#### **SCHEDULING STATUS**

S5

#### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**ZYTOMIL 5 mg** (film coated tablet)

**ZYTOMIL 10 mg** (film coated tablet)

**ZYTOMIL 15 mg** (film coated tablet)

**ZYTOMIL 20 mg** (film coated tablet)

#### Please read this leaflet carefully before using ZYTOMIL tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### 1. WHAT ZYTOMIL CONTAINS

#### **Active ingredient:**

**ZYTOMIL 5 mg:** Each coated tablet contains escitalopram oxalate equivalent to 5 mg

escitalopram.

**ZYTOMIL 10 mg:** Each coated tablet contains escitalopram oxalate equivalent to 10 mg

escitalopram.

**ZYTOMIL 15 mg:** Each coated tablet contains escitalopram oxalate equivalent to 15 mg

escitalopram.

**ZYTOMIL 20 mg:** Each coated tablet contains escitalopram oxalate equivalent to 20 mg

escitalopram.

#### **Inactive ingredients:**

Microcrystalline Cellulose PH112, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Purified Water, Microcrystalline Cellulose PH102, Colloidal Silicon Dioxide, Magnesium Stearate, Polyethylene Glycol 400, Talc, Titanium Dioxide.

#### 2. WHAT ZYTOMIL IS USED FOR

#### **ZYTOMIL** is used for:

- Major depression
- Panic disorders

#### 3. BEFORE YOU USE ZYTOMIL

#### Do not take ZYTOMIL:

- If you are allergic (hypersensitive) to escitalopram or any of the ingredients in the formulation (see "WHAT ZYTOMIL CONTAINS").
- If you are taking any other medication for depression such as monoamine oxidase inhibitors (MAOI). At least 14 days should elapse between stopping such medication and starting with ZYTOMIL.
- If you are born with or have had an episode of abnormal heart rhythm (seen as ECG;
   an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm.
- If you are pregnant or breastfeeding, do not take ZYTOMIL.
- ZYTOMIL must not be used by children under the age of 18 years.

### Take special care with ZYTOMIL:

- If you are an elderly person.
- If you have liver or kidney impairment.
- If you get seizures (epilepsy) or have a history thereof.
- If you have pre-existing slow heart rate.

- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If you are a diabetic (high blood sugar).
- If you have suicidal thoughts.

### Taking ZYTOMIL tablets with food or drink:

The **ZYTOMIL** tablets can be taken with or without food.

### Using other medicines with ZYTOMIL:

- Consult with your doctor or pharmacist or healthcare professional if you need to take
  any other medicines for advice. If you are taking other medicines on a regular basis,
  including complementary or traditional medicines, the use of ZYTOMIL with these
  medicines may cause undesirable interactions.
- Consult your doctor or pharmacist before taking such medicines.
- Do not take any other medications to treat depression (for example monoamine oxidase inhibitors, imipramine, other serotonergic medicines and moclobemide)
   without consulting your doctor as they may interact with ZYTOMIL.
- Do not use alcohol while taking ZYTOMIL.
- ZYTOMIL may interact with medicines used to treat blood clotting such as warfarin consult your doctor if you are or have to use such medications.
- Medications used to treat heart burn or stomach ulcer such as cimetidine interacts
   with the breakdown of escitalopram, and the dose of ZYTOMIL should be changed.

### **Pregnancy and Breastfeeding**

**DO NOT** use **ZYTOMIL** if you are pregnant or suspect that you are pregnant. Contact your doctor immediately.

**DO NOT** use **ZYTOMIL** if you are breast-feeding.

## **Driving and using machinery:**

**ZYTOMIL** may impair your ability to drive and use machinery, do take care if you feel dizzy, tired or drowsy while using **ZYTOMIL**.

#### 4. HOW TO TAKE ZYTOMIL

The recommended dosage of **ZYTOMIL** is one tablet once a day either in the morning or the evening with or without food.

The dose of **ZYTOMIL** will be different for different patients and may depend on a number of things, including what the medicine is being used for, and whether or not other medicines are also being taken. If you have any questions about the proper dose of **ZYTOMIL**, ask your doctor.

#### If you take more ZYTOMIL than you should:

In the event of overdose, your doctor will treat the symptoms of the side effects which may include increasing tiredness, weakness, sedation, dizziness, tremor, nausea, somnolence and increase heart rate.

#### If you forget to take your ZYTOMIL:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time.

Do not stop taking your medication abruptly. Your doctor will prescribe the gradual lowering of the dose.

#### 5. POSSIBLE SIDE-EFFECTS

**ZYTOMIL** as all other medicines may have side effects. Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following side-effects continue or are bothersome:

### Frequent

- Abnormal heart rate, tremor
- Sweating
- Weight changes
- Nausea, constipation, diarrhoea, dyspepsia (disturbed digestion and/or bloatedness),
   dry mouth
- Sleep disturbances, restlessness, tiredness, dizziness, weakness
- Urinary disorders
- Headache

Other side-effects may include:

- Agitation, confusion, impaired concentration, mania, convulsions (seizures)
- Nasal congestion
- Yawning

### 6. STORAGE AND DISPOSAL OF ZYTOMIL

- Store at or below 25 °C. Protect from light.
- Keep blisters in outer carton until required for use.
- Keep bottles tightly closed.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)
- KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.