ANZACK TABLETS

Fluoxetine Hydrochloride (20mg)

What is in this leaflet

What Anzack Tablets is used for

Fluoxetine is the active ingredient for Anzack Tablets. It is used for the treatment of the symptoms of depressive illness, with or without associated anxiety (feeling of unease, such as worry or fear that can be mild or severe) symptoms. It is also used for obsessive-compulsive disorder (a disorder that characterized by persistent thoughts that lead to repetitive behaviors) and pre-menstrual dysphoric (a condition in which a woman has severe depression symptoms, irritability and tension before menstruation) disorder.

How Anzack Tablets works

Fluoxetine is a selective inhibitor serotonin reuptake and it works by acting on the brain chemicals.

Before you take Anzack Tablets

- *When you must not use it*
  - If you have hypersensitivity to fluoxetine or any of the ingredients.
  - If you have been or are taking monoamine oxidase inhibitors (MAOIs). Please talk to your Pharmacist or Doctor if you are not sure about this.

- *Before you start to use it*

  You must tell your doctor if:
  - You have allergies to any medicine which you have taken previously to treat your current condition.
  - You are pregnant, trying to become pregnant or breast-feeding.
  - You have a history of seizures.
  - You have a history of hypomania (a less severe form of mania) / mania (excitement manifested by mental and physical hyperactivity, disorganization of behavior, and elevation of mood).
  - You have significant liver dysfunction
  - You are diabetic.
  - You have heart problem.
  - You have weight loss.
  - You are taking oral anticoagulant, medications known to affect platelet function, medications that may increase risk of bleeding or have a history of bleeding disorders.
  - You are taking any serotonergic and/or neuroleptic medications. Talk to your Pharmacist or Doctor if you are not sure about this.
  - Pregnancy and lactation

    Pregnancy: fluoxetine can be used during pregnancy but with caution especially during late pregnancy or just prior to the onset of labour, the following effects have been reported in new born infants such as irritability, tremor, low muscle tone, persistent crying, difficult in sucking or in sleeping.

    Lactation: Fluoxetine and its metabolite, norfluoxetine, are known to found in human breast milk. Adverse effects have been reported in breast-feeding infants.

- *Taking other medicines*

  Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription. The following medication interacts with fluoxetine:
  - Monoamine oxidase inhibitors
  - Benzodiazepines – increase in blood concentration of diazepam
  - Tricyclic antidepressants such as nortriptyline, desipramine, imipramine – tricyclic toxicity such as dry mouth, constipation and memory impairment.
  - Phenytoin – changes in blood levels of Phenytoin.
  - Serotonergic medicines (medications that contain serotonin) – increased risk of serotonin syndrome (symptoms may include increased heart rate, shivering, sweating, nausea, diarrhea, tremor, muscle twitching, high blood pressure, high body temperature, agitation, confusion and coma). Use with triptans carries the additional risk of blood vessels narrowing and high blood pressure.
  - Lithium and tryptophan – reports of serotonin syndrome.
  - CYP2D6 isoenzyme metabolised medication such as flecainide, encainide, carbamazepine – dose should be adjusted to the low end of their dose range.
  - Oral anticoagulants – increased bleeding.
  - Alcohol – intake is not advisable
  - St John's Wort – increase of undesirable effects
  - Electroconvulsive therapy (ECT) – rare reports of prolonged seizures in people on fluoxetine receiving ECT treatment.

How to use Anzack Tablets
Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- *How much to use*
  Depression with or without associated anxiety symptoms
  Adults and elderly: 20mg/day is recommended.

  Obsessive-compulsive disorder: 20 to 60mg/day. A dose of 20mg/day is recommended as the initial dose.

  Pre-menstrual Dysphoric Disorder (PMDD) – 20mg/day. Initial treatment should be limited to 6 months, after which individual should be reassessed regarding the benefit of continued therapy.

  Other uses: The recommended dose may be increased or decreased. Doses above 80mg/day have not been evaluated.

  Children:
  The use of Anzack is not recommended as safety and efficacy have not been established.

