PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

THRYVE 5, THRYVE 10 and THRYVE 15

(uncoated tablets)

Aripiprazole tablets Contains: Lactose

Read all of this leaflet carefully before you start taking THRYVE

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **THRYVE** 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.

What is in this leaflet

1. What **THRYVE** is and what it is used for
2. What you need to know before you take **THRYVE**
3. How to take **THRYVE**
4. Possible side effects

5 How to store **THRYVE**

6. Contents of the pack and other information

1. WHAT THRYVE IS AND WHAT IT IS USED FOR:

THRYVE contains the active substance aripiprazole

and belong to a group of medicines called antipsychotics. It is used to treat adults and adolescents aged 18 years and older who suffer from a disease characterised by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

THRYVE is used to treat adults who suffer from a condition with symptoms such as feeling “high”, having excessive amounts of energy, needing much

less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It also prevents this condition from returning in patients who have responded to the treatment with **THRYVE**

2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE THRYVE:**

Do not take THRYVE:

- If you are allergic to aripiprazole or any of the other ingredients of **THRYVE.**
- If you are under the age of 18 years.

Warnings and precautions

Take Special Care with **THRYVE:**

Suicidal thoughts and behaviours have been reported during aripiprazole treatment. Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself**.**

Before you start taking THRYVE, tell your doctor if you suffer from any of the following:

- If you have high blood sugar (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, and feeling weak) or family history of diabetes
- If you suffer from fits (seizures)
- Involuntary, irregular muscle movements, especially in the face.
- If you have muscle stiffness or inflexibility with high fever, sweating, altered mental status
- If you have cardiovascular disease (diseases of the heart and circulation),
- family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure, or very rapid or irregular heartbeat.

Tell your doctor, pharmacist, nurse or other health care provider:

- If you have blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- If you have a past experience of excessive gambling
- If you notice you are gaining weight, develop unusual movements, experience tiredness, sleepiness that interferes with normal daily activities, any difficulty

in swallowing or allergic symptoms (such as rash, swelling or difficulty to breathe), please tell your doctor.

- If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your care giver/relative should tell your doctor if you have ever had a stroke or "mini" stroke.
- If you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat.
- if you or your family/caregiver notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

THRYVE may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.

Other medicines and THRYVE

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

Blood pressure-lowering medicines: **THRYVE** may increase the effect of medicines used to lower the blood pressure.

Taking **THRYVE** with some medicines may mean the doctor will need to change your dose of **THRYVE** or the other medicines. It is especially important to tell your doctor if you are taking any of the following medicines:

- medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide)
- antidepressants or herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, venlafaxine, St. John’s Wort)
- antifungal medicines (such as ketoconazole, itraconazole)

- certain medicines to treat HIV infection (such as efavirenz, nevirapine, and protease inhibitors e.g. indinavir, ritonavir)
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenytoin, phenobarbital)
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin)

These medicines may increase the risk of side effects or reduce the effect of **THRYVE**; if you get any unusual symptom taking any of these medicines together with **THRYVE** you should see your doctor.

Tell your doctor, pharmacist or healthcare worker if you are taking medicines for depression, generalised anxiety disorder, obsessive-compulsive disorder (OCD) and social phobia as well as migraine and pain. This include:

- triptans, tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain
- SSRI s (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression
- tricyclic's (such as clomipramine and amitriptyline) used for depressive illness
- St John's Wort (Hypericum perforatum) used as a herbal remedy for mild depression
- pain killers (such as tramadol and pethidine) used for pain relief
- triptans (such as sumatriptan and zolmitriptan) used for treating migraine

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with **THRYVE**, you should see your doctor or healthcare provider.

THRYVE with food and drink and alcohol

THRYVE can be taken with or without food.

Alcohol should be avoided when taking **THRYVE**.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not use **THRYVE** if you are pregnant or breast feeding.

