

## TRINICALM FORTE

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

Abbreviated Prescribing information for TRINICALM FORTE (Trifluoperazine 5mg + Chlorpromazine 50 mg + Trihexiphenidyl (Benzhexol Hydrochloride) 2 mg Tablets.) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES** A piperazine, phenothiazine tranquiliser with potent anti-psychotic, anxiolytic and antiemetic activity. Chlorpromazine has depressant actions on the Central Nervous System, with alpha-adrenergic blocking and anticholinergic activities. It inhibits Dopamine and Prolactin release-inhibitory factor, thus stimulating the release of Prolactin. It increases the turnover of Dopamine in the brain. Benzhexol hydrochloride resembles atropine in its peripheral actions on autonomic effector cells, having an inhibitory effect on the parasympathetic nervous system. **INDICATION:** Trinicalm Forte is indicated for the management of schizophrenia in adults.

**DOSAGE AND ADMINISTRATION:** Trinicalm forte must be taken as directed by physician and for oral use.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients. Do not use trifluoperazine in comatose patients, particularly if associated with other central nervous system depressants. Do not use in those with existing blood dyscrasias or known liver damage. Patients with uncontrolled cardiac decompensation should not be given trifluoperazine, Hypothyroidism, Bone marrow depression, Pheochromocytoma, Myasthenia gravis, Risk of angle-closure glaucoma, Risk of urinary retention related to urethroprostatic disorders, History of agranulocytosis, Dopaminergic antiparkinsonism agents, Nursing mothers, Citalopram, escitalopram.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**WARNINGS & PRECAUTIONS:** Trifluoperazine should be discontinued as the first sign of clinical symptoms of tardive dyskinesia and Neuroleptic Malignant Syndrome. Risk of acute withdrawal symptoms, venous thromboembolism (VTE), increased mortality in elderly people with dementia. Benzhexol should not be withdrawn abruptly in patients on long-term therapy, to avoid recurrence of the original symptoms and possible anticholinergic rebound. Drug should be avoided or used with great caution in patients with myasthenia gravis. Chlorpromazine should be used with caution in patients with cardiovascular disease and risk of agranulocytosis, retinopathy, intestinal pseudo-obstruction, fatal hyperthermia and heat stroke. Signs of overdose of toxic drugs may be masked which obscure conditions such as intestinal obstruction and brain tumor. Exercise caution while use in patients with impaired liver function or alcoholic liver disease. **DRUG INTERACTIONS:** Interacts with CNS depressants (such as alcohol, hypnotics, anaesthetics and strong analgesics), antihypertensives, anticholinergics, antidepressants, levodopa, lithium, desferrioxamine, anticoagulants, antacids, Monoamine oxidase inhibitors (MAOI's), antihistamines, disopyramide, phenothiazines, tricyclic antidepressants, amphetamines, Antacids, epinephrine and hypotensive agents when used concomitantly. **ADVERSE REACTIONS:** Trifluoperazine: Lassitude, drowsiness, dizziness, transient restlessness, insomnia, dry mouth, blurred vision, muscular weakness, anorexia, mild postural hypotension, skin reactions including photosensitivity reactions, weight gain, oedema, hyperprolactinaemia, ECG changes, extrapyramidal symptoms, cholestatic jaundice, blood dyscrasias such as agranulocytosis, pancytopenia, leucopenia and thrombocytopenia and confusion may occasionally occur. Tachycardia, constipation, urinary hesitancy and retention, and hyperpyrexia have been reported very rarely. Benzhexol Hydrochloride: Dizziness, mild nausea or nervousness. Potential side-effects associated with the use of any atropine-like drugs include constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilation of the pupil, increased intra-ocular tension, weakness, and headache. Tachycardia may result from

vagal inhibition and induce angina of effort in patients with coronary heart disease. Chlorpromazine: strong sedative, hypotensive and anticholinergic properties and mild to moderate extrapyramidal effects. Urinary retention, priapism, inhibition of ejaculation, photosensitivity, paralytic ileus, Cholestatic jaundice, various dermatoses, blood dyscrasias, photosensitivity, anaphylactoid reaction, sudden death peculiar skin-eye syndrome and Neuroleptic Malignant Syndrome.

**MARKETED BY:**



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**IN/ TRINICALM FORTE/5, 50, 2mg/ May 2022/02/AbPI**

(Additional information is available on request)