**Patient Information Leaflet for**

**ABIPIP 5 / 10 / 15 / 30**

**SCHEDULING STATUS:**

S5

**ABIPIP 5**, 5 mg tablets

**ABIPIP 10**, 10 mg tablets

**ABIPIP 15**, 15 mg tablets

**ABIPIP 30**, 30 mg tablets

**Aripiprazole**

**Contains sugar: crystalline maltose**

ABIPIP 5: each tablet contains 28 mg of crystalline maltose

ABIPIP 10: each tablet contains 56 mg of crystalline maltose

ABIPIP 15: each tablet contains 84 mg of crystalline maltose

ABIPIP 30: each tablet contains 168 mg of crystalline maltose

**Read all of this leaflet carefully before you start taking ABIPIP**

- 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.
- ABIPIP 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 ABIPIP is and what it is used for

2.What you need to know before you take ABIPIP

3.How to take ABIPIP

4.Possible side effects

5.How to store ABIPIP

## 1. What ABIPIP is and what it is used for

ABIPIP contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics.

ABIPIP works in the brain to improve the symptoms of certain types of mental disorders such as strange or frightening thoughts, feeling alone and confused, hallucinations (e.g. hearing unexplained voices) and changes in your behaviour (schizophrenia).

**Schizophrenia**

ABIPIP is indicated for the treatment of schizophrenia and for the maintenance of clinical improvement in adults.

It is used to treat adults suffering from a disease characterized 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.

**Bipolar Mania**

ABIPIP is indicated for the treatment of acute manic episodes associated with Bipolar I Disorder and for prevention of recurrence of new manic episodes in patients who experienced predominantly manic episodes and who responded to ABIPIP treatment.

ABIPIP 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.

## 2. What you need to know before you take ABIPIP

**Do not take ABIPIP:**

- if you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of ABIPIP (listed in **section 6**),
- if you are an elderly patient (older than 65 years), suffering from dementia (a loss of brain function). If you have this condition, ABIPIP may increase the risk of death,
- if you are younger than 18 years.

**Warnings and precautions**

**Take special care with ABIPIP:**

- if you are depressed or if you are thinking about suicide, as ABIPIP may cause some patients to try and commit suicide. The risk of suicide persists beyond the first four weeks of treatment. If you are a caregiver, tell the doctor straight away if your patient shows signs of worsened depression, suicidal thoughts, or changes in behaviour,

- if you have a disorder known as tardive dyskinesia (TD), which may include signs such as involuntary, irregular muscle movements, especially in the face. ABIPIP may make these symptoms worse,
- if you cannot resist gambling, as ABIPIP may lead to addictive gambling in some patients (see **section 4**),
- if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat,
- if you have a history of seizures ("fits"),
- if you have previously had a stroke, or if you are at risk of getting a stroke. Some of the risks include having high blood pressure, smoking, heart fluttering and old age (over 80 years),
- if you have a coronary heart disease or irregular heartbeats,
- if you have blood vessel disorders that affect the circulation of blood to the brain,
- if you have high blood sugar (characterised by the symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak) or if you or a family member has a history of diabetes (see **section 4**),
- if you have high blood cholesterol,
- if you have a thyroid gland disorder,
- if you have allergic symptoms,
- if you have blood disorders, such as low white blood cell counts, or too few platelets in the blood (bleeding into the tissues, bruising, and slow blood clotting after injury),
- if you have trouble swallowing, as ABIPIP make it worse,

- if you do intense exercising or have lost a lot of water. ABIPIP may make it harder for your body to cool down when it gets very hot. Be sure to drink plenty of water every day while you are taking ABIPIP,
- if you are treated for ADHD (attention deficit hyperactivity disorder), as some of the medicines used for treating this disorder may interact with ABIPIP.

If you notice 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 disorder and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or pre-occupation with an increase in sexual thoughts or feelings.

Tell your doctor if you develop a condition called neuromuscular syndrome. Some symptoms may be muscle weakness, with twitching, cramps, aches, pains, numbness, tingling, and droopy eyelids.

You should know that ABIPIP may cause dizziness, light-headedness, and fainting when you get up too quickly from a lying position, as well as sleepiness and changes in your ability to move and balance. Caution should be taken, particularly if you are an elderly patient or have some debility. Always get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

If you have difficulty walking you may be at risk to fall and fracture a bone. Do not take alcohol or medicines simultaneously that can affect your balance and

concentration. It is important to tell your doctor if you are taking any other medicines (see **Other medicines and ABIPIP**).

You may need regular weight checks while taking ABIPIP as it may cause weight gain in some patients (see **section 4**).

**Children and adolescents**

Do not use this medicine in children and adolescents under 18 years of age. It is not known if it is safe and effective in these patients.

