APPR2OVED PATIENT INFORMATION LEAFLET

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RECITA 10 mg (Tablet)

RECITA 20 mg (Tablet)

RECITA 40 mg (Tablet)

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

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- **RECITA** 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 RECITA CONTAINS

RECITA 10 mg:

Each film-coated tablet contains citalopram hydrobromide corresponding to 10 mg of citalopram.

RECITA 20 mg:

Each film-coated tablet contains citalopram hydrobromide corresponding to 20 mg of citalopram.

RECITA 40 mg:

Each film-coated tablet contains citalopram hydrobromide corresponding to 40 mg of citalopram.

The other ingredients are cellulose microcrystalline, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate and maize starch. The coating material contains hypromellose, macrogol 400 and titanium dioxide (C.I number: 77891).

2. WHAT RECITA IS USED FOR

RECITA is a psychoanaleptic medicine used for the following:

Treatment of depression and prevention of relapse.

Treatment of panic disorder with or without agoraphobia which is the irrational fear of open or public spaces.

Treatment of obsessive compulsive disorder (OCD).

3. BEFORE YOU TAKE RECITA

Do not take RECITA:

- if you are hypersensitive (allergic) to citalopram hydrobromide or any of the other ingredients of **RECITA**.
- if you have severely impaired kidney function (creatinine clearance of less than 20 ml/min).
- if you have an inborn heart condition where you may have irregular heartbeats (QT-prolongation).
- if you are taking medicines that may prolong the QT interval.
- if you are taking medicines that fall into the class of monoamine oxidase inhibitors which are commonly used to treat depression.
- if you are pregnant or breast-feeding.
- if you are younger than 18 years.

Take special care with RECITA:

Tell your doctor:

- If you enter the manic phase and are suicidal.
- If you suffer from epilepsy or a history of such disorders (avoid **RECITA** if the epilepsy is poorly controlled).
- If you suffer from congestive heart failure, slow heartbeats or if you are taking any another medication that affects your heartbeat, you need to be monitored closely by your doctor and undergo regular ECG monitoring.
- If you suffer from liver problems as your dose needs to be lowered accordingly.
- If you have a slow heart rate.
- If you suffer from diabetes mellitus as it may cause a rare occurrence of hypoglycaemia where your blood sugar drops too low.

- If you are taking a medicine known as pimozide, which is used as an antipsychotic medicine as it may further prolong your QT interval of your heart beat when taken with **RECITA**.
- If you taking other serotonergic medicines or medicines with serotonergic activity for example linezolid (an antibiotic), St. John's Wort (a herbal remedy used to treat depression), as it may increase your risk of developing a condition known as serotonin syndrome which may be fatal when taken with **RECITA.**

Pregnancy and Breast-feeding

Safety in pregnancy and lactation has not been established. Infants exposed to citalopram in late pregnancy may have an increased risk for persistent pulmonary hypertension and other respiratory complications. Therefore if you are pregnant, your physician should carefully consider both the potential risks and benefits of treatment before prescribing **RECITA.**

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **RECITA**.

Important information about some of the ingredients of RECITA:

RECITA contains lactose and should not be taken if you are lactose intolerant or suffer from a condition called Lapp lactase deficiency or glucose-galactose malabsorption.

Driving and using machinery:

The potential for dizziness, impaired concentration, confusion and headache should be taken into account before patients on **RECITA** drive or use machinery.

Taking other medicines with RECITA:

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

Tell your doctor if you are taking the following medicines:

- Medicines known as monoamine oxidase inhibitors (MAOI), which are commonly used to treat depression as it may cause serious or life-threatening reactions.
- Imipramine, a medicine used for depression. This may cause an increase in the effect of imipramine.
- Other serotonergic medicines or medicines with serotonergic activity for example linezolid (an antibiotic), St. John's Wort (a herbal remedy used to treat depression), moclobemide (a MAOI used for depression) with **RECITA** it may increase your risk of developing serotonin syndrome which may be fatal.
- Warfarin (a medicine used to prevent the clotting of blood).
- Cimetidine (used for the treatment of heartburn and peptic ulcers).
- Medicines that prolong your QT interval of your heart beat for example pimozide, used as an antipsychotic medicine, it may further prolong your QT interval.
- The effects of alcohol may be increased if taken with **RECITA**.

