Amitriptyline Tablets BP

Composition:
Each film Coated Tablet Contains:
Amitriptyline Hydrochloride BP 25 mg
Approved Colour used
Excipients Q.S.

Therapeutic indications
Amitriptyline is indicated for:
Treatment of major depressive disorder in adults
The treatment of neuropathic pain in adults
Prophylactic treatment of chronic tension-type headache (CTTH) in adults
Prophylactic Treatment of Migraine in Adults
The treatment of nocturnal enuresis in children 6 years of age and older, when organic pathology, including spina bifida and related disorders, were excluded and no response was achieved in all other non-drug and drug treatments, including antispasmodics and related products. vasopressin. This medication should only be prescribed by a healthcare professional experienced in the treatment of persistent enuresis.

Posology and method of administration
Dosage
Not all dosage schedules can be achieved with all pharmaceutical forms/strengths. Appropriate formulation/strength should be selected for initial doses and any subsequent increments.
Major depressive disorder
Dosing should be started at a low level and gradually increased, carefully observing the clinical response and any evidence of intolerability.
Adults
Initially 25 mg twice a day (50 mg daily). If necessary, the dose can be increased by 25 mg every other day, up to 150 mg per day, divided into two doses.
The maintenance dose is the lowest effective dose.

Elderly patients over 65 and patients with cardiovascular disease
Initially 10 mg - 25 mg per day.
The daily dose can be increased up to 100 mg - 150 mg, divided into two doses, depending on individual patient response and tolerability.
Daily doses above 100mg should be used with caution.
The maintenance dose is the lowest effective dose.
pediatric population
Amitriptyline should not be used in children and adolescents under the age of 18 years, as long-term safety and efficacy have not been established (see section 4.4).
Duration of treatment
The antidepressant effect usually occurs after 2 - 4 weeks. Antidepressant treatment is symptomatic and therefore should be continued for an appropriate period of time, usually up to 6 months after recovery, to avoid relapses.
Neuropathic pain, prophylactic treatment of chronic tension headache and prophylactic treatment of migraine in adults
Patients should be individually titrated to the dose that provides adequate analgesia with tolerable adverse drug reactions. Generally, the lowest effective dose should be used for the shortest duration needed to treat symptoms.
Adults
Recommended doses are 25mg - 75mg daily in the evening. Doses above 100 mg should be used with caution.
The starting dose should be 10mg - 25mg in the evening. Doses can be increased by 10 mg - 25 mg every 3-7 days, as tolerated.
The dose can be taken once a day or divided into two doses. A single dose above 75 mg is not recommended.
The analgesic effect is usually seen after 2 to 4 weeks of administration.
Elderly patients over 65 and patients with cardiovascular disease
A starting dose of 10 mg to 25 mg in the evening is recommended. Doses above 75 mg should be used with caution.
It is generally recommended to start treatment in the lower dose range, as recommended for adults. The dose can be increased depending on individual patient response and tolerability.
Pediatric population

Amitriptyline should not be used in children and adolescents under the age of 18 years, as long-term safety and efficacy have not been established (see section 4.4).
Duration of treatment
Neuropathic pain
Treatment is symptomatic and therefore must be continued for an appropriate period of time. In many patients, therapy may be needed for several years. Regular reassessment is recommended to confirm that continuation of treatment remains appropriate for the patient.
Prophylactic treatment of chronic tension headache and prophylactic treatment of migraine in adults
Treatment must be continued for an appropriate period of time. Regular reassessment is recommended to confirm that continuation of treatment remains appropriate for the patient.
Nocturnal Enuresis
pediatric population
Recommended doses for:
children aged 6 to 10 years: 10mg - 20mg. A more suitable dosage form should be used for this age group.
children aged 11 and over: 25 mg - 50 mg per day
The dose should be increased gradually.
Dose to be administered 1-1½ hours before bedtime.
An ECG should be performed before starting amitriptyline therapy to exclude long QT syndrome.
Duration of treatment
The maximum treatment period should not exceed 3 months.
If repeated courses of amitriptyline are needed, a medical review should be performed every 3 months.
When stopping treatment, amitriptyline should be withdrawn gradually.
special populations
Reduced kidney function
This medicine can be administered in usual doses to patients with renal insufficiency.
reduced liver function
Careful dosing and, if possible, a determination of the serum level is recommended.
CYP2D6 cytochrome P450 inhibitors

