Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stemetil 12.5 mg/ml solution for injection - 1 ml Ampoule

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 12.5 mg of Prochlorperazine Mesilate.
Excipients: Also includes anhydrous sodium sulfite (E221) 1.0 mg per 1ml; sodium metabisulphite (E223) 0.75 mg per 1ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection.

A clear, bright solution, almost colourless or not more than very pale yellow, contained in a printed ring coded ampoule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Stemetil injections are recommended in the management of acute vertigo such as is associated with Meniere's syndrome, nausea and vomiting, migraine and anxiety states. The course of treatment should not normally exceed 2 weeks duration.

In the management of phobias, schizophrenia, acute mania, and similar psychotic reactions.

4.2 Posology and method of administration

Intramuscular

Recommended Dosage:

Adults:
For the management of migrane or nausea and vomiting: -
The usual total daily dosage is 12.5 mg followed by oral dosage 6 hours later if required.

In schizophrenia and other psychotic disorders:
The usual total daily dosage is 25-75mg in divided doses.

Elderly:
Stemetil should be used cautiously in the elderly owing to their susceptibility to drugs acting centrally on the nervous system. There is an increased risk of drug-induced Parkinsonism in the elderly particularly after prolonged use therefore a lower initial dosage is recommended. If required, dosage adjustment is recommended in this population (see section 4.4). Care should also be taken not to confuse the adverse effects of Stemetil, e.g. orthostatic hypotension, with effects due to the underlying disorder.

Children: Not recommended for use in children.

4.3 Contraindications

Use in patients with a known hypersensitivity to prochlorperazine or other Phenothiazines or to any of the other ingredients.
Use in patients with impaired liver function.
The use of prochlorperazine injection is contra-indicated in children as it has been associated with dystonic reactions after the cumulative dose of 0.5 mg/kg.

4.4 Special warnings and precautions for use

Stemetil should be avoided in patients with hepatic or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, phaeochromocytoma, myasthenia gravis, prostate hypertrophy. It should be avoided in patients with a history of narrow angle glaucoma or agranulocytosis.

Combination with alcohol should be avoided.

Hypersensitivity reactions
Hypersensitivity reactions including anaphylaxis, urticaria and angioedema have been reported with Stemetil use. In case of allergic reactions, treatment with Stemetil must be discontinued and appropriate symptomatic treatment initiated (see section 4.8).

Close monitoring is required in patients with epilepsy or a history of seizures, as phenothiazines may lower the seizure threshold.

Patients receiving phenothiazines over a prolonged period require regular and careful surveillance with particular attention to potential for inducing eye changes, liver dysfunction, myocardial conduction effects, particularly if other concurrently administered drugs also have potential effects on these systems.

Agranulocytosis neutropenia, and leukopenia have been reported with all phenothiazines. Regular monitoring of the complete blood count is recommended. The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8) and requires immediate haematological investigation. Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia should discontinue treatment and have their White Blood Cells (WBCs) followed until recovery.

Neuroleptic Malignant Syndrome:
With onset of a high fever, the possibility of neuroleptic malignant syndrome (NMS) must be considered. Other clinical manifestations of NMS are pallor, hyperthermia, autonomic dysfunction, altered consciousness, muscle rigidity. Treatment with prochlorperazine should be discontinued immediately and appropriate medical measures should be administered.

Signs of autonomic dysfunction, such as sweating and blood pressure instability, may precede the onset of hyperthermia and serve as early warning signs. Although neuroleptic malignant syndrome may be idiosyncratic in origin, dehydration and organic brain disease are predisposing factors.

Acute withdrawal symptoms, including nausea, vomiting, headaches, anxiety, agitation, dyskinesia, dystonia, disturbed temperature regulation and insomnia, have very rarely been reported following the abrupt cessation of high doses of neuroleptics. Relapse may also occur, and the emergence of extrapyramidal reactions has been reported. Therefore, gradual withdrawal is advisable. Symptoms of withdrawal can occur following treatment at any dose. Withdrawal of treatment should occur under close medical supervision.

There is a risk of a respiratory depressant effects in patients with COPD or when administered with other medications with a CNS depressant effect (see section 4.5 and 4.8).

Patients treated with prochlorperazine for chronic mental illness should receive regular ocular examinations. Ocular changes and Pigmentation disorders (the development of metallic greyish-mauve coloration of exposed skin) have been noted in some individuals mainly females, who have received phenothiazines including chlorpromazine continuously for long periods (4 to 8 years). This could possibly happen with Stemetil (see section 4.8).

