AGOG Pharma Ltd.
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1.5.3 Patient information leaflet (PIL)

MIPRAM TABLETS

(Imipramine Tablets BP 25 mg)

Composition:
Each sugar coated tablet contains
Imipramine Hydrochloride BP 25 mg

Category: antidepressant

Clinical Pharmacology:
Imipramine hydrochloride, the original tricyclic antidepressant, is a member of the dibenzazepine group of compounds. It is designated 5-[3-(Dimethylamino) propyl]-10, 11-dihydro-5 H-dibenz[b,f]-azepinemonohydrochloride.
The mechanism of action of imipramine hydrochloride is not definitely known. However, it does not act primarily by stimulation of the central nervous system, The clinical effect is hypothesized as being due to potentiation of adrenergic synapses by blocking uptake of norepinephrine at nerve endings. The mode of action of the drug in controlling childhood enuresis is thought to be apart from its antidepressant effect.

Indication:
Depression-
For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. One to three weeks of treatment may be needed before optimal therapeutic effects are evident.
Childhood Enuresis-
May be useful as temporary adjunctive therapy in reducing enuresis in children aged 6 years and older, after possible organic causes have been excluded by appropriate tests. In patients having daytime symptoms of frequency and urgency, examination should include voiding cystourethrography and cystoscopy, as necessary. The effectiveness of treatment may decrease with continued drug administration.

Dosage & Administration:
Depression:
Adults – 25mg three times a day increasing to 150mg-200mg a day in divided doses. In severe cases (treated in hospital) the dose may be increased up to a maximum of 100 mg three times a day. The usual maintenance dose is between 50mg and 100mg a day in divided doses.
Elderly (over 60 years) - Initially 10mg a day increasing to 30-50mg a day.

Nightly bedwetting:
Children only, to be taken at bedtime (for no longer than 3 months and up to a maximum of 75mg a day):
Over 11 years (35-54kg) - 50-75mg a day.
8-11 years (25-35kg) - 25-50mg a day.
6-7 years (20-25kg) - 25mg a day.
Under 6 years - not recommended.
*Please take the medication as directed by the physician

Contraindication:
•The concomitant use of monoamine oxidase inhibiting compounds is contraindicated. Hyperpyretic crises or severe convulsive seizures may occur in patients receiving such combinations. The potentiation of adverse effects can be serious, or even fatal. When it is desired to substitute imipramine hydrochloride in patients receiving a monoamine oxidase inhibitor, as long an interval should elapse as the clinical situation will allow, with a minimum of 14 days. Initial dosage should be low and increases should be gradual and cautiously prescribed.
• The drug is contraindicated during the acute recovery period after a myocardial infarction. Patients with a known hypersensitivity to this compound should not be given the drug. The possibility of cross-sensitivity to other dibenzazepine compounds should be kept in mind.

Adverse Effects:
• Like all medicines, Imipramine tablets can cause side effects, although not everybody gets them:
Stop taking the tablets and contact a doctor at once if you have the following allergic reaction, pneumonitis (fever, chills, cough, difficulty breathing, and unusual weight loss, feeling sick), a skin rash, which may be itchy, sensitivity to the sun or sun lamps, puffy, swollen face or tongue, which may be severe causing shortness of breath, shock and collapse.
Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
• **Blood:** reduction in some blood cells (you may experience a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily)
• **Endocrine system and metabolism:** disturbances in sexual function or sex drive, breast swelling in men and women, production or over-production of breast milk, changes in blood sugar levels, weight gain or loss, SIADH (syndrome of inappropriate antidiuretic hormone secretion)
• **Brain and central nervous system:** disorientation, dizziness, tiredness or sleepiness, weakness, headache, difficulty concentrating, confusion, agitation, mood swings, aggressiveness, difficulty sleeping, delusions, seeing things that are not there, anxiety, restlessness, pins and needles, tremor, muscle spasm or lack of muscle control, speech problems, fits. Anticholinergic effects (dry mouth, constipation, blurred or double vision, sweating, hot flushes, difficulty passing water (urine), dilation of the pupil of the eye, glaucoma and blockage of the small intestine)
• **Heart:** feeling faint when getting up (postural hypotension), high or severely low blood pressure, fast/racing heart, palpitations, irregular heart-beats, changes in ECG readings
• **Stomach and intestines:** feeling or being sick, loss of appetite, inflammation of the mucus membranes in the mouth, tongue lesions
• **Liver:** impaired liver function, hepatitis, including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and/or whites of the eyes)
• **Other:** hair loss, ringing in the ears, small purple red spots. An increase risk of bone fractures has been observed in patients taking this type of medicine.
• **Withdrawal symptoms:** feeling or being sick, stomach pain, diarrhoea, difficulty sleeping, nervousness, anxiety, headache, irritability
• **Children:** changes in behavior.

STORAGE:
Store under normal storage condition.
(15°C to 30°C).

Protect from light.

Keep all medicines out of reach of children.

PRASENTATION:
A Bulk pack of 100's Tablets / 200 Tablets

Manufactured in India by :
AGOG PHARMA LTD.
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Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.