PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MYTRA 15 (**mirtazapine** 15 mg tablet)

MYTRA 30 (**mirtazapine** 30 mg tablet)

Read all of this leaflet carefully before you start taking MYTRA

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

MYTRA 15 and **MYTRA 30**

The active ingredient of each film-coated tablet is 15 mg or 30 mg mirtazapine respectively.

The other ingredients are:

Core: Hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, silica, colloidal anhydrous.

Coating 15 mg tablet: Opadry Yellow 20A52560 which consists of hydroxypropyl cellulose, hypromellose, iron oxide yellow (E 172), titanium dioxide.

Coating 30 mg tablet: Opadry Brown 20A56788 which consists of hydroxypropylcellulose, hypromellose, iron oxide black (E 172), iron oxide yellow (E 172), iron oxide red (E 172), titanium dioxide.

MYTRA contains sugar (lactose monohydrate).

2. WHAT IS MYTRA USED FOR

MYTRA is used to:

Treat depressive illness (**MYTRA** belongs to a group of medicines called antidepressants).

3. BEFORE YOUR TAKE MYTRA

Do not take MYTRA:

- If you are hypersensitive (allergic) to mirtazapine or any of the other ingredients of **MYTRA**.
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).
- If you are pregnant or breastfeeding.
- If you are under 18 years of age.

Take special care with MYTRA:

Thoughts of suicide and worsening of your depression

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants such as **MYTRA**, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital

straight away.

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Also take special care with **MYTRA**

If you have, or have ever had one of the following conditions:

- seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking **MYTRA** and contact your doctor immediately;
- liver disease, including jaundice. If jaundice occurs, stop taking **MYTRA** and contact your doctor immediately;
- kidney disease;
- eye disease, such as increased pressure in the eye (glaucoma);
- difficulty in passing water (urinating), which might be caused by an enlarged prostate;
- heart disease, or low blood pressure;
- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines);
- schizophrenia. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away;
- manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking **MYTRA** and contact your doctor immediately;
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking **MYTRA** and consult your doctor immediately for a blood test. In rare cases these symptoms can be signs of disturbances in blood cell production in the bone marrow. While rare, these symptoms most commonly appear after 4 - 6 weeks of treatment;
- if you are an elderly person. You could be more sensitive to the side-effects of antidepressants.

Taking MYTRA with food or drink:

You may get drowsy if you drink alcohol while you are taking **MYTRA**. You are advised not to drink any alcohol when taking **MYTRA**.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professionals for advice before taking **MYTRA**.

You should not take **MYTRA** if you are pregnant or breastfeeding (refer to **Do not take MYTRA**).

Driving and using machinery:

MYTRA can affect your concentration or alertness. Patients should not drive or use machines until they have determined how they are affected.

Important information about some of the ingredients of MYTRA:

MYTRA contains lactose and should not be taken by patients who have inherited problems such as intolerance to some sugars, Lapp lactose deficiency (this is when the body is unable to digest milk or milk products due to lack of an enzyme) or glucose galactose malabsorption.

Taking other medicines with MYTRA:

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

MYTRA may interact with the following medicines:

Do not take Mirtazapine in combination with:

- **Monoamine oxidase inhibitors (MAO inhibitors).** Also, do not take **MYTRA** during the two weeks after you have stopped taking MAO inhibitors. If you stop taking **MYTRA**, do not take MAO Inhibitors during the next two weeks either. Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking **MYTRA** in combination with:

- **Antidepressants such as SSRIs**, **venlafaxine** and **L-tryptophan**, or **triptans** (used to treat migraine), **tramadol** (a pain-killer), **linezolid** (an antibiotic), **venlafaxin**e (used to treat depression), **lithium** (used to treat some psychiatric conditions) and **St. John's Wort** - *Hypericum perforatum* preparations (a herbal remedy for depression). In very rare cases **MYTRA** alone or the combination of **MYTRA** with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.
- **Warfarin** - medicines to prevent blood clotting. **MYTRA** can increase the effects of warfarin on the blood.
- **Carbamazepine and phenytoin** (medicines for epilepsy), **rifampicin** (medicines for tuberculosis). In combination with **MYTRA** these medicines can reduce the amount of **MYTRA** in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of **MYTRA**, or when these medicines are stopped to lower the dose of **MYTRA** again.
- **Ketoconazole** (medicines for fungal infections), **cimetidine** (medicines for treating and preventing stomach ulcers or treating gastroesophageal reflux disease), **erythromycin** (medicines for bacterial infections), **HIV protease inhibitors**, (medicines for HIV/AIDS), **nefazodone**

(antidepressant). It can increase the amount of **MYTRA** in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of **MYTRA**, or when use of nefazodone is stopped, to increase the dose of **MYTRA** again.