Contact skin sensitisation may occur rarely in those frequently handling preparations of certain phenothiazines. Skin rashes of various kinds may also be seen in patients treated with the drug.
Patients on high dosage should be warned that they may develop photosensitivity in sunny weather and should avoid exposure to direct sunlight.

It should be used with caution in the elderly, particularly during very hot or very cold weather (risk of hyper-, hypothermia).

Elderly or volume depleted subjects are particularly susceptible to postural hypotension, sedation and extrapyramidal side effects (see section 4.8).

Stemetil should be used cautiously in the elderly owing to their susceptibility to drugs acting on the central nervous system and a lower initial dosage is recommended. There is an increased risk of drug-induced Parkinsonism particularly after prolonged use. This is likely to be particularly severe in the elderly and children.Care should also be taken not to confuse the adverse effects of Stemetil, e.g. orthostatic hypotension, with the effects due to the underlying disorder.

Postural hypotension with tachycardia as well as local pain or nodule formation may occur after i.m. administration.

Prolonged administration of any phenothiazine may result in persistent or tardive dyskinesias, particularly in the elderly and children.

Phenothiazines should only be used with great caution in patients with coronary insufficiency, cardiovascular disorders which may predispose to prolongation of the QT interval.

As with other neuroleptics, very rare cases of QT interval prolongation have been reported with Stemetil, increasing the risk of onset of serious ventricular arrhythmias (e.g. torsade de pointes) and sudden death.

Cases of QT prolongation, possibly dose related have been reported with neuroleptic drugs. This effect can increase the risk of serious ventricular disorders such as torsade de pointes. As a precaution before administration of Prochlorperazine, it is recommended, if possible, to eliminate the risk factors for cardiac rhythm disturbances:

- Brachycardia <55 beats/minute
- Hypokalemia
- Congenital or acquired QT prolongation
- Ongoing treatments with drugs which can result in brachycardia (<55 beats/minute), hypokalemia, slowed intracardiac conduction, QT prolongation (see section 4.5 interactions).

It is recommended that an ECG be performed as part of the initial evaluation of patients due to receive treatment with a neuroleptic drug and periodically during treatment as clinically indicated.

Pre-existing cardiac disease, old age, hypokalaemia and concurrent tricyclic antidepressants may predispose to cardiac arrhythmias.

There have been isolated reports of sudden death, with possible causes of cardiac origin, as well as cases of unexplained sudden death, in patients receiving neuroleptic phenothiazines (see section 4.8).

This medicinal product contains less than 1 mmol of sodium (23 mg) per 1 ml ampoule, that is to say essentially 'sodium-free'.

Hyperglycaemia or intolerance to glucose has been reported in patients treated with Stemetil. Screening for diabetes is recommended before starting or when treatment is changed. Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes who are started on Stemetil, should get appropriate gylcaemic monitoring during treatment (see section 4.8). Regular testing is recommended to identify patients who develop diabetes after starting treatment.

Stroke: In randomized clinical trials versus placebo performed in a population of elderly patients with dementia and treated with certain atypical antipsychotic drugs, a 3-fold increase of the risk of cerebrovascular events has been observed. The mechanism of such risk increase is not known. An increase in the risk with other antipsychotic drugs or other populations of patients cannot be excluded. Stemetil should be used with caution in patients with stroke risk factors.

Increased Mortality in Elderly Patients with Dementia

Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known.

Although the causes of death in clinical trials with atypical antipsychotics were varied, most of the deaths appeared to be either cardiovascular (e.g. heart failure, sudden death) or infectious (e.g. pneumonia) in nature (see section 4.8).

Stemetil is not licensed for the treatment of dementia-related behavioural disturbances.

Priapism has been reported in patients treated with Stemetil. Patients who develop abnormally sustained or frequent and painful erections should be advised to seek immediate medical attention (see section 4.8).

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Stemetil and preventative measures undertaken.

Jaundice occurs in a very small percentage of patients treated with neuroleptics. It has normally been reversible on stopping the drug, but extremely rare cases of progressive liver disease have been reported. In most cases the jaundice has appeared between one to four weeks after the start of the treatment.

Prodromal symptoms of fever chills, malaise, fatigue, myalgias, arthralgias, gastrointestinal complaints and pruritis have preceded jaundice by an average of 7-10 days.

