizanidine Hydrochloride in these patients population is not recommended.

Pregnancy and Lactation

Tizanidine has no teratogenic effects in rats and rabbits. As there have been no controlled studies in pregnant women, however, it should be used during pregnancy until the benefit clearly outweighs the risk. Although only small amounts of Tizanidine are excreted in animal milk. Tizanidine should not be taken by lactating women.

Side-effects

Tizanidine may cause drowsiness, fatigue, dizziness, dry mouth, nausea, gastrointestinal disturbance, hypotension, bradycardia, insomnia, hallucination and altered liver enzymes and rarely acute hepatitis.

Contraindications

Tizanidine is contraindicated in patients with known hypertensive to Tizanidine or any of its ingredients and it is also contraindicated in significantly impaired hepatic function.

Precautions

Tizanidine should be used with caution in patients with renal or hepatic insufficiency, patients of hypotension, women taking oral contraceptives, when patients drive a vehicle and machinery. Since hepatic dysfunction has been reported in association with Tizanidine, but rarely at daily doses up to 12 mg, it should be used with caution in patients with significant hepatic impairment. It is recommended that liver function tests should be monitored monthly for the first 4 months in patients receiving doses of 12 mg and higher.

Drug interactions

Alcohol or other CNS depressants may enhance the CNS effects of Tizanidine Hydrochloride. There may be an additive hypotensive effect when Tizanidine is used in patients receiving antihypertensive therapy.

Over dosage

In case of over dosage, it is recommended to eliminate the ingested drug by repeated administration of high doses of activated charcoal. Forced diuresis is expected to accelerate the elimination of Tizanidine. Future treatment should be symptomatic.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Presentation

Tizadin[®] 2 mg tablet: Each tablet contains Tizanidine 2mg as Hydrochloride INN.

Package quantities

Tizadin[®] 2 mg tablet: Carton of 50 tablets in blister.

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