4. HOW TO TAKE RECITA

Always take **RECITA** 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 **RECITA** is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

Adults:

Treating depression

You doctor will determine your correct dose for your condition.

The usual starting dose is 20 mg daily. Dependent on individual patient response this may be increased to a maximum of 40 mg daily.

Swallow the tablet, do not chew. The daily single dose may be taken in the morning or evening, not necessarily with food.

Your doctor will determine how long you should use **RECITA** depending on your condition.

If you take more RECITA than you should:

Overdosage may result in tiredness, weakness, sedation, dizziness, tremor, nausea and somnolence.

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 RECITA:

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

5. POSSIBLE SIDE EFFECTS

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

RECITA can have side-effects.

If you experience any of the following side effects please contact your doctor or go to your nearest hospital immediately:

- A sudden allergic reaction which may cause an itchy rash and/ or swelling of the face or throat which causes difficulty breathing.
- Chest pain, fast or slow heartbeat, shortness of breath, dizziness or fainting as it may indicate that you have a change in the electrical activity of your heart caused by QT prolongation or Torsades de Pointes.
- Serotonin syndrome which may manifest with the following symptoms: agitation, hallucinations, coma or other changes in mental status, co-ordination problems, muscle twitching, sweating, vomiting or diarrhoea.

If you experience the following side effects, you should contact your doctor as soon as possible:

- Sleep disturbances and difficulty sleeping
- “Pins and needles” feeling through your body
- Fatigue

- Restlessness
- Headache
- Confusion
- Impaired concentration
- Convulsions/ fits
- Changes in your weight
- Dry mouth
- Constipation or diarrhoea
- Digestion problems such as bloated feeling, heart burn, pain in the upper abdomen
- Problems during urination
- Sexual dysfunction such as decreased libido, decreased libido, problems with ejaculation, inability to orgasm
- Eye disturbances
- Nasal congestion
- Yawning
- Suicidal thoughts

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF RECITA

Store all medicines out of the reach of children.

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

Keep the HDPE container well closed. The blister strips must not be removed from the carton until required for use.

Return all unused medicine to your pharmacist.

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

Do not use after the expiry date stated on the carton.

7. PRESENTATION OF RECITA

RECITA 10 mg:

1. Blisters:

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC and Printed Aluminium foil with 7 gsm Heat seal Lacquer. Each blister contains 10 and 14 tablets.

Pack size: **30's & 28's** – Each carton contains 3 blisters of 10 tablets and 2 blisters of 14 tablets each.

2. Containers:

Tablets are packed in 40 ml white opaque colour HDPE container of 33 mm neck finish (OFC 51 ml) with a white opaque polypropylene stock ribbed closure with wad having induction sealing liner. The void space of the container is filled with Rayon Coil. Each container contains 30 tablets.

Pack size: **30's -** One HDPE container of 30 tablets

RECITA 20 mg:

Tablets are packed in Clear PVC (250 microns) coated with PVdC (60 gsm) as the forming material and aluminium foil (25 microns) as the lidding material. Each blister contains 14 tablets.

Pack size: **28's** – Each carton contains 2 blisters of 14 tablets each.

RECITA 40 mg:

1. Blisters:

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC (width 188 mm) and Printed Aluminium foil with 7 gsm Heat seal Lacquer coating. Each blister contains 10 and 14 tablets.

Pack size: **30's & 28's** – Each carton contains 3 blisters of 10 tablets and 2 blisters of 14 tablets each.

2. Containers:

Tablets are packed in 40 ml white opaque colour HDPE container of 33 mm neck finish (OFC 51 ml) with a white opaque polypropylene stock ribbed closure with wad having induction sealing liner. The void space of the container is filled with Rayon Coil. Each container contains 30 tablets.

Pack size: 30's - One HDPE container of 30 tablets

8. IDENTIFICATION OF RECITA

RECITA 10 mg: White coloured, biconvex, round shaped film coated tablets debossed with 'A' on one side and '05' on the other side.

RECITA 20 mg: White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '0' and '6' on the other side.

RECITA 40 mg: White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '0' and '7' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

RECITA 10 mg: 42/1.2/0855

RECITA 20 mg: 42/1.2/0531

RECITA 40 mg: 42/1.2/0856

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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