TRINICALM PLUS

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

Abbreviated Prescribing information for TRINICALM PLUS (Trifluoperazine 5mg and Benzhexol Hydrochloride 2 mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Trifluoperazine is a potent anti-psychotic, anxiolytic and antiemetic agent. It has fairly pronounced tendency to cause extrapyramidal reactions. Benzhexol hydrochloride is a centrally acting anticholinergic drug.

INDICATION: Treatment of symptoms and prevention of relapse in schizophrenia and in other psychoses, especially of the paranoid type, but not in depressive psychoses. Also as an adjunct in the short-term management of severe psychomotor agitation and of dangerously impulsive behaviour in, for example, mental subnormality.

DOSAGE AND ADMINISTRATION: Dosage: Adults-The recommended starting dose for physically fit adults is one tablet of Trinicalm plus twice a day; after a week dose may be increased. When satisfactory control has been achieved, dosage should be reduced gradually until an effective maintenance level has been established. Gradual withdrawal from high-dosage treatment is advisable.

CONTRAINDICATION: In patients with comatose condition, existing blood dyscrasias or known liver damage, uncontrolled cardiac decompensation, closed-angle glaucoma or narrow angle between the iris and cornea, paralytic ileus, and hypersensitivity to Trinicalm plus, related compounds, or any of the excipients.

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 Benzhexol should not be withdrawn abruptly in patients on long-term therapy, to avoid recurrence of the original symptoms and possible anticholinergic rebound.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. **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 and tricyclic antidepressants 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 occur occasionally. Tachycardia, constipation, urinary hesitancy and retention, and hyperpyrexia have been reported very rarely. Benzhexol Hydrochloride: Dizziness, mild nausea or nervousness may be experienced by 30 to 50 per cent of patients on benzhexol. 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.

MARKETED BY:

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(Additional information is available on request)