

Sentix®

Flupentixol film coated tablet

DESCRIPTION

Sentix® is the preparation of flupentixol dihydrochloride. It is a low dose neuroleptic of the thioxanthene group. In low doses (up to 3 mg/day) flupentixol has an anxiolytic, antidepressant and mood stabilizing effect and certain, activating properties. It acts mainly through a blockage of central monoamine receptors, especially in the dopaminergic system.

INDICATIONS

Flupentixol is indicated in the short-term symptomatic treatment of depression of mild to moderate severity (with or without anxiety) or where treatment with other antidepressants has failed.

It is also indicated in schizophrenia and other psychoses, particularly with apathy and withdrawal but not mania or psychomotor hyperactivity.

DOSAGE AND ADMINISTRATION

Adult: Standard initial dosage is 1 mg as a single morning dose. After one week the dose may be increased to 2 mg if there is inadequate clinical response. Daily dosage of more than 2 mg should be in divided doses up to a maximum 3 mg. In view of the activating properties of flupentixol, it is advisable to give the last dose of the day no later than evening.

Patients often respond to flupentixol within two or three days. If no effect has been observed within one week at maximum dosage the drug should be withdrawn.

In psychosis: Standard initial dosage is 3 to 9 mg twice daily adjusted according to the response; maximum 18 mg daily.

Elderly: Standard initial dosage is 0.5 mg as a single morning dose. After one week, if response is inadequate, dosage may be increased to 1 mg once a day. Caution should be exercised in further increasing the dosage but occasional patients may require up to a maximum of 2 mg a day which should be given in divided doses (1 mg at breakfast time and 1 mg at about evening).

Children: It is not recommended in children.

CONTRAINDICATIONS

It may be contra-indicated in excitable and overactive patients, comatose states, Pre-existing CNS depression, bone marrow suppression and phaeochromocytoma. Severe alcohol, barbiturate and opiate intoxications. Flupentixol is not recommended for the treatment of severe depression requiring ECT and/or hospitalization. Most antipsychotics are best avoided during pregnancy, unless essential and it is advisable to discontinue breast feeding during treatment.

USE IN PREGNANCY AND LACTATION

As there is no unequivocal evidence as to the safety of flupentixol in human pregnancy, use during pregnancy, especially the first and last trimesters, should be avoided. Flupentixol is excreted in small amounts in breast milk. It is recommended that mothers receiving flupentixol should not breast feed.

SIDE-EFFECTS

Main side effects is extrapyramidal symptoms, it consists of:

Parkinsonian symptoms (including tremor), which may occur more commonly in adults or the elderly and may appear gradually; dystonia (abnormal face and body movements) and dyskinesia, which occur more commonly in children or young adults and appear after only a few doses;

Akathisia (restlessness), which characteristically occurs after large initial doses and may resemble an exacerbation of the condition being treated; and

Tardive dyskinesia (rhythmic, involuntary movements of tongue, face, and jaw), which usually develops on long-term therapy or with high dosage, but it may develop on short-term treatment with low doses-short-lived tardive dyskinesia may occur after withdrawal of the drug.

Other side-effects include: drowsiness; apathy; agitation, excitement and insomnia; convulsions; dizziness; headache; confusion; gastro-intestinal disturbances; nasal congestion; antimuscarinic symptoms (such as dry mouth, constipation, difficulty with micturition, and blurred vision); cardiovascular symptoms (such as hypotension, tachycardia, and arrhythmias); ECG changes (cases of sudden death have occurred); endocrine effects such as menstrual disturbances, galactorrhoea, gynaecomastia, impotence, and weight gain; blood dyscrasias (such as agranulocytosis and leucopenia), photosensitisation, contact sensitisation and rashes, and jaundice (including cholestatic); corneal and lens opacities, and purplish pigmentation of the skin, cornea, conjunctiva, and retina.

PRECAUTIONS

It should be used with caution in patients with hepatic impairment, renal impairment, cardiovascular disease, Parkinson's disease (may be exacerbated by antipsychotics), epilepsy (and conditions predisposing to epilepsy), depression, myasthenia gravis, prostatic hypertrophy, or a personal or family history of angle-closure glaucoma (avoid chlorpromazine, pericyazine and prochlorperazine in these conditions). Caution is also required in severe respiratory disease and in patients with a history of jaundice or who have blood dyscrasias (perform blood counts if unexplained infection or fever develops). Antipsychotics should be used with caution in the elderly, who are particularly susceptible to postural hypotension and to hyper or hypothermia in very hot or cold weather. Serious consideration should be given before prescribing these drugs for elderly patients. As photosensitisation may occur with higher dosages, patients should avoid direct sunlight and in porphyria.

WARNINGS

Flupentixol should be used with caution in patients with Parkinson's disease, severe arteriosclerosis, senile confusional state or severe hepatic, renal, cardiovascular, cerebrovascular or respiratory disease.

DRUG INTERACTIONS

When given with other drugs that produce postural hypotension dosage adjustments may be necessary. Phenothiazines have been reported to reduce the antihypertensive action of guanethidine and other adrenergic neuron blockers. Phenothiazines may potentiate the adverse effects of other antimuscarinics. Concomitant administration of metoclopramide may increase the risk of neuroleptic-induced extrapyramidal effects and antiarrhythmics which prolong the QT interval may increase the likelihood of ventricular arrhythmias.

PHARMACEUTICAL PRECAUTIONS

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

PACKAGING

Sentix® 0.5 tablet : Box containing 5 strips of 10 tablets each. Each film coated tablet contains Flupentixol Dihydrochloride BP equivalent to Flupentixol 0.5 mg.

Sentix® 1 tablet : Box containing 3 strips of 10 tablets each. Each film coated tablet contains Flupentixol Dihydrochloride BP equivalent to Flupentixol 1 mg.

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Manufactured by
ESKAYEE PHARMACEUTICALS LTD.
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