PATIENT INFORMATION LEAFLET
AMITRIPTYLINE TABLETS BP 25 MG
[Amitriptyline Hydrochloride BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT AMITRIPTYLINE TABLETS BP 25 MG IS AND WHAT IT IS USED FOR

It contains the active substance Amitriptyline hydrochloride. This belongs to a group of medicines a tricyclic antidepressant with marked anticholinergic and sedative properties. Its mode of action in depression is not fully understood, though it is thought to increase the synaptic concentration of norepinephrine and serotonin in the CNS by inhibiting their re-uptake by the pre-synaptic neuronal membrane. It is indicated in symptoms of in major depressive disorder (especially where sedation is required) and neuropathic pain in adults. The prophylactic treatment of chronic tension type headache in adults. The prophylactic treatment of migraine in adults. Nocturnal enuresis where organic pathology is excluded. The treatment of nocturnal enuresis in children aged 6 years and above when organic pathology, including spina bifida and related disorders, have been excluded and no response has been achieved to all other non-drug and drug treatments, including antispasmodics and vasopressin- related products. This medicinal product should only be prescribed by a healthcare professional with expertise in the management of persistent enuresis.

2. BEFORE YOU USE AMITRIPTYLINE TABLETS BP 25 MG

Do not use Amitriptyline Tablets BP 25 mg. If you are known hypersensitivity to amitriptyline hydrochloride or any other component of the product. It should not be given concomitantly with monoamine oxidase inhibitors. It is desired to replace a monoamine oxidase inhibitor with Amitriptyline Tablet, a minimum of 14 days should be allowed to elapse after the former is discontinued. It should not be given concurrently with Cisapride due to the potential for increased QT interval and increased risk for arrhythmia. It is not recommended for use during the acute recovery phase following myocardial infarction.

Warnings and precautions:

Amitriptyline should be used with caution in patients with a history of epilepsy, and those with impaired liver function. Due to its atropine-like action, it should be used with caution in patients with a history of urinary retention, prostatic hypertrophy, narrow-angle glaucoma, or increased intra-ocular pressure. Patients with cardiovascular disorders, hyperthyroid patients and those receiving thyroid medication or anticholinergic drugs should be used with caution and the dosage of all medications carefully adjusted. When used for the depressive component of schizophrenia, amitriptyline may aggravate psychotic symptoms. In manic depressives, a shift towards the manic phase may occur. Paranoid delusions, with or without associated hostility, may be aggravated. The risk of suicide remains during treatment of depressed patients and until significant remission

occurs such patients require careful supervision. Concurrent administration with Electroconvulsive Therapy may increase the hazards of treatment, and should be limited to patients for whom it is deemed essential. Amitriptyline should be discontinued several days before surgery. If emergency surgery is unavoidable, the anesthetist should be informed that the patient is being treated with amitriptyline, since anesthesia may increase the risk of hypotension and arrhythmias. Hyponatremia (usually in the elderly and possibly due to inappropriate secretion of antidiuretic hormone) has been associated with all types of antidepressants and should be considered in all patients who develop drowsiness, confusion or convulsions while taking an antidepressant. Hepatic impairment: Use with caution in patients with hepatic impairment.

Using other medicines: Please tell your physician, health care provider or pharmacist if you are taking or have recently taken any other following medicines: monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson's disease). These should not be taken at the same time as do not take amitriptyline tablets, adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics) medicine to treat high blood pressure for example calcium-channel blockers (e.g. diltiazem and verapamil), guanethidine, betanidine, clonidine, reserpine and methyldopa, anticholinergic drugs such as certain medicines to treat parkinsons disease and gastrointestinal disorders (e.g. atropine, hyoscyamine), thioridazine (used to treat schizophrenia), nefopam, tramadol and morphine (painkillers) buprenorphine (a drug used for severe pain or opioid drug addiction). Contact your doctor when experiencing such symptoms: medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole), sedatives (e.g. babiturates), antidepressants (e.g SSRIs (fluoxetine, paroxetine, fluvoxamine), duloxetine and bupropion), medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics), cimetidine (used to treat stomach ulcers), methylphenidate (used to treat ADHD). Ritonavir (used to treat HIV). Oral contraceptives, rifampicin (to treat infections), phenytoin and carbamazepine (used to treat epilepsy), St. John´s Wort (hypericum perforatum) a herbal remedy used for depression, thyroid medication. Valproic acid. Increased muscle tension, body temperature above 38°C. This medicine may interact with amitriptyline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, medicines to treat irregular heartbeats (e.g. quinidine and sotalol), agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. If patient are going to have an operation and receive general or local anaesthetics, If you have any further questions about this you should speak to your physician.

Taking Amitriptyline Tablets BP 25 mg with food and drink: Do not intake with alcohol.

Pregnancy and Lactation: Take advice by talk to physician or pharmacist before taking Amitriptyline Tablets BP 25 mg. **Pregnancy:** Category C: Amitriptyline crosses the placenta. Amitriptyline should be used only during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus. **Lactation:** Amitriptyline is detectable in breast milk. Because of the potential for serious adverse reactions in infants from amitriptyline, it is not recommended during lactation.

Driving and using machines: It is a sedative drug. Patients who are prescribed psychotropic medication may be expected to have some impairment in general attention and concentration and should be cautioned about their ability to drive or operate machinery. These adverse effects can be potentiated by the concomitant intake of alcohol. If this happens to you, wait until these feelings go away before driving or using machines.