Neuroleptic jaundice has the biochemical and other characteristics of obstructive jaundice and is associated with obstruction of the canaliculi by bile thrombi: The hepatotoxic effect of phenothiazines is not completely understood but may involve a combination of physiochemical, immune, and direct toxic effects. Transient abnormalities of liver function tests may occur in the absence of jaundice. Treatment should be withheld on the development of jaundice (see section 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

QT prolonging drugs
There is an increased risk of arrhythmias when antipsychotics are used with concomitant QT prolonging drugs, and drugs causing electrolyte imbalance (see section 4.4):

- Bradycardia-inducing medications such as beta-blockers, bradycardia-inducing calcium channel blockers such as diltiazem and verapamil, clonidine; digitalis.
- Medications which induce electrolyte imbalance, in particular those causing hypokalaemia (such as hypokalaemic diuretics, stimulant laxatives, IV amphotericin B , glucocorticoids, tetracosactides). Electrolyte imbalance should be corrected.
- Class Ia antiarrhythmic agents such as quinidine, disopyramide.
- Class III antiarrhythmic agents such as amiodarone, sotalol.
- Other medications such as pimozide, sultopride, haloperidol, imipramine antidepressants, lithium, cisapride, thioridazine, IV erythromycin, IV vincamine, halofantrine, pentamidine, sparfloxacin.

Adrenaline

The use of adrenaline should be avoided in the treatment of hypotension for patients treated with Stemetil because of the possibility of a paradoxical further lowering of blood pressure.
Adrenaline must not be used in patients overdosed with Stemetil (see section 4.9).

CNS depressants

The CNS depressant actions of prochlorperazine may be intensified (additively) by alcohol, barbiturates and other sedatives. Respiratory depression, dizziness and sedation may occur (see section 4.4 and 4.7). Patients should be advised not to consume alcohol and alcohol-containing drugs throughout treatment. Additive adverse effects may also occur in patients treated with monoamine oxidase inhibitors, antidepressants (i.e. SSRIs, SNRIs, tricyclic antidepressants) and analgesics (i.e. opiates).

Drug combinations requiring precautions:

Phenothiazines are potent inhibitors of CYP2D6. There is a possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines, and CYP2D6 substrates. Co-administration of prochlorperazine with a tricyclic antidepressant (TCA) such as amitriptyline/amitriptylinoxide, a CYP2D6 substrate, may result in elevated plasma concentrations of one or both drugs as well as additive adverse effects. Increased risk of serious adverse effects such as tardive dyskinesia, prolongation of the QT interval and excessive anticholinergic effects have been reported. Patients should be monitored for dose-dependent adverse reactions (see section 4.8).

Anticholinergic agents may reduce the antipsychotic effect of neuroleptics and the mild anticholinergic effect of neuroleptics may be enhanced by other anticholinergic drugs, possibly leading to blurred vision, dry mouth, constipation, heat stroke, urinary retention and altered mental status (delirium, hallucinations, agitation, restlessness). Occasionally serious or life-threatening interactions have been reported.

Antacids interfere with absorption of neuroleptic agents.

Lithium: Severe neurotoxicity has been reported in patients treated with lithium plus a phenothiazine. In some cases this has been irreversible. Lithium toxicity in combination with phenothiazines may increase the risk of neuroleptic malignant syndrome. Patients receiving such combined therapy should be monitored closely for early evidence of neurologic toxicity and treatment discontinued promptly if such signs appear.

The action of some drugs may be opposed by phenothiazine neuroleptics: *Amphetamine:* The appetite suppressant and other effects of amphetamines, are opposed by phenothiazine neuroleptics.

Dopaminergic anti-Parkinson's agents (e.g. levodopa): Prochlorperazine may reduce the effectiveness of dopaminergic anti-Parkinson treatments. Concomitant use of dopaminergic drugs with anti-dopaminergic agents should generally be avoided as this can result in extrapyramidal reactions and exacerbation of the symptoms of Parkinson's disease. Anticholinergic anti-Parkinsonian agents should be used in preference to dopaminergic agents (e.g. levodopa) for treatment of phenothiazine induced extrapyramidal symptoms.

Guanethidine: Phenothiazines may inhibit the antihypertensive effect of guanethidine, through inhibition of guanethidine neuronal uptake.

Antidiabetic agents

Treatment with phenothiazines can impact on blood glucose control and reduce the response to diabetic medications. Blood glucose levels of diabetic patients should be monitored especially during the starting and stopping of antipsychotic therapy and dosage adjustments of antidiabetic drugs made as necessary (see section 4.4).