4. HOW TO TAKE MYTRA

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

Always take **MYTRA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting dose is 15 or 30 mg every day. Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day). The dose is usually the same for all ages.

However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

Your doctor will tell you how long your treatment with **MYTRA** will last.

If you have the impression that the effect of **MYTRA** is too strong or too weak, tell your doctor or pharmacist.

If you take more MYTRA 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.

The most likely signs of an overdose of **MYTRA** tablets (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate.

If you forget to take a dose of MYTRA:

If you forget to use a dose of **MYTRA**, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with MYTRA is stopped:

Do not stop taking **MYTRA** without talking to your doctor.

If you stop too early, your depression might come back. Once you are feeling better, talk to your doctor. Your doctor will decide when treatment can be stopped. Do not suddenly stop taking **MYTRA** tablets, even when your depression has lifted. If you suddenly stop taking **MYTRA** tablets you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

5. POSSIBLE SIDE EFFECTS

MYTRA can have side effects.

Not all side effects reported for **MYTRA** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **MYTRA**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking **MYTRA** and contact your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- A rash or itching
- Fainting

- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MYTRA**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Increase in appetite and weight gain
- Abnormal dreams, confusion
- Anxiety, inability to sleep
- Drowsiness
- Headache
- Lack of energy
- Shakiness (tremor)
- Dry mouth
- Constipation
- Nausea, vomiting
- Diarrhoea
- Tiredness.

Less frequent side effects

Deficiency of granulocytes in the blood, causing increased vulnerability to infection

- Reduced levels of sodium in your blood
- Feeling elated or emotionally 'high' (mania) – stop taking **MYTRA** and tell your doctor straight away

- Nightmares, feeling agitated, hallucinations, urge to move
- Feelings of anger
- Abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- Restless legs
- Convulsions or fits
- Muscle twitching or contractions
- Spinning feeling, feeling agitated
- Low blood pressure
- Feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
- Sensations of numbness in the mouth (oral hypoaesthesia)
- Thirst
- Inflammation of the pancreas
- Rash or skin eruptions (exanthema)
- Pain in your joints (arthralgia), muscles (myalgia) and back pain
- Abnormal physical weakness
- Flu like symptoms and increased sweating.

Side effects of unknown frequency

- Disturbances in the production of blood cells (bone marrow depression).
- Some people become less resistant to infection because **MYTRA** can cause a temporary shortage of white blood cells (granulocytopenia).
- Shortage of red and white blood cells, as well as blood platelets (aplastic anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia).

- Inappropriate anti-diuretic hormone secretion.
- Thoughts of harming or killing yourself – contact your doctor or go to a hospital straight away.
- Combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. In very rare cases these can be signs of serotonin syndrome.
- Abnormal sensations in the mouth (oral paraesthesia).
- Motor speech disorder.
- Bitter taste in mouth, increased saliva.
- Skin blistering, localised eruption of the skin.
- Dissolution of skeletal muscle.
- Urinary retention.
- Sleepwalking.
- Increase in liver enzymes or creatinine kinase (an enzyme elevated after heart attacks, when the heart muscle is damaged).

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

6. STORING AND DISPOSING OF MYTRA

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25°C.
- Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.
- Do not use after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF MYTRA

Tablets are packed in clear PVC (250 µm) coated with PVdC (60 gm^2) as the forming material and aluminium foil (25 µm) as the lidding material, in the following pack sizes:

MYTRA 15: 30's

MYTRA 30: 30's

8. IDENTIFICATION OF MYTRA

MYTRA 15: Yellowish, biconvex, capsule shaped, film-coated tablets with a score line in between 0 and 8 on one side and "A" debossed on the other side.

MYTRA 30: Reddish brown, biconvex, capsule shaped, film-coated tablets with a score line in between 0 and 9 on one side and "A" debossed on the other side.

9. REGISTRATION NUMBER

MYTRA 15: A40/1.2/0652

MYTRA 30: A40/1.2/0653

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

To be allocated.