NOVARTIS

ANAFRANIL® (clomipramine)

25 mg coated tablets

Basic Succinct Statement (BSS)
Version 2.0

CODE: BSS RD 23 JAN 15; APPR 29 DEC 15

This material is only meant for Healthcare Professionals

ANAFRANIL®

Important note: Before prescribing, consult full prescribing information.

Presentation: Clomipramine hydrochloride, coated tablets of 25 mg.

Indications:

Adults: Treatment of depressive states of varying aetiology and symptomatology, e.g.

- endogenous, reactive, neurotic, organic, masked, and involutional forms of depression,
- depression associated with schizophrenia and personality disorders,
- depressive syndromes due to presenility or senility, to chronic painful conditions, and to chronic somatic diseases, depressive mood disorders of a reactive, neurotic, or psychopathic nature.

Obsessive-compulsive syndromes, phobias and panic attacks, cataplexy accompanying narcolepsy, chronic painful conditions.

Children and adolescents: Obsessive-compulsive syndromes; nocturnal enuresis (only in patients over the age of 5 and if organic causes have been excluded). Potential alternative therapies should be considered. In children and adolescents, there is not sufficient evidence of safety and efficacy of Anafranil in the treatment of depressive states of varying aetiology and symptomatology, phobias and panic attacks, cataplexy accompanying narcolepsy and chronic painful conditions. The use of Anafranil in children and adolescents (0-17 years of age) in these indications is therefore not recommended.

Dosage: Before initiating treatment with Anafranil, hypokalaemia should be treated. Administer with caution if other serotonergic agents (e.g. SSRIs, SNaRIs) are prescribed. Adapt to the individual patient's condition. Maintenance therapy and duration of treatment should be reviewed periodically.

Adults: Usually 75-150 mg/day (for panic attacks 25-100 mg/day). Initiate treatment with 1 tablet of 25 mg 2-3 times daily (for panic attacks start with1 tablet of 10 mg daily). Avoid abrupt discontinuation of treatment.

Children and adolescents: Obsessive-compulsive syndromes: 25 mg daily gradually increased during the first two weeks up to 3 mg/kg or 100 mg (whichever is smaller), then up up to 3 mg/kg or 200 mg (whichever is smaller). Nocturnal enuresis: 5-8 years: 20-30 mg; 9-12 years: 25-50 mg; children above 12 years of age: 25-75 mg. To be given as a single dose after the evening meal or part of the dose could be given beforehand (at 4 p.m) in children wetting their beds early in the night. No experience is available in children younger than 5 years of age. Avoid abrupt discontinuation of treatment.

Contraindications: Hypersensitivity to clomipramine or excipients, cross-sensitivity to tricyclic antidepressants of the dibenzazepine group. Recent myocardial infarction. Congenital long QT syndrome. Concomitant treatment with MAO inhibitors.

Warnings/Precautions: Risk of: QTc prolongation and Torsades de Pointes, particularly at supra-therapeutic doses or plasma concentrations, low convulsive threshold, suicide. Caution is advised in case of: increase in dosage in specific population (geriatric population and adolescents)

cardiac conduction disorders, cardiovascular insufficiency, narrow-angle glaucoma, disturbances of micturition, severe liver disease, tumours of the adrenal medulla, electroconvulsive therapy, hyperthyroidism or concomitant treatment with thyroid preparations, chronic constipation, surgical intervention, withdrawal. Avoid during pregnancy or breast-feeding. Caution in road/machinery users. Monitoring of blood count, hepatic, and renal function.

Interactions: Concomitant use with SSRIs, SNaRIs, antiarrhythmics, drugs that prolong QTc interval or can cause accumulation of clomipramine should be avoided. Caution is required when used in combination with several antihypertensive drugs, diuretics, sympathomimetics, CNS depressants, anticholinergics, neuroleptics, lithium, liver-enzyme inducers, anticoagulants, terbinafine, cimetidine, methylphenidate, estrogens, valproate, colestipol, cholestyramine, grapefruit, grapefruit juice, St John's wort or cranberry juice.

Adverse reactions: **Very common:** accommodation disorder, vision blurred, dry mouth, constipation, nausea, fatigue, weight increased, increased appetite, somnolence, dizziness, tremor, headache, myoclonus, restlessness, micturition disorder, libido disorder, erectile dysfunction, hyperhidrosis. **Common:** sinus tachycardia, palpitation, orthostatic hypotension, clinically irrelevant ECG changes (e.g. ST and T changes) in patients of normal cardiac status, tinnitus, mydriasis, vomiting, abdominal disorders, diarrhoea, transaminases increased, decreased appetite, muscular weakness, memory impairment, disturbance in attention, speech disorder, paraesthesias, muscle hypertonia, dysgeusia, confusional state, disorientation, hallucinations (particularly in elderly patients and patients with Parkinson's disease), anxiety, agitation, sleep disorder, mania, hypomania, aggression, depersonalisation, aggravation of depression, insomnia, nightmares, delirium, galactorrhoea, breast enlargement, yawning, dermatitis allergic (skin rash, urticaria), photosensitivity reaction, pruritus, hot flush. **Uncommon:** activation of psychotic symptoms, convulsions, ataxia, arrhythmias, blood pressure increased. **Very rare:** leucopenia, agranulocytosis, thrombocytopenia, eosinophilia, purpura, conduction disorder (e.g. widening of QRS complex, prolonged QT interval, PQ changes, bundle-branch block, torsade de pointes, particularly in patients with hypokalaemia), SIADH (inappropriate antidiuretic hormone secretion syndrome, glaucoma, hyperpyrexia, oedema (local or generalised), alopecia, hepatitis with or without jaundice, anaphylactic and anaphylactoid reactions including hypotension, EEG abnormal, NMS, urinary retention, alveolitis allergic (pneumonitis) with or without eosinophilia. Increased risk of bone fractures in patients 50 years of age or older with SSRIs and TCAs. **Not known:** serotonin syndrome, extrapyramidal symptoms (including akathisia and tardive dyskinesia), rhabdomyolysis (as a complication of NMS), blood prolactin increased, ejaculation failure, ejaculation delayed.