Depending on individual patient response, a lower dose of amitriptyline should be considered if a strong CYP2D6 inhibitor (eg, bupropion, quinidine, fluoxetine, paroxetine) is added to treatment with amitriptyline (see section 4.5).
Known weak metabolizers of CYP2D6 or CYP2C19
These patients may have higher plasma concentrations of amitriptyline and its active metabolite nortriptyline. Consider a 50% reduction from the recommended starting dose.
administration mode
Amitriptyline is for oral use.
Tablets should be swallowed with water.
treatment interruption
When stopping therapy, the drug should be withdrawn gradually over several weeks.
Contraindications
Hypersensitivity to the active substance, tricyclic antidepressants or to any of the excipients listed in section 6.1;
Recent myocardial infarction. Any degree of heart block or heart rhythm disturbances and coronary artery failure.
Concomitant treatment with MAOIs (monoamine oxidase inhibitors) is contraindicated (see section 4.5).
Concurrent administration of amitriptyline and MAOIs can cause serotonin syndrome (a combination of symptoms, possibly including agitation, confusion, tremor, myoclonus and hyperthermia).
Treatment with amitriptyline can be started 14 days after discontinuation of irreversible non-selective MAOIs and at least one day after discontinuation of reversible moclobemide. MAOI treatment can be started 14 days after discontinuation of amitriptyline.
severe liver disease.
Porphyria.
In children under 6 years of age.

Fertility, pregnancy and breastfeeding
Pregnancy
For amitriptyline, only limited clinical data are available on exposed pregnancies. Animal studies have shown reproductive toxicity (see section 5.3).
Amitriptyline is not recommended during pregnancy unless clearly necessary and only after careful consideration of risk/benefit.
During chronic use and after administration in the last weeks of pregnancy, neonatal withdrawal symptoms may occur. This can include irritability, hypertonia, tremor, irregular breathing, lack of drinking and loud crying, and possibly anticholinergic symptoms (urinary retention, constipation).
Breast-feeding
Amitriptyline and its metabolites are excreted in breast milk (corresponding to 0.6% to 1% of the maternal dose). A risk to the nursing child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from therapy for this medication, taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.
Fertility
Amitriptyline reduced the pregnancy rate in rats (see section 5.3).
There are no data available on the effects of amitriptyline on human fertility.
Overdose
Symptoms
Anticholinergic symptoms: mydriasis, tachycardia, urinary retention, dry mucous membranes, reduced intestinal motility. Seizures. Fever. Sudden occurrence of CNS depression. Lowered consciousness progressing to coma. Respiratory depression. Hyperreflexia may be present with plantar extensor reflexes. Hypothermia may occur.
Cardiac symptoms: Arrhythmias (ventricular tachyarrhythmias, torsade de pointes, ventricular fibrillation). Characteristically, the electrocardiogram shows prolonged PR interval, widening of the QRS complex, prolongation of the QT interval, flattening or inversion of the T wave, ST-segment depression, and varying degrees of heart block progressing to cardiac arrest. The widening of the QRS complex generally correlates well with the severity of toxicity after acute overdoses. Heart failure, hypotension, cardiogenic shock. Metabolic acidosis, hypokalemia, hyponatremia .
Ingestion of 750 mg or more by an adult can result in severe toxicity. The effects of overdose will be potentiated by the simultaneous ingestion of alcohol and other psychotropic drugs. There is considerable individual variability in response to overdose. Children are especially susceptible to cardiotoxicity, seizures, and hyponatremia.
During awakening, possibly again confusion, agitation and hallucinations and ataxia. Treatment
1. Admission to hospital (intensive care unit), if necessary. Treatment is symptomatic and supportive.
2. Assess and treat the ABCs (airway, breathing, and circulation) as appropriate. Secure IV access.
Rigorous monitoring, even in seemingly simple cases.
3. Examine clinical resources. Check urea and electrolytes - look for low potassium and monitor urine output. Check arterial blood gases - look for acidosis. Perform electrocardiograph - look for QRS> 0.16 seconds
4. Do not give flumazenil to reverse benzodiazepine toxicity in mixed overdoses.
5. Consider gastric lavage only if within an hour of a potentially fatal overdose.
6. Give 50g of charcoal if it is within an hour of eating.
7. Airway patency is maintained by intubation when necessary. Treatment on the respirator is recommended to avoid possible respiratory arrest. Continuous monitoring of cardiac function by ECG for 3-5 days. The treatment of the following will be decided on a case-by-case basis:
- Wide QRS intervals, heart failure and ventricular arrhythmias
- circulatory failure
- Hypotension
- Hyperthermia
- convulsions
- metabolic acidosis.
8. Agitation and seizures can be treated with diazepam.
9. Patients who show signs of toxicity must be monitored for a minimum period of 12 hours.
10. Monitor rhabdomyolysis if the patient has been unconscious for a considerable time.
11. As overdose is often deliberate, patients may attempt suicide by other means during the recovery phase. Deaths have occurred from deliberate or accidental overdose with this class of drug.

Storage: Store in a cool, dark and dry place below 30°C.

Keep medicines out of reach of children.

Presentation: 100 x 10 Tablets.

Manufactured by:

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in