

AMITRIP[®]

Amitriptyline Tablets

COMPOSITION:

Each tablet contains Amitriptyline HCl BP 25mg.

ACTION:

It is one of the most potent antidepressants of tricyclic structure. Amitriptyline has marked antimuscarinic and sedative properties, and prevents the re-uptake (and hence the inactivation) of noradrenaline and serotonin at nerve terminals. Its mode of action in depression is not fully understood.

PHARMACOKINETICS:

Amitriptyline is readily absorbed from the gastrointestinal tract, peak plasma concentrations occurring within a few hours of oral administration. Since amitriptyline slows gastro-intestinal transit time, absorption can, however, be delayed, particularly in overdosage.

Amitriptyline undergoes extensive, first-pass metabolism and is demethylated in the liver to its primary active metabolite, nortriptyline. Other paths of metabolism of amitriptyline include hydroxylation and N-oxidation; nortriptyline follows similar paths. Amitriptyline is excreted in the urine, mainly in the form of metabolites, either free or in conjugated form. Both the drug and its active metabolites are widely distributed throughout the body and are extensively bound to plasma and tissue proteins. Amitriptyline has an estimated elimination half-life ranging from 9 to 36 hours which may be considerably extended in overdosage. Plasma concentrations of amitriptyline and nortriptyline vary very widely between individuals and no simple correlation with therapeutic response has been established. Both the drug and active metabolite cross the placenta and are excreted in breast milk.

INDICATIONS:

For use in the treatment of endogenous depression of the depressed phases of manic-depressive disorders as well as evolutionary, climacteric, senile, arteriosclerotic and other depressions. It also may be useful in psychovegetative and neurotic depressions. For treatment of depressive reactions associated with schizophrenia it is also recommended, however long-term treatment may aggravate schizophrenic symptoms. In severe psychiatric cases it may be used as an adjunctive therapy to electroconvulsions, it supplements, however does not completely substitute, electroconvulsion treatment.

SIDE EFFECTS:

The incidence and severity of untoward reaction produced by AMITRIPTYLINE appear to be less than those of the other antidepressants used. Drowsiness, dryness of the mouth, tremor, fatigue, constipation, epigastric pains, blurring of vision, hypotension may manifest themselves. Most of these reactions may be controlled by reducing dosage.

CONTRA-INDICATIONS:

Contra-indicated in glaucoma and where urinary retention is present or may be expected. It is not a monoamine oxidase inhibitor, but its concomitant administration with such drugs may lead to serious complications. It should not be given with, or for at least three weeks after discontinuing the use of, a monoamine oxidase inhibitor.

PRECAUTION:

The administration of AMITRIPTYLINE calls for close supervision in epileptics and aged patients, since hypomania, confusion and tremor may be produced.

DOSAGE:

By mouth, in a single or divided daily dose of 75mg initially, gradually increased if necessary to 150mg daily, the additional doses being given in the late afternoon or evening. Single daily doses are normally given in the evenings or bed time.

Therapy may also be initiated with a single dose of 50mg to 100mg at bed time, increased by 25 or 50mg as necessary to a total of 150mg daily. Maintenance doses are usually 50 to 100mg daily and therapy should be continued for at least 3 months before being gradually withdrawn.

Severely depressed patients may require doses up to 200mg daily and, occasionally, up to 300mg daily. Adolescents and elderly patients have reduced tolerance to amitriptyline and initial doses of 10 to 50mg daily may be adequate, given either as divided doses or as a single dose, preferably at bed time. Half the usual maintenance dose will be sufficient.

LEGAL CATEGORY: Prescription Only Medicine (POM).

THERAPEUTIC CATEGORY: ATC: N05A (Antidepressant)

STORAGE: Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION: Available in blister packs of 10 x 10's and bulk packs of 1000 tablets.

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LICENCE HOLDER: LABORATORY & ALLIED LTD.



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