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## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

**S5**

### **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**ZOLID 50 mg (Tablet)**

**ZOLID 100mg (Tablet)**

Sertraline Hydrochloride

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ZOLID** 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 ZOLID CONTAINS**

The active substance is Sertraline Hydrochloride.

#### **ZOLID 50 mg:**

Each film-coated tablet contains Sertraline Hydrochloride equivalent to Sertraline 50 mg.

#### **ZOLID 100 mg:**

Each film-coated tablet contains Sertraline Hydrochloride equivalent to Sertraline 100 mg.

The other ingredients are Calcium hydrogen phosphate dihydrate, Hydroxypropylcellulose, Magnesium Stearate, Microcrystalline cellulose, Opadry White OY-S-7355 and Sodium starch glycolate.

### **2. WHAT ZOLID IS USED FOR**

**ZOLID** is a psychoanaleptic (antidepressant) medicine used for the treatment of major depressive disorders such as single episodes and recurrent depression, obsessive compulsive disorder and panic

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disorder.

Panic disorder:

Panic disorder is characterised by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and by a significant change in behaviour related to the attacks.

Panic disorder is characterised by recurrent unexpected panic attacks, i.e., a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: (1) palpitations, pounding heart, or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, lightheaded, or faint; (9) derealisation (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of losing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes.

### **3. BEFORE YOU TAKE ZOLID**

**Do not take ZOLID**

If you are hypersensitive (allergic) to Sertraline Hydrochloride or any of the other ingredients of **ZOLID**.

If you are using a monoamine oxidase inhibitor (MAOI).

If you are a child under the age of 18 years.

**Take special care with ZOLID:**

- If activation of mania/hypomania occurs when treated with other antidepressants and antiobsessional agents.
- If significant weight loss is undesirable.
- **ZOLID** should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. **ZOLID** should be discontinued if you develop seizures.
- If there is a possibility of a suicide attempt.
- If you have liver disease, a lower or less frequent dose should be considered.
- If you have kidney disease, the dose of **ZOLID** may have to be reduced.

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Abrupt discontinuation of **ZOLID** may lead to withdrawal symptoms which include dizziness, sweating, nausea, insomnia, tremor, confusion, sensory disturbances, agitation and anxiety.

**Investigations:**

Asymptomatic elevations of serum transaminases (SGOT and SGPT) have been reported infrequently (approximately 0, 8%) in association with **ZOLID** therapy. There have been rare reports of altered platelet function and/or abnormal clinical laboratory results in patients taking **ZOLID**.

Hyponatraemia, possibly due to inappropriate antidiuretic hormone secretion, has been associated with the use of antidepressants, particularly in the elderly.

**Taking ZOLID with food and drink:**

Take **ZOLID** tablets as a single daily dose with or without food.

**Pregnancy and Breastfeeding:**

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

**Driving and using machinery:**

Exercise caution when driving a car or operating machinery.

**Taking other medicines with ZOLID:**

**Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).**

**ZOLID** interacts with MAOI's (including selegiline and moclobemide), tryptophan, fenfluramine, CNS depressants and alcohol, diazepam, tolbutamide and warfarin.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ZOLID** with these medicines may cause undesirable interactions. Please consult your doctor,

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pharmacist or other healthcare professional, for advice.

#### **4. HOW TO TAKE ZOLID**

Do not share medicines prescribed for you with any other person.

Always take **ZOLID** exactly as your doctor has instructed you, You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ZOLID** is too strong or too weak, talk to your doctor or pharmacist.

**ZOLID** tablets should be given as a single daily dose with or without food.

##### Depression

The starting dose is 50 mg daily and the usual therapeutic dose in depression is 50 mg daily. In difficult to treat patients, the dose may be titrated up in 50 mg increments at 2 weekly intervals, to 150 mg - 200 mg.