3. HOW TO USE AMITRIPTYLINE TABLETS BP 25 MG

Always use Amitriptyline Tablets BP 25 mg exactly as your physician or health care provider has told you or as directed by physician. **Method of administration:** Oral, The tablets should be swallowed whole with water.

Therapy should be started with a low dosage and increased gradually, according to the clinical response and any evidence of intolerance.

Adults:

Initial dose: Usually 75 mg daily in divided doses (or a single dose at night). This may be increased if necessary to a total of l 50mg a day, with the additional doses being given in the late afternoon and/or bedtime. The sedative effect is usually rapidly apparent while antidepressant activity may be seen within 3 or 4 days or may take up to 30 days to develop adequately. **Maintenance Dose:** The usual maintenance dosage is 50-100 mg daily. The total dosage may be given in a single dose preferably in the evening or at bedtime. When satisfactory improvement has been reached, dosage should be reduced to the lowest amount that will maintain relief of symptoms. Maintenance therapy should be continued for 3 months or longer to lessen chances of relapse. **Elderly:** An initial dosage of 10-25 mg three times daily is recommended, which should be increased slowly. A daily dosage of 50 mg may be satisfactory in elderly patients who may not tolerate higher doses. The required dosage may be administered either as divided doses or as a single dose preferably in the evening or at bedtime.

Pediatrics: Depression: Amitriptyline is not recommended for treatment of depression in children, under 16 years of age. **Enuresis:** Children from 11-16 years may need 25 mg-50mg a day. **Treatment should not exceed three months**.

If you more Amitriptyline Tablets BP 25 mg than you should: Do not use more than the recommended dose. If taking more than the recommended dose may cause Symptoms: Overdose effects are mainly due to anticholinergic (atropine-like) effects at autonomic nerve endings and in the brain. Commonly include peripheral symptoms sinus tachycardia, hot dry skin, dry mouth and tongue, dilated pupils and urinary retention. The most important ECG feature of toxicity is prolongation of the QRS interval, which indicates a high risk of ventricular tachycardia. In very severe poisoning the ECG may be bizarre. Common central symptoms include ataxia, nystagmus and drowsiness, which may lead to deep coma and respiratory depression. Increased tone and hyperreflexia may be present with extensor plantar reflexes. Treatment: An ECG should be taken and in particular the QRS interval should be assessed since prolongation signifies an increased risk of arrhythmia and convulsions. Give activated charcoal by mouth or naso-gastric tube if more than 4 mg/kg has been ingested within one hour, provided the airway can be protected. Tachyarrhythmias arc treated by correction of hypoxia and acidosis. Control convulsions with intravenous diazepam or lorazepam. Give oxygen and correct acid base and metabolic disturbances.

If you forget to Amitriptyline Tablets BP 25 mg: If you forget to take a dose, Do not take a double dose (two doses at the same time) to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your physician or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines can cause side effects, although not everybody gets them. **Cardiovascular:** Orthostatic hypotension, syncope, postural hypotension, hypertension, palpitations, tachycardia, myocardial infarction, heart block stroke and non-specific ECG changes. CNS and **Neuromuscular:** Disturbed concentration, disorientation, confusion, coordination impaired, insomnia, nightmares, delusions, hallucinations, hypomania, excitement, anxiety, restlessness, peripheral neuropathy, numbness, tingling and paraesthesia of the extremities, ataxia, tremors, coma, convulsions, extra-pyramidal symptoms including abnormal involuntary movements and tinnitus. **Anticholinergic:** Blurred vision, accommodation disturbance, increased intra-ocular pressure, mydriasis, constipation, paralyticileus, urinary retention, urinary tract dilation, hyperpyrexia and dry mouth. **Allergic:** Skin rash, urticarial, photosensitivity, alopecia. **Hematological:** Bone marrow depression including agranulocytosis, eosinophilia and purpura. **Gastro-intestinal:** Nausea, vomiting, diarrhea, weight gain, epigastric distress, anorexia,

dyspepsia, stomatitis, unpleasant taste, parotid swelling, black tongue. **Endocrine :** Gynecomastia, breast enlargement, galactorrhea, testicular swelling, changes in libido, impotence, interference with sexual function, elevation or lowering of blood sugar levels, syndrome of inappropriate ADH secretion. **Other reactions:** Dizziness, weakness, fatigue, headache, urinary frequency and drowsiness. Abrupt withdrawal after prolonged administration has caused nausea, headache and malaise. If any of above the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

5. HOW TO STORE AMITRIPTYLINE TABLETS BP 25 MG

Keep the medicine out reach of children. Store below 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as Amitriptyline hydrochloride BP. Each film-coated tablet contains: Amitriptyline hydrochloride BP 25 mg **Excipients:** Purified Talc, Colloidal Anhydrous silica (Aerosil), Microcrystalline Cellulose (PH 102), Croscarmellose Sodium, Magnesium Stearate, Colour Brilliant Blue(SP), Purified Water. **Shelf life:** 36 Months**. Size:** Oral Tablets, Blue coloured round shaped biconvex, film coated table plain on both sides. Such 10 Tablets are packed in Alu-PVC Blister Pack. Such 10 Blisters are packed in a printed Carton with Packing Insert.

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