

**PATIENT INFORMATION LEAFLET  
DYNA SERTRALINE**

**SCHEDULING STATUS**

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**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM****DYNA SERTRALINE 50** film coated tablets**DYNA SERTRALINE 100** film coated tablets

**Read this entire 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 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 DYNA SERTRALINE CONTAINS*****Active ingredient:***

**DYNA SERTRALINE 50:** Each film coated tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

**DYNA SERTRALINE 100:** Each film coated tablet contains sertraline hydrochloride equivalent to 100 mg sertraline.

***Inactive ingredients:*** Calcium hydrogen phosphate anhydrous, microcrystalline cellulose, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, Opadry Blue (containing hypromellose, titanium dioxide, macrogol, polysorbate, FD&C Blue / Indigo Carmine Aluminium) as the colouring agent for **DYNA SERTRALINE 50** and Opadry Yellow (containing hypromellose, titanium dioxide, macrogol, iron oxide yellow, polysorbate) as the colouring agent for **DYNA SERTRALINE 100**.

**DYNA SERTRALINE 50** and **DYNA SERTRALINE 100** is sugar free.

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## **2. WHAT DYNA SERTRALINE IS USED FOR**

**DYNA SERTRALINE** is indicated for the treatment of:

- Depression
- Obsessive compulsive disorder (OCD)
- Panic disorder and post-traumatic stress disorder

## **3. BEFORE YOU USE DYNA SERTRALINE**

**Do not take this medicine if:**

- You are allergic (hypersensitive) to any of the ingredients in this medicine (see **WHAT DYNA SERTRALINE CONTAINS**).
- You are using a monoamine oxidase inhibitor (MAOI) for used in the treatment of depression such as procarbazine or selegiline.

***The use of MAO inhibitors and DYNA SERTRALINE is contra-indicated. A wash-out period of at least 14 days should elapse between the last dose of the old medication and the first dose of the new medication.***

- You have a liver or kidney disorders or disease.
- You are pregnant or breastfeeding a baby.
- You are under the age of 18 years.

**Talk to your doctor before taking DYNA SERTRALINE if you or the person taking this medicine if:**

- You have suicidal tendencies
- You have hypomania or mania
- You have epilepsy and/or seizures
- You have a kidney or liver disorder
- You have a recent history of heart disease or had a heart attack
- You are taking central nervous system depressants and/or alcohol

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- You have a problem with low body weight

### **Taking DYNA SERTRALINE with food or drink:**

**DYNA SERTRALINE** may be taken with or without food.

### **Pregnancy and breastfeeding**

**Do not** use **DYNA SERTRALINE** if you are pregnant or suspect that you are pregnant.

Contact your doctor or healthcare professional immediately.

**Do not** use **DYNA SERTRALINE** if you are breastfeeding.

### **Driving and using machines**

If you suffer from seizures, dizziness, headaches, tiredness or nausea make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

### **Using other medicines with DYNA SERTALINE**

If you are taking other medicines on a regular basis including complementary medicines together with **DYNA SERTALINE**, it may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Do not take **DYNA SERTRALINE** with the following medication:

- Moclobemide, procarbazine, selegiline, tryptophan (used in the treatment of depression)
- Fenfluramine (used in the treatment of obesity)
- Diazepam (used for the short-term relief of symptoms related to anxiety disorders)
- Tolbutamide (used in the treatment of high blood sugar or diabetes)
- Warfarin (used to thin the blood)

Care should also be exercised when switching from one antidepressant to another, particularly from switching from long-acting medicines such as fluoxetine.

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#### **4. HOW TO TAKE DYNA SERTRALINE**

The dose of **DYNA SERTRALINE** will be different for each patient and depends on what the medicine is being used for and if other medicines are also being used at the same time. Your doctor will decide the appropriate dose for your condition. If you have any questions about the proper use of **DYNA SERTALINE**, ask your doctor or pharmacist.

The tablets should be swallowed whole with a glass of water and should be taken the same time each day. It is important to keep taking your medicine for as long as your doctor prescribes them.

**Do not stop taking your medicine without consulting your doctor first.**

#### **Treatment of Depression:**

The recommended dose is one **DYNA SERTRALINE 50** tablet daily. If necessary your doctor may increase the dose to up to two **DYNA SERTRALINE 100** tablets daily – do not make any dose adjustments by yourself, your doctor or healthcare professional will know the correct dosage for your condition.

#### **Treatment of Obsessive-Compulsive Disorder**

The recommended dose is one **DYNA SERTRALINE 50** tablet daily. The dosage may be increased after several weeks if your doctor decides it is necessary.

#### **Treatment of Panic Disorder or Posttraumatic Stress Disorder**

The recommended dose is one **DYNA SERTRALINE 50** tablet daily.

The recommended starting dose for panic disorder is half of a **DYNA SERTRALINE 50** tablet (25mg), which may be increased to one **DYNA SERTRALINE 50** tablet after one week.

**Use in the elderly** –The usual adult dosage is recommended.

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**Use in children** – The use of **DYNA SERTRALINE** in children is not recommended.

### **If you forget to take DYNA SERTALINE:**

If you miss a dose, take it as soon as you remember. Do not take **DYNA SERTRALINE** if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of **DYNA SERTRALINE** at the same time.

### **If you take more DYNA SERTRALINE than you should:**

In the event of over dosage, consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

## **5. POSSIBLE SIDE EFFECTS**

**DYNA SERTRALINE** may cause side effects in some patients.

***Not all side-effects reported for DYNA SERTRALINE tablets are included in this leaflet.***

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

*The following more frequent side-effects may occur:*

- Headaches, dizziness, nervousness, tremors, sleep disorders.
- Weight loss, thirst, diarrhoea, nausea, vomiting, stomach disorders and bloatedness.
- Sexual disorders (loss of sexual appetite in women, delay in ejaculation in men).
- Skin rash, itching, hives, increased sweating
- Twitching, seizures, difficulty to concentrate, anxiety
- Weight loss, constipation, increased appetite, stomach pain
- Urinary disorders, dry mouth
- Joint pain, muscle pain, back pain
- Visual disturbances, ringing in the ears, taste disorders
- Fever, hot flushes

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- Tiredness, yawning

**6. STORAGE AND DISPOSAL OF DYNA SERTALINE**

Store at or below 25 °C. Store in a cool dry place

Do not remove the blisters from the carton until required for use

Do not use **DYNA SERTRALINE** tablets after the expiry date printed on the blister strip or carton

Return all expired or unused medicine to your pharmacist for safe disposal

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

**KEEP DYNA SERTRALINE TABLETS OUT OF THE REACH AND SIGHT OF CHILDREN.**