

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

'Stelazine Forte' Oral Solution 1mg/1ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains 1 mg trifluoperazine present as the hydrochloride.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral solution
Yellow oral solution with a peach odour and flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Low dosage 'Stelazine Forte' is indicated as an adjunct in the short-term management of anxiety states, depressive symptoms secondary to anxiety, and agitation. Orally it is also indicated in the symptomatic treatment of nausea and vomiting.

High dosage 'Stelazine Forte' is indicated for the treatment of symptoms and prevention of relapse in schizophrenia and in other psychoses, especially of paranoid type, but not in depressive psychoses. It may also be used as an adjunct in the short-term management of severe psychomotor agitation and of dangerously impulsive behaviour in, for example mental subnormality.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults

Low-dosage 2-4 mg (2-4ml) a day given in divided doses, according to the severity of the patient's condition. If necessary, dosage may be increased to 6mg (6ml) a day, but above this level extrapyramidal symptoms are more likely to occur in some patients

High-dosage The recommended starting dose for physically fit adults is 5 mg(5ml) twice a day, after a week this may be increased to 15 mg(15ml) a day. If necessary, further increases of 5 mg (5ml) may be made at three-day intervals, but not more often. When satisfactory control has been achieved, dosage should be reduced gradually, until an effective maintenance level has been established.

As with all major tranquillisers, clinical improvement may not be evident for several weeks after starting treatment, and there may be delay before recurrence of symptoms after stopping treatment. Gradual withdrawal from high dosage treatment is advisable.

Children

Low-dosage: For children aged 3-5 years, up to 1 mg (*1ml*) a day given in divided doses. For children aged 6-12 years, the dosage may be increased to a maximum of 4 mg (*4ml*) a day

High-dosage: For children aged under 12 years, the initial oral dosage should not exceed 5 mg (*5ml*) a day, given in divided doses. Any subsequent increase should be made with caution at intervals of not less than three days, and taking into account age, body weight and severity of symptoms.

Elderly

Reduce starting dose in elderly or frail patients by at least half

Administration

Oral.

4.3 Contra-indications

Do not use 'Stelazine Forte' in comatose patients, particularly if associated with other central nervous system depressants. Do not use 'Stelazine Forte' in those with existing blood dyscrasias or known liver damage, or in those hypersensitive to the active ingredient or related compounds. Patients with uncontrolled cardiac decompensation should not be given 'Stelazine Forte'.

4.4 Special warnings and special precautions for use

'Stelazine Forte' should be discontinued at the first sign of clinical symptoms of tardive dyskinesia and Neuroleptic Malignant Syndrome.

Care should be taken when treating elderly patients, and initial dosage should be reduced. Such patients can be especially sensitive, particularly to extrapyramidal and hypotensive effects. Patients with cardiovascular disease including arrhythmias should also be treated with caution. Because 'Stelazine Forte' may increase activity, care should be taken in patients with angina pectoris. If an increase in pain is noted, the drug should be discontinued. Patients who have demonstrated bone marrow suppression or jaundice with a phenothiazine should not be re-exposed to 'Stelazine Forte' (or any trifluoperazine) unless in the judgement of the physician the potential benefits of treatment outweigh the possible hazard.

In patients with Parkinson's disease, symptoms may be worsened, and the effects of levodopa reversed. Since phenothiazines may lower the convulsive threshold, patients with epilepsy should be treated with caution. Although 'Stelazine Forte' has minimal anticholinergic activity, this should be borne in mind when treating patients with narrow angle glaucoma, myasthenia gravis or prostatic hypertrophy.

Nausea and vomiting as a sign of organic disease may be masked by the anti-emetic action of 'Stelazine Forte'.

4.5 Interaction with other medicaments and other forms of interaction

Potential may occur if antipsychotic drugs are combined with CNS depressants such as alcohol, hypnotics, anaesthetics and strong analgesics, or with antihypertensives or other drugs with hypotensive activity, anticholinergics or antidepressants. Phenothiazines may antagonise the action of guanethidine, avoid drugs that depress leucopoiesis.

Desferrioxamine should not be used in combination with 'Stelazine Forte', since prolonged unconsciousness has occurred after combination with the related prochlorperazine.

Trifluoperazine may diminish the effect of oral anticoagulants.

Phenothiazines should be used with care in extremes of temperature since they may affect body temperature control.

Patients on long-term phenothiazine therapy require regular and careful surveillance with particular attention to tardive dyskinesia and possible eye changes, blood dyscrasias, liver dysfunction and myocardial conduction defects, particularly if other concurrently administered drugs have potential effects in these systems.

4.6 Pregnancy and lactation

'Stelazine Forte' has been available since 1958. There are some animal studies that indicate a teratogenic effect, but results are conflicting. There is no clinical evidence (including follow-up surveys in over 800 women who had taken low dosage 'Stelazine Forte' during pregnancy) to indicate that trifluoperazine has a teratogenic effect in man. Nevertheless, drug treatment should be avoided in pregnancy unless essential, especially during the first trimester. Trifluoperazine crosses the placenta and passes into the milk of lactating dogs, breast feeding should only be allowed at the discretion of the physician.

