AMITRIPTYLINE 10 mg, 25 mg AND 50 mg TABLETS

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

1. What AMITRIPTYLINE is and what it is for

AMITRIPTYLINE is used to treat depression.

2. Before you take AMITRIPTYLINE

You may be more likely to think like this:

• depressed and/or have anxiety disorders
• thoughts of suicide and worsening of your depression or anxiety is getting worse, or if they recur
• if you are pregnant or planning to become pregnant
• if you are under 16 years of age.
The maintenance dose is usually 50-100 mg a day, given as a single dose preferably in the evening or at bedtime.

**Effects on the liver:**
Rarely hepatitis (inflammation of the liver), jaundice characterised by yellowing of the skin and whites of the eyes.

**Effects on the hormone system:**
Inappropriate secretion of the antidiuretic hormone.

**Effects on the reproductive system and breast-feeding:**
Testicular swelling, breast enlargement in both men and women, milk production by women even if they are not breast-feeding, and sexual problems.

Other adverse effects include, changes in blood sugar levels and low blood sodium levels, distension, weakness, fatigue, pre-dawn, or needing to pass water often, increased perspiration, hair loss, increased appetite, and weight gain may occur (due to the drug or as a result of the relief of depression).

An increased risk of bone fractures has been observed in patients taking this type of medicines. There have also been reports of breathing problems and agitation in babies whose mothers took this type of drug.

If you are elderly, you are more likely to experience effects of agitation, confusion, low blood pressure on standing causing dizziness, difficult or tiring, or to develop low blood levels of sodium, which can cause tiredness, confusion, muscle twitching and fits.

**How to Store Amitriptyline**
Keep out of the reach and sight of children. The tablets should be stored in the package or container supplied. Do not transfer them to another container.

Do not use Amitriptyline after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Further Information**
What Amitriptyline Tablets contain:
- The active ingredient is amitriptyline hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, calcium phosphate dibasic, ethylcellulose, silica colloidal anhydrous, magnesium stearate, hypromellose (E464), titanium dioxide (E171).
- The 10 mg tablets also contain macrogol, dispersed blue (E131) and titanium dioxide (E171); the 25 mg tablets also contain polyethylene glycol, quinoline yellow, FD and blue 21 (E110); the 50 mg tablets also contain polyethylene glycol and red iron oxide (E172).

What Amitriptyline Tablets look like and contents of the pack:
- Amitriptyline 10 mg Tablets are sky blue, biconvex, film-coated tablets, engraved “D” on one side and plain on the reverse.
- Amitriptyline 25 mg Tablets are yellow, biconvex, film-coated tablets, engraved “D” on one side and plain on the reverse.
- Amitriptyline 50 mg Tablets are red/brown, biconvex, film-coated tablets, engraved “D” on one side and plain on the reverse.
- All strengths of tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 500, or 1500 tablets. The 25 mg tablets are also available in a pack size of 25 tablets, and the 50 mg tablets are also available in a pack size of 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder is Teva Pharmaceutical Industries Ltd, and the Person responsible for manufacture is TEVA UK Limited, Eastbourne, BN22 9AG.

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