

[EXHIBIT 2]

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Indications: Tofranil is recommended for the treatment of depressive states of diverse psychopathology.

Contraindications: The concomitant use of Tofranil and monoamine oxidase-inhibiting (M.A.O.I.) compounds is contraindicated. Hyperpyretic crises or severe convulsive seizures may occur. Potentiation of adverse effects can be serious, or even fatal. An interval of at least 7 days after M.A.O.I. therapy has been discontinued should be allowed before Tofranil may be substituted. Initial Tofranil dosage should be low, increases should be gradual, and the patient's progress should be carefully observed.

Warning: Clinical reports have suggested that there may be a risk of teratogenesis associated with the use of this compound during the first trimester of pregnancy. Unless, in the opinion of the prescribing physician, the potential benefits outweigh the

possible risks, Tofranil should not be used during the first trimester of pregnancy.

Cardiovascular complications, including myocardial infarction and arrhythmias, have occasionally occurred in susceptible individuals. Patients with cardiovascular disease should be given the drug only under careful observation and in low dosage.

Precautions: Since suicide is always a possibility in severely depressed patients and one which may persist until significant remission occurs, such patients should be carefully supervised during early treatment with Tofranil. Some severely depressed patients may also require hospitalization and/or concomitant electroconvulsive therapy.

Because of its anticholinergic effect, caution should be observed in prescribing Tofranil for patients with increased intraocular pressure.

In rare instances, transient cardiac arrhythmias have occurred in hyperthyroid patients and in patients receiving thyroid medication when Tofranil was added to the regimen. Imipramine may block the pharmacologic activity of guanethidine and other related adrenergic neuron-blocking agents.

The drug is not recommended at the present time in patients under 12 years of age.

Adverse reactions: Dryness of the mouth, tachycardia, constipation, disturbances of accommodation, sweating, dizziness, weight gain, urinary frequency or retention, nausea and vomiting, peripheral neuritis, mild parkinson-like syndrome, tremors, rare cases of falling in elderly patients, confusional states (with such symptoms as hallucinations and disorientation), activation of psychosis in schizophrenics and agitation (includ-