- *When to use it*
  Your doctor will decide when it is appropriate for you to use Anzack Tablets according to the type of condition you have. The tablet may be taken with or without food.

- *How long to use it*
  Continue taking Anzack Tablets for as long as doctor recommends.

- *If you forget to take it*
  - If you forget a dose, take it as soon as you remember it.
  - However, if it is nearly time for the next dose, skip the missed dose.
  - Do not take a double dose to make up for a forgotten dose.

- *If you use too much (overdose)*
  Contact your doctor immediately or go to Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

  Symptoms: nausea, vomiting, seizures, cardiovascular dysfunction (heart problem), pulmonary dysfunction (lung problem) and signs of altered central nervous system status ranging from exicitation to coma.

While you are using it

- *Things you must do*
  - If you do become pregnant whilst taking Anzack Tablets, tell your doctor.
  - You should discontinue treatment if there is appearance of rash or other allergic phenomena.
  - You should monitor closely for suicide thinking or unusual changes in behavior especially in children and adolescents during the first few weeks of treatment.
  - You should discontinue treatment on the development of serotonin syndrome or neuroleptic malignant syndrome like events – condition characterized by overheating of the body, rigidity, quick, involuntary muscle jerk, autonomic nervous system instability with possible rapid fluctuation of vital signs, mental status changes including confusion, irritability, extreme agitation progressing to delirium (affect the consciousness and thinking ability) and coma.

- *Things you must not do*
  Do not give Anzack Tablets to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Anzack Tablets for you and your condition.

- *Things to be careful of*
  Do not operate any vehicles or machinery as Anzack may impair judgement, thinking or motor skills.

Side effects
Like all medicines, Anzack Tablets can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Body: hypersensitivity (itching, rash, hives), chills, serotonin syndrome, photosensitivity and very rarely toxic epidermal necrolysis (condition that causes large portions of the skin's outermost layer, to detach from the layers of skin below).
- Digestive system: gastro-intestinal disorders such as diarrhoea, nausea, vomiting, dyspepsia (indigestion), dysphagia (difficulty in swallowing), taste perversion (deviate from normal), dry mouth.
- Nervous system: headache, sleep abnormalities, dizziness, anorexia (self-starvation and excessive weight loss), fatigue, euphoria (a feeling of great happiness), transient abnormal movement, seizures and psychomotor restlessness. Hallucinations, manic reactions, confusion, agitation, anxiety, panic attacks and very rarely serotonin syndrome.
- Urogenital system: urinary retention, urinary frequency.
- Reproductive disorders: sexual dysfunction, priapism (condition that causes a persistent, and often painful, penile erection), galactorrhoea (secretion of breast milk in men or in women who are not breastfeeding an infant).

- Hyponatremia (low sodium level in blood): rare and reversible when treatment is discontinued.
- Respiratory system: pharyngitis (throat inflammation), dyspnoea (breathing difficulty). Lung problem have been reported rarely.

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

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Anzack Tablets

- *Storage*
  Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

  Store below 30°C in a well-closed containers. Protect from light, heat and moisture.

  Keep out of the reach and sight of children.

- *Disposal*
  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.

Product Description

- *What it looks like*
  The tablets are round, light green, scored, flat of diameter 7mm with 'MPI' logo.

  They are supplied in 10 x 10's and 100 x 10's blisterpack.

- *Ingredients*
  - Active ingredient
    Each tablet contains active ingredient, fluoxetine hydrochloride equivalent to 20mg of fluoxetine.

  - Inactive ingredient
    The other ingredients are lactose, corn starch, croscarmellose sodium, povidone k-30, magnesium stearate, colloidal silicone dioxide, fast green fcf, quinoline yellow and isopropyl alcohol.

- *MAL number:*
  MAL06071075AZ

Manufacturer and Product Registration Holder
Malaysian Pharmaceutical Industries Sdn. Bhd.
Plot 14, Lebuhraya Kampung Jawa,
11900 Bayan Lepas, Penang, Malaysia.

Date of Revision
23/02/2016

Serial Number:
BPFK(R4/1)230216/00054