Telazine®

Trifluoperazine film coated tablet

PRESENTATION

Blue, film-coated tablet, containing either 1 mg or 5 mg trifluoperazine present as hydrochloride.

USES

Telazine® is a piperazine phenothiazine tranquiliser 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.

Low dosages: **Telazine**® is indicated as an adjunct in the short-term management of anxiety states, depressive symptoms, secondary to anxiety and agitation. It is also indicated in the symptomatic treatment of nausea and vomiting when reason is with major indication.

High dosages: **Telazine**® is indicated for the treatment of symptoms and prevention of relapse in schizophrenia and in other psychoses, especially of the 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 for example, mental subnormality.

DOSAGE AND ADMINISTRATION

Adults: Low dosage: 2-4 mg a day as tablet given in divided doses according to the patient's condition. If necessary, dosage may be increased to 6 mg 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 twice a day; after a week this may be increased to 15 mg a day. If necessary, further increase of 5 mg may be made at three days interval 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 tranquilisers clinical improvement may not be evident for several weeks after starting treatment and there may also be delay before recurrence of symptoms after stopping treatment. Gradual withdrawal from high dosage treatment is advisable.

Elderly: Reduce starting dose in elderly of frail patients by at least half.

Children: Low dosage: For children aged 3-5 years, 1 mg a day. For children aged 6-12 years the dosage may be increased to a maximum of 4 mg a day or as directed by the physician.

High dosage: For children aged under 12 years, the initial oral dosage should not exceed 5 mg 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.

CONTRA-INDICATIONS, WARNINGS, ETC.

Contra-indications : Do not use **Telazine**® in comatose patients or in those with existing blood dyscrasias or known liver damage or in those hypersensitive to the active ingredient or related compounds.

Cautions : 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 **Telazine**® may increase activity. Care should be taken in patients with angina pectoris.

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 and metrizamide should be avoided. Although **Telazine**® has minimal anticholinergic activity, this should be borne in mind when treating patients with narrow angle glaucoma, myasthenia gravis and prostatic hypertrophy.

Nausea and vomiting as a sign of organic disease may be masked by the anti-emetic action of **Telazine**® Potentiation may occur if antipsychotic drugs are combined with CNS depressants such as alcohol, hypnotics and strong analgesic, Phenothiazines may antagonise the action of guanethidine.

Patients who drive or operate machinery should be warned of the possibility of drowsiness.

Use in pregnancy and lactation : Based on animal studies and clinical experience (including follow up surveys in over 800 women who had taken low-dosage **Telazine**® during pregnancy), there is no evidence to suggest any associated hazard to the foetus. Nevertheless, drug treatment should be avoided in pregnancy unless essential, especially during the first trimester. Trifluoperazine passes into the milk of lactating dogs.

ADVERSE REACTIONS : 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 rearely. Adverse reactions tend to be dose related and to disappear.

Hyperprolactinaemia may occur at higher dosages with associated effects such as galactorrhoea or amenorrhoea. 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 **Telazine**®. In some patients especially non-psychotic patients **Telazine**® even at low dosage may cause unpleasant symptoms of being dulled or paradoxically of being agitated.

Extrapyramidal symptoms are rare at daily dosages of 6 mg or less: they are considerably more common at higher level. 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 protusion and abnormal eye movements including oculogyric crises. 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 **Telazine**®. 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, with organic brain damage. Particular caution should be observed in treating such patients. Periodic gradual reduction of dosage to reveal persisting dyskinesia has been suggested, so that treatment may be stopped if necessary. Anticholinergic antiparkinsonism agents may aggravate the condition. Since the occurence of tardive dyskinesia may be related to length of treatment and dosage **Telazine**® should be given for as short a time and at as low a dosage as possible. Mild 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 and lenticular opacities have been reported with **Telazine**®.

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 contra-indicated.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Telazine® 1 mg : Box containing 10 strips of 10 tablets each. Each film coated tablet contains Trifluoperazine Hydrochloride BP equivalent to 1 mg Trifluoperazine base.

Telazine® 5 mg : Box containing 10 strips of 10 tablets each. Each film coated tablet contains Trifluoperazine Hydrochloride BP equivalent to 5 mg Trifluoperazine base.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

® REGD. TRADEMARK

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