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Stemetil®

Prochlorperazine Maleate Tablet BP
Prochlorperazine Mesylate Injection BP

50027

Presentation
Stemetil tablet : Off-white to cream uncoated tablets, each containing Prochlorperazine Maleate BP 5mg. The tablets are impressed "STEMETIL 5" on one face, reverse plain. Tablets contain lactose.
Stemetil injection : Colorless solution containing Prochlorperazine Mesylate BP 12.5 mg per ml in ampoules of 1ml. The injection solution also contains sodium sulphite, sodium metabisulphite, sodium chloride and ethanolamine.

Uses
Stemetil is a potent phenothiazine neuroleptic. It is used in vertigo due to Meniere's syndrome, labyrinthitis and for nausea and vomiting from whatever cause including that associated with migraine, schizophrenia (particularly in the chronic stage), acute mania and as an adjunct to the short term management of anxiety.

Dosage and administration
Oral Administration :
Adults :

Indication	Dosage
Prevention of nausea and vomiting	5 to 10mg b.d or t.d.s
Treatment of nausea and vomiting	20mg start followed if necessary by 10mg two hours later.
Vertigo and Meniere's syndrome	5mg t.d.s increasing if necessary to a total of 30mg daily. After several weeks dosage may be reduced gradually to 5-10mg daily.
Adjunct in the short-term management of anxiety	15-20mg daily in divided doses initialy but this may be increased if necessary to a maximum of 40mg daily in divided doses
Schizophrenia and other psychotic disorders	Usual effective daily oral dosage is in the order of 75-100mg daily. Patients vary widely in response. The following schedule is suggested : Initially 12.5mg twice daily for 7 days, the daily amount being subsequently increased by 12.5mg at four to seven days intervals until a satisfactory response is obtained. After some weeks at the effective dosage, an attempt should be made to reduce this dosage. Total daily amounts as small as 50mg or even 25mg have some times been found to be effective.

Intramascular Administration :
Adults :

Indication	Dosage
Treatment of nausea and vomiting	12.5mg by deep i.m. injection followed by oral medication six hours later if necessary.
Schizophrenia and other psychotic disorders	12.5mg to 25mg two or three times a day by deep i.m. injection until oral treatment becomes possible.

Children's Dosage : Oral route only :

Indication	Dosage
Prevention and treatment of nausea and vomiting	If it is considered unavoidable to use Stemetil for a child the dosage is 250 micrograms/kg body weight two or three times a day. Stemetil is not recommended for children weighing less than 10kg.

Intramascular Stemetil should not be given to children

Elderly : Stemetil should be used cautiously in this group in psychotic disorders. Elderly patients are susceptible to centrally acting drug hence lower initial dosage is recommended.

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Contra-indications, warnings, etc.
Pregnancy : Stemetil is contra-indicated in pregnancy. There is inadequate evidence of the safety of Stemetil in human pregnancy but it has been widely used for many years without apparent ill consequence. Phenothiazines may be excreted into milk, breast feeding should be suspended during treatment.

Precaution
Stemetil should be avoided in patients with liver or renal dysfunction, epilepsy Parkinson's disease, hypothyroidism, phaeochromocytoma, myasthenia gravis, prostate hypertrophy, It should be avoided in patient known to be hypersensitive to phenothiazines or with a history of narrow angle glaucoma.
Patients should be warned about drowsiness during the early days of treatment and advised not to drive or operate machinery.

Interaction of phenothiazine neuroleptics
The CNS depressant actions of neuroleptic agent may be intensified (additively) by alcohol barbiturates and other sedatives. Respiratory depression may occur.
The hypotensive effect of alpha adrenoceptor blocking agents may be exaggerated by neuroleptics.
The action of some drugs may be opposed by phenothiazine neuroleptics; these include amphetamine, levodopa, clonidine, guanethidine, adrenaline.
Anticholinergic agents may reduce the antipsychotic effect of neuroleptics.
Some drugs interfere with absorption of neuroleptic agents : antacids, anti-parkinson lithium.
Increases or decreases in the plasma concentrations of a number of drugs, e.g. propanolol, phenobarbitone have been observed but were not of clinical significance.
High doses of neuroleptics reduce the response to hypoglycaemic agents the dosage of which might have to be raised.
Most of the above interaction are of a theoretical nature and not dangerous.
Simultaneous administrations of desferrioxamine and prochlorperazine has been observed to induce a transient metabolic encephalopathy.

Adverse effects of neuroleptics :
Jaundice, usually transient, occours in a very small percentage of patients taking neuroleptics.
Hypotension usually postural commonly occurs.
Cardiac arrhythmias, including atrial arrhythmia, A-V block, ventricular tachycardia and fibrillation have been reported during neuroleptic therapy possibly related to dosage.
Blood picture : A mild leukopenia occurs in up to 30% of patients on prolonged high dosage. Agranulocytosis may occur rarely.
Acute dystonias or dyskinesias, usually transitory are commoner in children and young adults.
Parkinsonism is commoner in adults and the elderly.
Tardive dyskinesia : If this occurs it is usually but not necessarily after prolonged or high dosage.
Skin and eyes : Patients on high dosage should be warned that they may develop photosensitivity in sunny weather and should avoid exposure to direct sunlight.
Endocrine : hyperprolactinaemia
Neuroleptic malignant syndrome may occur with any neuroleptic.

Toxicity and treatment of overdosage
Symptoms of phenothiazine overdosage include drowsiness or loss of conciousness hypotension, tachycardia E.C.G changes, ventricular arrhythmias and hypothermia, Severe extra pyramidal dyskinesias may occur. If the patients is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose gastric lavage may be attempted. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

Pharmaceutical precautions
Protect from light. Stemetil injection repidly discolours on exposure to light : any such solution should be discarded.

Package quantities
Stemetil Tablet (Export): Box of 25 × 20 × 5mg in blister packs
Stemetil Tablet (Trade): Box of 15 × 2 × 20 × 5mg in blister packs
Stemetil Injection: Box of 10 × 1ml ampoules
Do not use later than the date of expiry
Keep all medicines out of the reach of children
To be dispensed only on the prescription of a registered physician

Manufactured by:
synovia
Synovia Pharma PLC., Station Road, Tongi, Gazipur.
Under License From **Sanofi, France.**
544232

Direction Slip artwork legend

Product Name	:	Stemetil
Code number	:	544232
CCDS Version	:	00
Dimension	:	L 9.37 x W 4.44 inches
Min. size of text	:	8 pt
Used Colors	:	Black Red