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210mm

Movax® Tablets
(Tizanidine)

DESCRIPTION:
Movax®chemically tizanidine hydrochloride is a centrally acting alpha-2 adrenergic agonist which is a skeletal muscle relaxant. Its chemical name is 5-chloro-4-(2-imidazolin-2-ylamino)-2,1,3-benzothiodiazole hydrochloride.
Tizanidine molecular formula is $C_9H_8ClN_5S$-HCl, its molecular weight is 290.2gm.
Movax® is an agonist at α2-adrenergic receptors sites and presumably reduces spasticity by increasing presynaptic inhibition of motor neurons. The effects of **Movax**® (tizanidine) are greatest on polysynaptic pathways. The overall effect of these actions is thought to reduce facilitation of spinal motor neurons.

COMPOSITION:

Movax® 2mg Tablets
Each tablet contains:
Tizanidine Hydrochloride USP
equivalent to Tizanidine.....2mg

Movax® 4mg Tablets
Each tablet contains:
Tizanidine Hydrochloride USP
equivalent to Tizanidine.....4mg

PHARMACOLOGICAL PROPERTIES:
Absorption and bioavailability
Tizanidine is rapidly and almost completely absorbed, reaching peak plasma concentration in approx. 1 hour. Although tizanidine is well absorbed, the absolute oral bioavailability of tizanidine is about 30-40% due to extensive first pass metabolism.

Distribution
Tizanidine is only about 30% bound to plasma proteins.

Metabolism
Tizanidine undergoes rapid and extensive metabolism in the liver. Tizanidine metabolites are not known to be active.

Elimination
Excretion primarily is via renal route (approx. 70% of the administered dose). The elimination half-life of tizanidine from plasma is 2-4 hours in patients.
Concomitant food intake has no influence on the pharmacokinetic profile of tizanidine tablets.

THERAPEUTIC INDICATIONS:
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.
Muscular spasms associated with accidental trauma.

Spasticity due to neurological disorders
Like multiple sclerosis, chronic myelopathy, degenerative spinal cord diseases, cerebrovascular accidents and cerebral palsy.

DOSAGE AND ADMINISTRATION:
For oral administration
The effect of **Movax**® (tizanidine) on spasticity is maximum within 2-3 hours of dosing and it has a relatively short duration of action. The timing and frequency of dosing should therefore be tailored to the individual and **Movax**® (tizanidine) should be given in divided doses, up to 3-4 times daily, depending on the patient's needs. There is considerable variation in response between patients so careful titration is necessary. Care should be taken not to exceed the dose producing the desired therapeutic effect. It is usual to start with a single dose of 2mg increasing by 2mg increments at not less than half-weekly intervals.
The total daily dose should not exceed 36mg, although it is usually not necessary to exceed 24mg daily.

Elderly
Experience in the elderly is limited and use of tizanidine is not recommended unless the benefit of treatment clearly outweighs the risk. Pharmacokinetic data suggest that renal clearance in the elderly may be decreased by up to three folds.

Children
Experience with tizanidine in patients under the age of 18years is limited. **Movax**® (tizanidine) is not recommended for use in children.

Patients with Renal impairment
In patients with renal insufficiency (creatinine clearance <25mL/min) treatment should be started with 2mg once daily with slow titration to achieve the effective dose. Dosage increases should be in increments of no more than 2mg according to tolerability and effectiveness.
It is advisable to slowly increase the once-daily dose before increasing the frequency of administration. Renal function should be monitored as appropriate in these patients.

Patients with Hepatic Impairment
Movax®(tizanidine) is contraindicated in patients with significantly impaired hepatic function.

OR
As directed by the physician

CONTRAINDICATIONS:
Hypersensitivity to tizanidine or any other component of the product. The use of **Movax**®(tizanidine) in patients with significantly impaired hepatic function is contraindicated, because tizanidine is extensively metabolised by the liver.

PRECAUTIONS:
Use in Renal Impairment
Patients with renal impairment may require lower doses and therefore, caution should be exercised when using **Movax**® (tizanidine) in these patients.

Liver Function
Hepatic dysfunction has been reported in association with tizanidine. It is recommended that liver function tests should be monitored monthly for the first four months in all patients and in those who develop symptoms suggestive of liver dysfunction such as unexplained nausea, anorexia or tiredness. Treatment with Tizanidine should be discontinued if serum levels of SGPT and/or SGOT are persistently above three times the upper limit of normal range.

INTERACTIONS:
As **Movax**®(tizanidine) may induce hypotension it may potentiate the effect of antihypertensive drugs, including diuretics, and caution should therefore, be exercised in patients receiving blood pressure lowering drugs. Caution should also be exercised when **Movax**® (tizanidine) is used concurrently with ß-blocking drugs or digoxin as the combination may potentiate hypotension or bradycardia.
Caution should be exercised when **Movax**® (tizanidine) is prescribed with drugs known to increase the QT interval.
Alcohol or sedatives may enhance the sedative action of **Movax**® (tizanidine).

PREGNANCY & LACTATION:
Pregnancy Category C. The safety of **Movax**® (tizanidine) in pregnancy has not been established and its safety in breast-fed infants of mothers receiving **Movax**® (Tizanidine) is not known. Therefore, **Movax**® (tizanidine) should not be used in pregnant or nursing mothers unless the likely benefit clearly outweighs the risk.

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ADVERSE EFFECTS:
The most frequently reported adverse events occurring in association with **Movax**® (Tizanidine) include drowsiness, fatigue, dizziness, somnolence, dry mouth, nausea, gastrointestinal disturbances, muscle weakness, insomnia, sleep disorder, hypotension and a reduction in blood pressure. With slow upward titration of the dose of **Movax**® (Tizanidine) these effects are usually not severe enough to require discontinuation of treatment. Increase in hepatic serum transaminases, which are reversible on stopping treatment, have occurred. Infrequent cases of acute hepatitis have been reported. Muscle weakness has been reported infrequently, although in controlled clinical trials it was clearly demonstrated that **Movax**® (Tizanidine) does not adversely affect muscle strength. Allergic reactions (e.g. pruritus and rash) have rarely been reported.

OVER DOSE:
Symptoms: Nausea, vomiting, hypotension, dizziness, somnolence, miosis, restlessness, respiratory distress, coma.
Treatment: General supportive measures are indicated and an attempt should be made to remove uningested drug from the gastro-intestinal tract using gastric lavage or activated charcoal. The patient should be well hydrated. Further treatment should be symptomatic.

SHELF LIFE:
See expiry on the pack

AVAILABILITY:
Movax® 2mg tablet in a pack of 20's
Movax® 4mg tablet in a pack of 10's

INSTRUCTIONS:
Dosage: As advised by the physician.
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

موویکس ٹیبلٹ
(ٹیزانیڈین)

ہدایات:
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو گرمی، روشنی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

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F-95, S.I.T.E., Karachi-Pakistan
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