The following symptoms may occur in newborn babies, of mothers that have used **THRYVE** in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

You may feel dizzy, confused or lightheaded and vision problems may occur after taking **THRYVE**. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure

THRYVE contains:

THRYVE contain Lactose. Patients with the rare hereditary conditions of lactose intolerance should not take **THRYVE.**

3. HOW TO TAKE THRYVE

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

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

THRYVE can be started at a dose of 10 or 15 mg/day and thereafter the usual dose is 15 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day. If you have the impression that the effect of **THRYVE** is too strong or too weak, talk to your doctor or pharmacist.

Try to take the **THRYVE** tablet at the same time each day. It does not matter whether you take it with or without food.

Always take the tablet with water and swallow it whole.

Even if you feel better, do not alter or stop taking the daily dose of **THRYVE** without first talking to your doctor. Your doctor will tell you how long your treatment with **THRYVE** will last

IF YOU TAKE MORE THRYVE THAN YOU SHOULD:

If you realise you have taken more **THRYVE** than you should (or if someone else has taken your **THRYVE,** consult your doctor or pharmacist other healthcare provider immediately. If no one is available, contact the nearest hospital or poison control centre and take the pack of **THRYVE** with you.

If you forget to take THRYVE

If you miss a dose of **THRYVE**, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take [~~a double dose~~] two doses in one day to make up for forgotten individual doses.

If you stop taking THRYVE

Do not stop the daily dose of **THRYVE** without first consulting your doctor even if you feel better.

4. POSSIBLE SIDE EFFECTS

THRYVE can have side-effects but not everybody gets them.

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

If any of the following happens, stop taking **THRYVE** and tell your doctor pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital:

• allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, hives), which may cause difficulty in swallowing or breathing.

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

Tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• thoughts of suicide, suicide attempt and suicide.
• combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome).
• seizure.
• life-threatening irregular heartbeat.
• heart attack.
• blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

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

Tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:
• feeling restless and unable to keep still, difficulty sitting still.
• uncontrollable twitching, jerking or writhing movements, restless legs.
• uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
• muscle disorder causing twisting movements (dystonia)
• weight gain
• inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include: - strong impulse to gamble excessively despite serious personal or family consequence altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive - uncontrollable excessive shopping - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger) - a tendency to wander away.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor, pharmacist or healthcare provider if you notice any of the following:

Frequent side effects:

• diabetes mellitus,

• difficulty sleeping,

• feeling anxious,

• trembling,

• headache,

• tiredness,

• sleepiness,

• light-headedness,

• shaking and blurred vision,

• decreased number of or difficulty making bowel movements,

• indigestion,

• feeling sick,

• more saliva in mouth than normal,

• vomiting,

• feeling tired.

Less Frequent:

• increased blood levels of the hormone prolactin,

• too much sugar in the blood,

• depression,

• altered or increased sexual interest,

• double vision,

• fast heartbeat,

• a fall in blood pressure on standing up which causes dizziness, light-headedness

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse drug Reaction reporting Form**", found online under SAHPRA's publications : https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of **THRYVE**

5. HOW TO STORE THRYVE

Store at or below 25 °C in original container. Protect from moisture. Do not remove the tablets from the blisters strips until required for use

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Any unused medicine or waste material should be returned to the pharmacy for destruction. Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What THRYVE contains

The active substance is aripiprazole.

Excipients: Colloidal silicon dioxide, colourants, corn starch, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

What THRYVE looks like and contents of the pack

THRYVE 5 mg: Off white to light pink colour, modified rectangular shaped, uncoated mottled tablets debossed with '250' on one side and plain on other side

THRYVE 10 mg: White to off white colour, modified rectangular shaped, uncoated tablets debossed with '252' on one side and plain on other side

THRYVE 15 mg: White to off white colour, round shaped, bevelled edge, uncoated tablets debossed with '253' on one side and plain on other side.

THRYVE tablets are available in: Aluminium/aluminium blister packs of 30 or 100 tablets packed in a carton

- In packs of 30 or 100 tablets in a white opaque HDPE bottle with a child resistant cap (with silica gel pillow pack and cotton pharmaceutical coil).

- In packs of 30 or 100 tablets in a white opaque HDPE bottle with a screw cap (with silica gel pillow pack and cotton pharmaceutical coil).

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Access to the corresponding Professional information.
A copy of the professional Information is contained in the packaging of **THRYVE.**