The hypotensive effect of most antihypertensive drugs especially alpha adrenoceptor blocking agents may be exaggerated by neuroleptics.

Increases or decreases in the plasma concentrations of a number of drugs, e.g. propranolol has been observed but were not of clinical significance.

Concomitant use of phenothiazines with barbiturates may reduce the plasma concentrations and therapeutic effects of both agents

Desferrioxamine

Simultaneous administration of prochlorperazine and desferrioxamine has been observed to induce a transient metabolic encephalopathy characterised by loss of consciousness for 48-72 hours.

Myelosuppressive drugs
There is an increased risk of agranulocytosis when neuroleptics are used concurrently with drugs with myelosuppressive potential, such as carbamazepine or certain antibiotics and cytotoxics.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of Stemetil in pregnant women and there is inadequate evidence of safety in pregnancy. Available data from animal studies are insufficient to determine the reproductive toxicity. Use of Stemetil in pregnancy is not recommended except in cases where in the judgment of the physician, drug intervention is required and potential benefits outweigh possible risks. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with Stemetil.

Neonates exposed to antipsychotics (including Stemetil) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. Consequently, newborns should be monitored carefully in order to plan appropriate treatment (see section 4.8).

Lactation
Phenothiazines may be excreted in milk, therefore breast feeding should be suspended during treatment.

Fertility
No human or animal data on the effect of Stemetil on fertility are available.

4.7 Effects on ability to drive and use machines

Stemetil has moderate influence on the ability to drive and use machines.
It may cause drowsiness, blurred vision, dizziness therefore the product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety. Therefore, patients should be advised not to drive or operate machinery until their individual susceptibility is known. In addition, anticholinergic effects in the eye (accommodation disturbances, mydriasis) impair the ability to react.

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable:
Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%;
Rare ≥ 0.01 and < 0.1%; Very rare < 0.01%; Not known (cannot be estimated from available data).

MedDRA System Organ Class	**Frequency**	**Undesirable effect**
Immune systems disorders	Not known	Anaphylactic reaction, Type I hypersensitivity reactions such asangioedema and, urticaria ~~and anaphylactic reactions~~
Blood and lymphatic system disorders	Not known	Agranulocytosis and leukopenia, thrombocytopenia (including thrombocytopenic purpura), eosinophilia (see section 4.4)
Endocrine disorders	Not known	Hyperprolactinaemia which may result in galactorrhoea, gynaecomastia, amenorrhoea and impotence.
Reproductive system and breast disorders	Not known	Priapism Ejaculation disorder Erectile dysfunction
Metabolism and nutrition disorders	Not known	Hyponatraemia Syndrome of inappropriate antidiuretic hormone secretion (SIADH) Hyperglycaemia or impaired glucose tolerance (see section 4.4)
Nervous system disorders	Common	Extrapyramidal effects*:

		• Dystonia or dyskinesias, usually transitory, are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases. • Parkinsonism is more common in adults and the elderly. It usually develops after weeks or months of treatment. One or more of the following may be seen: tremor, rigidity, akinesia or other features of Parkinsonism (commonly just tremor).
	Not known	Akathisia. Tardive dyskinesia* Insomnia Agitation Seizure Dizziness Somnolence
Eye disorders	Not known	Corneal deposits, cataract and retinopathy Accommodation disorder
Cardiac disorders	Not known	Arrhythmias, including ventricular arrhythmias such as torsade de pointes and Arrhythmia supraventricular, A-V block, ventricular tachycardia, which may result in ventricular fibrillation or cardiac arrest Sudden death
Investigations	Not known	Electrocardiogram abnormalities, usually benign, include: • ECG QT prolonged* • ECG ST segment depression • ECG U-Wave abnormality • ECG abnormal T-Wave (see section 4.4)
Vascular disorders	Common	Hypotension, usually orthostatic
	Not known	Embolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs (see section 4.4)
Gastrointestinal disorders	Not known	Anticholinergic effects such as dry mouth, constipation, Ileus paralytic
Renal and urinary disorders	Not known	Risk of urinary retention
Respiratory, thoracic and mediastinal disorders	Not known	Respiratory depression Nasal congestion
Hepatobiliary disorders	Not known	Cholestatic jaundice Abnormal liver function test
Skin and subcutaneous tissue disorders	Rare	Skin sensitisation
	Not known	Pigmentation disorder (the development of metallic greyish-mauve colouration of exposed skin) Photosensitivity Rash
General disorders and administration site conditions	Not known	Pain and injection site nodule Withdrawal syndrome Neuroleptic malignant syndrome* Hypothermia and hyperthermia (impaired thermoregulation)

