

**Sanit[®]**Nortriptyline and Fluphenazine
*Psycholeptic antidepressant***COMPOSITION**

Sanit[®] tablet : Each film coated tablet contains Nortriptyline 10 mg (as Nortriptyline HCl BP) and Fluphenazine HCl BP 0.5 mg.

PHARMACOLOGY

Nortriptyline hydrochloride is a tricyclic antidepressant. Nortriptyline inhibits the uptake of norepinephrine and serotonin at nerve terminals. In contrast to its parent compound amitriptyline which is equally potent in inhibiting the uptake of norepinephrine and serotonin, Nortriptyline has a greater effect on norepinephrine reuptake than on serotonin reuptake.

Fluphenazine is a tranquilizer of the phenothiazine type with piperazine side chain. Fluphenazine primarily acts as a neuroleptic drug whose main therapeutic effect is believed to reside in potent dopamine (specially D₂) receptor antagonism.

Due to the nature of the two active constituents and the larger inter and intra subject variability seen in trials, accurate and consistent pharmacokinetic data are not available. This can be illustrated by the fact that studies of nortriptyline hydrochloride have produced half life values ranging from 16 to 38 hours. In the case of Fluphenazine hydrochloride these values have been 10 to 16 hours.

INDICATION

Sanit[®] provides effective therapy in the management of patients exhibiting mild to moderate anxiety, tension and/or agitation with or without co-existing depression.

Various forms of neurosis (anxiety, hysteria, depression, neurasthenia), disorder of sleep are amenable to treat with Sanit[®].

Sanit[®], in addition, patients exhibiting general neurotic feelings, fear, mild to moderate depression and mild to moderate anxiety have responded well to Sanit[®].

DOSAGE AND ADMINISTRATION

Adult: One Sanit[®] tablet three times daily. The course of the treatment should be limited to three months. If the patient does not respond after 4 weeks, an alternative treatment should be given.

Children: Not indicated for the treatment of children.

CNS PREPARATIONS

Sanit[®]

Elderly: Elderly patients should be started on one Sanit[®] tablet twice daily. If one tablet three times a day required subsequently three tablets may be given.

CONTRAINDICATION AND PRECAUTION

Phenothiazines and tricyclic antidepressants have been shown to lower the threshold for electrically induced convulsions in animals; hence, this combination is not recommended for patients with a history of epilepsy or brain damage. This combination is further contraindicated in patients with blood dyscrasias, severe cardiac insufficiency, renal or liver damage.

It is inadvisable to give monoamine oxidase inhibitors (MAOIs) with this combination, nor should they be given in two weeks after cessation of treatment with MAOIs.

This combination should be given with caution to patients with glaucoma and to those who have a propensity for urinary retention. This combination should be used with caution in patients with cardiac failure, especially when there is evidence of rhythm disturbance and in patients with recent myocardial infarction.

SIDE EFFECT

Tardive dyskinesias have been reported in phenothiazine therapy, usually after prolonged courses given at doses adequate to control psychotic illness. Consequently, treatment with this drug should be limited to three months.

Dryness of mouth, drowsiness, faintness and constipation. Occasionally tachycardia, nasal congestion, blurred vision and excitement are seen.

Extrapyramidal reactions are unlikely to occur with this dose of fluphenazine alone, and it is probable that the anticholinergic activity of nortriptyline affords protection against such effects.

As with all neuroleptic drugs the presence of unexplained hyperthermia could indicate neuroleptic malignant syndrome. In this event, this combination and associated neuroleptic treatment should be discontinued until the origin of the fever has been determined.

DRUG INTERACTION

Interaction with barbiturates, alcohol and narcotic drugs may occur, so central nervous depressants should be administered with caution. This

combination may diminish the anti-hypertensive effect of an adrenergic blocking agent and could potentiate the pressor response to locally injected sympathomimetic agents.

USE IN PREGNANCY AND LACTATION

Do not use during pregnancy, especially in the first and last trimesters unless there are compelling reasons. There is no evidence as to drug safety in human pregnancy, nor are the results of animal studies conclusive. Breast feeding is not recommended for women receiving this combination.

OVERDOSE

Overdosage should be treated symptomatically and supportively. If the patient is conscious, prompt gastric lavage, dilution of the stomach contents to delay absorption, or stimulation of vomiting should be attempted. An open airway should be maintained. Extrapyrmidal symptoms are amenable to anti-parkinsonian drugs.

In severe hypotension, all the standard procedures for the management of circulatory shock should be substituted, e.g. vasoconstrictors and/or intravenous fluids. If vasoconstrictors are required, metaraminol, mephentermine or noradrenaline should be administered but not adrenaline, as this will further lower the blood pressure through interaction with the phenothiazine.

STORAGE CONDITION

Store below 25°C. Protect from light & moisture.

HOW SUPPLIED

Sanit[®] tablet : Box containing 10 x 10 tablets in blister pack.

