SUMMARY OF PRODUCTS CHARACTERISTICS

1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Amileb-25 Tablet**
1.2 Generic Name : **Amitriptyline Tablets BP 25mg**
1.3 Strength : **25mg/ Tablets**
1.4 Pharmaceutical Form: **Oral Tablets**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:
Amitriptyline Hydrochloride BP 25mg
Colour: Color Quinoline Yellow & Titanium Dioxide BP

1.	Amitriptyline HCl
2.	Starch (Maize)
3.	Dibasic Calcium Phosphate
4.	Lactose
5.	Gelatin
6.	Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)
7.	Sod. Propyl Hydroxybenzoate (Sodium Propylparaben)
8.	Purified Talc (Talcum)
9.	Magnesium Stearate
10.	Colloidal Anhydrous Silica (Colloidal Silicon dioxide)
11.	Sodium Starch Glycolate
12.	Hypromellose (HPMC-15cps)
13.	Colour Titanium Dioxide (77891)
14.	Diethyl Phthalate
15.	Colour Quinoline Yellow
16.	Methyl Alcohol
17.	Dichloromethane (Methylene Chloride)

3. PHARMACEUTICAL FORM

Tablet Oral
Yellow round shaped, biconvex film coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Amitriptyline is indicated in symptoms of depression (especially where sedation is required), depressive illness, neuropathic pain & migraine prophylaxis.

4.2 Posology and method of administration

Depression: Adult and Child over 16 years: Initially 75 mg (elderly and adolescents 30–75 mg) daily in divided doses or as a single dose at bedtime, increased gradually as necessary to 150–200 mg;

Child under 16 years: Not recommended for depression.

Nocturnal Enuresis:

Child 7–10 years: 10–20 mg,

11–16 years: 25–50 mg at night; max. Period of treatment (including gradual withdrawal) 3 months: full physical examination before further course.

Neuropathic Pain: Initially 10–25 mg daily at night, increased if necessary to 75 mg daily; Higher doses under specialist supervision.

Migraine prophylaxis: Initially 10 mg at night, increased if necessary to maintenance of 50–75 mg at night, max.150 mg at night.

4.3 Contraindications

Tricyclic and related anti-depressants are contra-indicated in the immediate recovery period after myocardial infarction, in arrhythmias (particularly heart block), and in the manic phase of bipolar disorder. Avoid treatment with tricyclic anti-depressant drugs in acute porphyria.

4.4 Special warnings and special precautions for use

Tricyclic and related antidepressant drugs should be used with cautions in patient with cardiovascular disease because of the risk of arrhythmias, patients with concomitant condition such as hyperthyroidism and phaeochromocytoma should be treated with care. Care is also needed in patients with epilepsy and diabetes. It has antimuscarinic activity and therefore cautions is needed in patients with prostatic hypertrophy, chronic constipation, increased intra-ocular pressure, urinary retention, susceptible to angle closure glaucoma, it should be used caution in patient with the significant risk of suicide, or a history of psychosis or bipolar disorder because antidepressant therapy may aggravate these condition, treatment should be stopped if thepatients enter a manic phase. Elderly patients are particularly susceptible to many of the side effect particularly of psychiatric and cardiac side effect.

Hepatic Impairement: Tricyclic antidepressants should be avoided in severe liver diseases.

CSM ADVICE : Tricyclic and related antidepressant drugs should be used with cautions in patients with cardiovascular disease, antimuscarinic, Elderly patients: Low initial doses should be used, with close monitoring, particularly for psychiatric and cardiac side-effect. Withdraw should be slowly as withdraw symptoms include influenza like symptoms chills, myalgia, sweating, headache, nausea, insomnia, vivid dreams and may occasional include movement disorder and mania. It may affect the performance of skilled tasks (eg. driving)

and effect of alcohol enhanced. Tricyclic antidepressants are not effective for treating depression in children.

4.5 Interaction with other FPPs and Other forms of Interaction

A tricyclic or related antidepressant (or an SSRI or related antidepressant) should not be started until 2 weeks after stopping an MAOI .Conversely, an MAOI should not be started until at least 7–14 days after a tricyclic or related antidepressant has been stopped. It also interact with alcohol, alpha 2-adrenoceptor stimulants, altretamine, analgesics, anaesthetics, anti-arrhythmics, antibacterials, anticholinergics, antihypertensives, antiepileptics, antifungals, antihistamines, antivirals, antipsychotics, beta-blockers, calciumchannel blockers, diuretics, dopaminergics, disulfiram, muscle relaxants, nitrates, oestrogens and progestogens, sibutramine, sympathomimetics, ulcer-healing drugs & anxiolytics and hypnotics.

4.6 Pregnancy and lactation

Pregnancy: Amitriptyline is used only in pregnancy if a potential benefit outweighs risk.

Breast Feeding: The amount of tricyclic antidepressants secreted in to breast milk is too small to be harmful.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Side effects include arrhythmias and heart block, abdomial pain, stomatitis, palpitation, oedema, hypertension, restlessness, fatigue, mydriasis, increase intra-ocular pressure, high rate of fatality in overdose. CNS side effect are common particularly in elderly and include anxiety, dizziness, agitation , confusion, sleep disturbances etc, Antimuscarinic side effect includes dry mouth, blurred vision, constipation and urinary retention, Endocrine effects include breast enlargement, galactorrhoea and gynaecomastia.

Adverse effects include dizziness, headache, weight gain, side effects common to anticholinergics, but more such effects than other tricyclic antidepressants , cognitive effects such as delirium and confusion, mood disturbances such as anxiety and agitation, cardiovascular side effects such as orthostatic hypotension and sinus tachycardia, sexual side effects such as loss of libido and impotence, and sleep disturbances such as drowsiness and insomnia.

4.9 Overdose

Limited quantities of tricyclic anti-depressant should be prescribed at any one time because their cardiovascular and epileptogenic effects are dangerous in over dose. Particularly overdosage with amitriptyline is associated with a relatively high rate of fatality.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antidepressant.

ATC Code: N06AA09

Mechanism of action:

Amitriptyline is 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 noradrenaline and serotonin in the CNS by inhibiting their re-uptake by the pre-synaptic neuronal membrane.

5.2 Pharmacokinetic properties

Amitriptyline is readily absorbed from the GI tract, peak plasma levels occurring within approximately 6 hours of oral administration. Amitriptyline is extensively demethylated in the liver to its primary metabolite, nortriptyline. Paths of metabolism include hydroxylation, oxidation and conjugation with glucuronic acid. It is excreted in the urine, mainly in the form of its metabolites, either free or in conjugated form.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch (Maize)	BP
Dibasic Calcium Phosphate	BP
Lactose	BP
Gelatin	BP
Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)	BP
Sod. Propyl Hydroxybenzoate (Sodium Propylparaben)	BP
Purified Talc (Talcum)	BP
Magnesium Stearate	BP
Colloidal Anhydrous Silica (Colloidal Silicon dioxide)	BP
Sodium Starch Glycolate	BP
Hypromellose (HPMC-15cps)	BP
Colour Titanium Dioxide (77891)	BP
Diethyl Phthalate	BP
Colour Quinoline Yellow	IH
Methyl Alcohol	BP
Dichloromethane (Methylene Chloride)	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36month from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep away from moisture. Keep out of reach of Children.

6.5 Nature and contents of container

10 combipack strips of 2x10 tablets in an inner carton

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

04530/06894/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jun 12, 2019

10. DATE OF REVISION OF THE TEXT

Jun 12, 2019