##### Obsessive-Compulsive Disorders (OCD)

The minimum effective dose in OCD is also 50 mg daily and increases above 100 mg daily does not have any additional benefit. Full activity is usually seen after 2—4 weeks and even longer in COD. Effect may however be seen within 7 days.

##### Panic Disorder

For panic disorder, the minimum recommended effective dose of sertraline is 50 mg/day. However, therapy for panic disorder should commence at 25 mg/day, increasing to 50 mg/day after one week. This dosage regimen has been demonstrated to reduce the frequency of early treatment emergent side effects characteristic of panic disorder.

Use in the elderly - No special precautions are required. The usual adult dosage is recommended.

Use in children - The use of **ZOLID** in children is not recommended as safety and efficacy have not been established.

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Use in hepatic and renal impairment - check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **ZOLID** will last. Do not stop treatment early, without consulting your healthcare professional.

**If you take more ZOLID than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take ZOLID:**

Do not take a double dose to make up for forgotten individual doses.

**POSSIBLE SIDE EFFECTS**

**ZOLID can have side effects.**

Gastrointestinal disorders:

**Less Frequent:** Constipation, diarrhoea, nausea, vomiting, dyspepsia, flatulence, anorexia, abdominal pain, appetite increased, dry mouth, taste perversion.

Nervous system disorders:

**Less Frequent:** Headache, paresthesia, hypoesthesia, twitching, hypertonia, tremor; dizziness, insomnia, somnolence, convulsions.

Cardiac disorders: Palpitations

Skin and subcutaneous tissue disorders: Rash, erythema multiforme.

General disorders: Fatigue, increased sweating, hot flushes, fever, back pain.

Metabolism and nutrition disorders: Thirst.

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Musculoskeletal, connective tissue and bone disorders: Myalgia arthralgia, movement disorders (such as gait abnormalities).

Psychiatric disorders: Agitation, nervousness, anxiety, yawning, impaired concentration, psychosis, depressive symptoms, hallucinations, aggressive reaction, agitation.

Renal and urinary disorders: Micturition frequency, micturition disorder, urinary retention.

Hepato-biliary disorders: Pancreatitis and serious liver events (including hepatitis, jaundice and liver failure).

Reproductive system and breast disorders:

Menstrual Symptoms, female sexual dysfunction, sexual dysfunction (primarily ejaculatory delay in males).

Respiratory, thoracic and mediastinal disorders: Rhinitis, pharyngitis.

Eye disorders: Vision abnormal.

Ear and labyrinth disorders: Tinnitus.

Not all side effects reported for **ZOLID** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ZOLID**, please consult your doctor, pharmacist or other healthcare professional for advice.

## **6. STORING AND DISPOSING OF ZOLID**

Store all medicines out of the reach of children.

Store at or below 25 °C. Protect from light. Keep blisters in the carton until required for use.

Return all unused medicine to your pharmacist.

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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF ZOLID**

Two types of blister packaging material:

1. Tablets are packed in Clear PVC (250 microns) as the forming material and aluminium foil (25 microns) as the Adding material. Each blister contains 10 tablets.
2. Tablets are packed in Clear PVC (250 microns) coated with PVdC (60gsm) as the forming material and aluminium foil (25 microns) as the lidding material. Each blister contains 10 tablets.

ZOLID 50 mg: 30's (3 x 10's)

ZOLID 100 mg: 30's (3 x 10's)

## **8. IDENTIFICATION OF ZOLID**

**ZOLID 50 mg** - White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '8' and '1' on the other side.

**ZOLID 100 mg**- White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and '82' on the other side.

## **9. REGISTRATION NUMBER**

**ZOLID 50 mg:** 41/1.2/0584.

**ZOLID 100 mg:** 41/1.2/0585.

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

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## **11. DATE OF PUBLICATION**

Date of registration: 14 March 2013

Date of latest revision of the text as approved by Council: 20 May 2014

Date of notification with regard to amended Reg. 9 and 10: 23 January 2015