SPASFREE TABLETS

(Tizanidine Hydrochloride 2 mg)

COMPOSITION

Each Spasfree Tablet contains Tizanidine Hydrochloride equivalent to Tizanidine 2 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Tizanidine is a centrally acting alpha-2 adrenergic agonist that reduces skeletal muscle spasticity. It is believed to increase presynaptic inhibition of motor neurons, reducing excitatory input at spinal interneurons. Its action is relatively short, with greatest effect generally occurring within 1 to 2 hours after a dose and diminishing over the following hours.

INDICATIONS

For the management of spasticity in adults, including spasticity associated with neurological disorders, in accordance with locally approved indications. Because its effect is short-lived, dosing should be targeted to times when relief of spasticity is most needed.

DOSAGE AND ADMINISTRATION

For oral use. Treatment must be individualised by the prescriber. The usual starting dose is 2 mg; it may be repeated every 6 to 8 hours as needed, up to three doses in 24 hours. Depending on response and tolerability, each dose may be increased by 2 to 4 mg at intervals of 1 to 4 days. The maximum total daily dose is 36 mg. Single doses above 16 mg have not been studied.

DOSING PRECAUTIONS

Take consistently in relation to meals, since food may affect tizanidine exposure. Tablets and capsules are not necessarily interchangeable without reassessment. Do not exceed the prescribed dose or change the dosing schedule without medical advice.

DISCONTINUATION

Do not stop suddenly after prolonged or high-dose treatment. Dose reduction should be gradual under medical supervision to reduce the risk of rebound hypertension, fast heart rate and increased muscle tone. A gradual reduction of 2 to 4 mg per day may be considered when clinically appropriate.

RENAL & HEPATIC IMPAIRMENT

Use with caution in kidney impairment, especially creatinine clearance below 25 mL/min, and in any hepatic impairment. Lower individual doses during titration and monitor for adverse reactions. Monitoring of liver aminotransferases is recommended before treatment and about one month after reaching the maximum prescribed dose.

ELDERLY & PAEDIATRIC USE

Elderly patients may clear tizanidine more slowly and require cautious titration. Safety and effectiveness in paediatric patients have not been established.

CONTRAINDICATIONS

Hypersensitivity to tizanidine or any ingredient of the product. Concomitant use with potent CYP1A2 inhibitors, especially fluvoxamine or ciprofloxacin, is contraindicated because dangerously high tizanidine exposure may occur.

WARNINGS & PRECAUTIONS

Low blood pressure: Tizanidine may cause hypotension, dizziness, slow heart rate or fainting, especially when standing and when used with antihypertensive medicines. Monitor symptoms and blood pressure as indicated.

Liver injury: Liver enzyme elevations and serious liver injury can occur. Seek medical advice for unexplained fatigue, loss of appetite, nausea, dark urine or jaundice. Monitor liver function as directed.

Sedation: Drowsiness may impair driving, operating machinery or other hazardous activities. Alcohol, opioids and other sedatives can intensify this effect.

Hallucinations: Visual hallucinations or psychotic-like symptoms have been reported. Notify the prescriber if these occur.

Allergic reactions: Stop treatment and obtain urgent care for swelling of the face or throat, difficulty breathing, or serious allergic reactions.

DRUG INTERACTIONS

Do not combine with fluvoxamine or ciprofloxacin. Use caution with other CYP1A2 inhibitors, including certain fluoroquinolones, antiarrhythmics, cimetidine, famotidine, zileuton, acyclovir, ticlopidine and oral contraceptives. Interactions may increase sedation, hypotension or bradycardia.

Alcohol, opioids, benzodiazepines and other CNS depressants may produce additive sedation. Other alpha-2 agonists and medicines that lower blood pressure may increase hypotension. Tell the prescriber about all medicines being used.

PREGNANCY & LACTATION

Adequate human pregnancy data are limited; animal studies suggest possible fetal harm. Use during pregnancy only when the prescriber considers the expected benefit to outweigh potential risks. It is unknown whether tizanidine passes into human milk; discuss breastfeeding with the prescriber.

ADVERSE REACTIONS

Common adverse reactions include dry mouth, somnolence, tiredness or weakness, dizziness, constipation, nausea and low blood pressure. Less common or serious reactions may include marked hypotension, bradycardia, fainting, liver injury, hallucinations and hypersensitivity reactions. Seek urgent medical care for serious symptoms.

OVERDOSAGE

Overdose can cause profound drowsiness, confusion, hypotension, bradycardia, respiratory depression and coma. Seek emergency medical attention immediately. Management requires supportive treatment and monitoring of breathing, cardiovascular status and consciousness.

STORAGE CONDITIONS

Store protected from excessive heat and moisture in accordance with approved product specifications. Keep out of the reach of children. Do not use after the expiry date.

PRESENTATION

Spasfree Tablets 2 mg: pack of 10 tablets. For oral administration.

PATIENT ADVICE

Take only as prescribed. Avoid driving until you know how the medicine affects you. Rise slowly from sitting or lying positions. Avoid alcohol and do not discontinue abruptly after ongoing treatment. Inform your healthcare professional about all other medications.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.