Prescribing Information
Tranylcypromine 10 mg tablets

Presentation: Each sugar coated tablet contains tranylcypromine sulphate equivalent to 10mg of tranylcypromine base.

Indication: For the treatment of depressive illness especially where phobic symptoms occur or where the treatment with other types of antidepressants has failed. It is not recommended for mild depressive states.

Dosage and administration: For oral administration. Adults: Initially one tablet in the morning and afternoon. 1 tablet twice a day if concurrently administered with electroconvulsive therapy. Caution is required when dosage of 3 tablets a day is exceeded. Children: Not indicated for children under 18 years of age.

Contraindications: Severe hypertensive reactions may result if tranylcypromine is given with indirectly acting sympathomimetic amines, anti-obesity agents, narcotic analgesics and MAO Inhibitors. Avoid tranylcypromine until at least two weeks after stopping treatment with other MAOIs. Hyperactivity, hypertonicity, hyperpyrexia, coma and death have been associated with the use of tranylcypromine in combination with tricyclic antidepressants; tetracyclic antidepressants. Should not be given to patients with actual/suspected cerebrovascular disease, phaeochromocytoma, hyperthyroidism and blood dyscrasias or severe cardiovascular disease.

Precautions and warnings: Exercise caution when using tranylcypromine in elderly patients with cardiovascular disease, epileptic patients or patients with a history of dependence on drugs or alcohol. Symptoms of depression such as anxiety and agitation may be aggravated by tranylcypromine. Tranylcypromine should preferably be withdrawn at least two weeks before elective surgery because of possible drug interaction.

Interactions: Guanethidine, reserpine, methyl dopa, other hypotensive agents, oral hypoglycaemic agents or insulin, anticholinergic antiparkinsonism drugs narcotic analgesics monoamine oxidase inhibitors (MAOI), selective serotonin reuptake inhibitors (SSRIs) tricyclic antidepressants, antidepressants, opioids analgesics. Use of MAOIs may enhance the effects of barbiturates and possibly other hypnotics, hypoglycaemic, and possibly antimuscarinic agents. Patients taking MAOIs should not undergo surgery requiring general anaesthesia.

Pregnancy and lactation: Tranylcypromine should not be used in pregnancy, unless considered essential by the physician. The drug passes into the milk in lactating dogs.

Undesirable effects: Insomnia is the most frequent side effect. Other undesirable effects include postural hypertension, dizziness, drowsiness, fatigue, dry mouth, blurred vision, headache, diarrhoea, nausea and vomiting, sleep disturbances, and rash. Fatal, severe hypertensive reactions may occur. Cases of suicidal ideation and suicidal behaviours have been reported during tranylcypromine therapy or early after treatment discontinuation.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Signs and symptoms may include hyperpyrexia, tremor and convulsions. Treatment: Induction of vomiting and/or gastric lavage together with supportive and symptomatic measures. Pancuronium with mechanical ventilation may help reverse muscle spasm and pyrexia. Beta-adrenergic receptor blockade has been used successfully.

Legal Category: POM

Basic NHS Cost: £128.47 for 20 x 10mg tablets

Marketing Authorisation Number: PL 12762/0075

Marketing Authorisation Holder: Amdipharm Mercury Company Limited, 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL

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Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Amdipharm Mercury Medical Information via telephone on 08700 70 30 33 or via e-mail to medicalinformation@amcolimited.com