4.7 Effect on ability to drive and use machines

Patients who drive or operate machinery should be warned of the possibility of disturbances of the central nervous system.

4.8 Undesirable effects

Lassitude, drowsiness, dizziness, transient restlessness, insomnia, dry mouth, blurred vision, muscular weakness, anorexia, mild postural hypotension, skin reactions including photosensitivity reactions, weight gain, oedema and confusion may occasionally occur. Tachycardia, constipation, urinary hesitancy and retention, and hyperpyrexia have been reported very rarely. Adverse reactions tend to be dose related and to disappear. Hyperprolactinaemia may occur at higher dosages with associated effects such as galactorrhoea, amenorrhoea or gynaecomastia; certain hormone-dependent breast neoplasms may be affected. Phenothiazines can produce ECG changes with prolongation of the QT interval and T-wave changes; serious arrhythmias have been reported. Such effects are rare with 'Stelazine Forte'. In

some patients, especially non-psychotic patients, 'Stelazine Forte' even at low dosage may cause unpleasant symptoms of being dulled or, paradoxically, of being agitated

Extrapyramidal symptoms are rare at daily oral dosages of 6 mg or less; they are considerably more common at high dosage levels. These symptoms include parkinsonism, akathisia, with motor restlessness and difficulty in sitting still; and acute dystonia or dyskinesia, which may occur early in treatment and may present with torticollis, facial grimacing, trismus, tongue protrusion and abnormal eye movements including oculogyric crises. These effects are likely to be particularly severe in children. Such reactions may often be controlled by reducing the dosage or by stopping medication. In more severe dystonic reactions, an anticholinergic antiparkinsonism drug should be given.

Tardive dyskinesia of the facial muscles, sometimes with involuntary movements of the extremities, has occurred in some patients on long-term high dosage and, more rarely, low-dosage phenothiazine therapy, including 'Stelazine Forte'. Symptoms may appear for the first time either during or after a course of treatment, they may become worse when treatment is stopped. The symptoms may persist for many months or even years, and while they gradually disappear in some patients, they appear to be permanent in others. Patients have most commonly been elderly, female or with organic brain damage. Particular caution should be observed in treating such patients. If tardive dyskinesia occurs, 'Stelazine Forte' should be discontinued. Anticholinergic antiparkinsonism agents may aggravate the condition. Since the occurrence of tardive dyskinesia may be related to length of treatment and total cumulative dosage, 'Stelazine Forte' should be given for as short a time and at as low a dosage as possible.

The neuroleptic malignant syndrome is a rare but occasionally fatal complication of treatment with various neuroleptic drugs, and is characterised by hyperpyrexia, muscle rigidity, altered consciousness and autonomic instability. Intensive symptomatic treatment, following discontinuation of 'Stelazine Forte', should include cooling. Intravenous dantrolene has been suggested for muscle rigidity.

Cholestatic jaundice, and blood dyscrasias such as agranulocytosis, pancytopenia, leucopenia and thrombocytopenia have been reported very rarely. Signs of persistent infection should be investigated.

Very rare cases of skin pigmentation, retinopathy and lenticular opacities have been reported with 'Stelazine Forte'.

Acute withdrawal symptoms, including nausea, vomiting, sweating and insomnia have been described after abrupt cessation of antipsychotic drugs. Recurrence of psychotic symptoms may also occur, and the emergence of involuntary movement disorders (such as akathisia and dyskinesia) has been reported. Therefore, gradual withdrawal is advisable.

4.9 Overdosage

Signs and symptoms will be predominantly extrapyramidal, hypotension may occur. Treatment consists of gastric lavage together with supportive and symptomatic

measures. Do not induce vomiting. Extrapyramidal symptoms may be treated with an anticholinergic antiparkinsonism drug. Treat hypotension with fluid replacement, if severe or persistent, noradrenaline may be considered. Adrenaline is contraindicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

'Stelazine Forte' is a piperazine phenothiazine tranquilliser with potent antipsychotic, anxiolytic, and anti-emetic activity, and a pharmacological profile of moderate sedative and hypotensive properties, and fairly pronounced tendency to cause extrapyramidal reactions.

5.2 Pharmacokinetic properties

Trifluoperazine is well absorbed but undergoes extensive first pass metabolism. Distribution is wide and elimination occurs in the bile and urine.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sodium Saccharin
sodium benzoate
citric acid, anhydrous
sodium Citrate
sorbitol solution
quinoline Yellow (E104)
sunset Yellow (E110)
peach Flavour 85502 (Natural and Nature –identical
& propylene glycol
purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C. Keep container in the outer carton. Protect from light.

6.5 Nature and contents of container

Amber glass bottle with polypropylene cap containing 150ml, 200 ml or 500ml of syrup

6.6 Instructions for use/handling

None

7. MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd.
NLA Tower
12-16 Addiscombe Road
Croydon CR0 0XT
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 12762/0077

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Not applicable.

10. DATE OF APPROVAL/REVISION OF SPC

Not applicable.

Legal Category: POM