***Description of selected adverse reactions**

- **Neuroleptic malignant syndrome (NMS):** Neuroleptic malignant syndrome (NMS): Neuroleptic malignant syndrome has been reported as an effect of neuroleptic medications and can be fatal. It is characterised by fever, altered mental status, muscle rigidity, and autonomic dysfunction. (See section 4.4).

- **Electrocardiogram QT Prolongation:** Neuroleptic phenothiazines including prochlorperazine may cause QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias in particular torsade de pointes (TdP): (sSee section 4.4 and 4.5).

- **Tardive dyskinesia:** It manifests as involuntary movements affecting orofacial and tongue muscles, and less commonly the truncal region and extremities). If this occurs it is usually, but not necessarily, after prolonged or high dosage. It can even occur after treatment has been stopped. Dosage should therefore be kept low whenever possible.

- **Extrapyramidal effects**: There have been reports of extrapyramidal effects including acute dystonia, akathisia and parkinsonism following treatment with neuroleptic phenothiazines such as prochlorperazine: (sSee section 4.4).

Other special population(s)
Paediatric population: Symptoms of neonatal withdrawal (see section 4.6).
The following symptoms may occur in neonates exposed to Stemetil during the third trimester of pregnancy: tremor, musculoskeletal stiffness and/or asthenia, somnolence, agitation, respiratory disorder, bradycardia, tachycardia, abdominal distension, constipation and feeding disorder.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Symptoms of phenothiazine overdosage include drowsiness or loss of consciousness, coma, convulsions, mydriasis, cardiovascular symptoms (related to risk of QT interval prolongation), such as hypotension, ventricular tachycardia, ECG changes, ventricular arrhythmias, respiratory depression and hypothermia. Anticholinergic syndrome causing flushing, dry skin, mydriasis, altered mental state and fever can occur. Severe extrapyramidal symptoms including Parkinsonian syndrome may occur.

If the patient is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose, gastric lavage may be attempted. Pharmacological induction of emesis is unlikely to be of any use. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

Generalised vasodilatation may result in circulatory collapse; raising the patient's legs may suffice. In severe cases, volume expansion by intravenous fluids may be needed; infusion fluids should be warmed before administration in order not to aggravate hypothermia.

Positive inotropic agents such as dopamine may be tried if fluid replacement is insufficient to correct the circulatory collapse. Peripheral vasoconstrictor agents are not generally recommended. Avoid the use of adrenaline.

Ventricular or supraventricular tachy-arrhythmias usually respond to restoration of normal body temperature and correction of circulatory or metabolic disturbances. If persistent or life threatening, appropriate anti-arrhythmic therapy may be considered. Avoid lignocaine and, as far as possible, long-acting anti-arrhythmic drugs.

Pronounced central nervous system depression requires airway maintenance or, in extreme circumstances, assisted respiration. Severe dystonic reactions usually respond to procyclidine (5-10 mg) or orphenadrine (20-40 mg) administered intramuscularly or intravenously. Convulsions should be treated with intravenous diazepam.

Neuroleptic malignant syndrome should be treated with cooling. Dantrolene sodium may be tried.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Phenothiazines with piperazine structure. ATC code: N05AB04

Stemetil is a potent phenothiazine neuroleptic.

5.2 Pharmacokinetic properties

Potent phenothiazine neuroleptic with anti-emetic properties with an elimination t½ of approximately 6-12 hours depending on the route and formulation.

The rate of metabolism and excretion of phenothiazines decreases in old age.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Sodium sulphite (E221)
Sodium metabisulphite (E223)
Sodium chloride
Ethanolamine
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep ampoule in the outer carton.
After opening the ampoule, the solution should be used immediately.
Any solution remaining should be discarded. Discoloured solution should not be used.

6.5 Nature and contents of container

Injection solution of 1.25% w/v in boxes of 10 x 1 ml ampoules. The ampoules are white (clear) Type I glass, DIN form D, 1 ml or 2ml nominal capacity.

6.6 Special precautions for disposal and other handling

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

7 MARKETING AUTHORISATION HOLDER

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