**Other medicines and ABIPIP**

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

It is especially important to tell your doctor if you take:

- Anticholinergic medicines, used for spastic disorders of the gut or bladder (such as atropine, hyoscyamine),
- Medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide),
- Antidepressants (such as fluoxetine, paroxetine) or a herbal remedy used to treat depression and anxiety (St John's Wort),
- Certain medicines to treat HIV infection (such as efavirenz, nevirapine, protease inhibitors e.g. indinavir, ritonavir),
- Antifungal medicines (such as ketoconazole and itraconazole),
- Anticonvulsants, used to treat epilepsy (such as carbamazepine, phenytoin, primidone, phenobarbitone),

- Medicines to treat tuberculosis, such as rifampicin, rifabutin,
- Certain medicines for blood pressure, known as alpha$_1$-blockers (such as terazosin),
- Water pills (such as furosemide),
- Diltiazem (a medicine used for angina (chest pain) and hypertension (high blood pressure),
- Medicines to sleep, or help with anxiety (such as alprazolam, lorazepam, diazepam, zolpidem),
- Triptans (such as sumatriptan and zolmitripitan), tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive compulsive disorder (OCD) and social phobia, as well as migraine and pain,
- SSRIs (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,
- Strong pain-relieving medicines that make you drowsy or dizzy, like codeine,
- Alcohol, as ABIPIP will increase the effects of alcohol. You must not take alcohol if you take ABIPIP.

**ABIPIP with food, drink and alcohol**

ABIPIP can be taken with, or without, food. It must be swallowed with adequate water.

Alcohol can add to the drowsiness caused by ABIPIP. Do not drink alcohol while taking ABIPIP.

**Pregnancy, 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 ABIPIP.

You should not take ABIPIP if you are pregnant, as safety in pregnancy has not been determined.

The following symptoms may occur in newborn babies of mothers that have used ABIPIP tablets 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.

If you are taking ABIPIP, you should not breastfeed your baby. ABIPIP is excreted in human milk.

**Driving and using machines**

It is not always possible to predict to what extent ABIPIP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ABIPIP affects them.

ABIPIP may make you feel drowsy, light-headed, cause blurred vision or double vision and may potentially impair judgment, thinking or motor skills. If this happens, do not drive or use any tools or machines until you are feeling well again.

**ABIPIP contains crystalline maltose**

ABIPIP contains crystalline maltose, which may have an effect on your blood sugar control if you have diabetes.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ABIPIP.

## 3. How to take ABIPIP

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

Always take ABIPIP exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

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

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

The usual dose is one tablet daily; your doctor will prescribe a strength suitable for you. This will depend on your disease and condition. The recommended dose is 10 mg to 15 mg once a day with a maintenance dose of 15 mg daily. Your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

Try to take the ABIPIP 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 discontinue the daily dose of ABIPIP without first talking to your doctor.

**If you take more ABIPIP than you should**

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

If you have accidentally taken too many ABIPIP tablets, contact your doctor straight away. You may need urgent medical attention. Take the medicine pack with you.

**If you forget to take ABIPIP**

Try to take ABIPIP at the same time each day. If you forget to take ABIPIP, take the missed dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose, then continue with your normal schedule.

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

**If you stop taking ABIPIP**

Do not stop taking ABIPIP, unless your doctor tells you to. If you are not able to take ABIPIP as your doctor prescribed, contact your doctor immediately.

## 4. Possible side effects

ABIPIP can have side effects.

Not all side effects reported for ABIPIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ABIPIP, please consult your health care provider for advice.

If any of the following happens, stop taking ABIPIP and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- severe allergic (anaphylactic) reaction / angioedema: rash, hives, itching or

difficulty in breathing, tightness in the chest, swelling of the mouth, face, lips, tongue or limbs.

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

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

- feeling depressed and thinking about ending your life,
- high fever, sweating, unstable blood pressure, unconsciousness, stiff muscles, pale skin, and difficulty in breathing. You may have a life-threatening neurologic emergency,
- feeling tired or weak with a sore throat and having unusual bruising or bleeding (signs of blood problems),
- high blood sugar levels, diabetic coma (see **Warnings and precautions**),
- seizures, unusual movements of your body or face that you cannot control, difficulty in speaking, drooling, loss of balance, muscle trembling,
- changes in vision, double vision,
- slow, fast, or irregular heartbeat, chest pain,
- sudden coughing, bringing up blood with a sharp chest pain, which may be due to a clot in the lung and may need urgent attention,
- swelling in one or both legs, warm skin, pain or tenderness of the affected leg which may be due to the formation of a blood clot,
- difficulty walking, dizziness, difficulty speaking or understanding others,

blurred vision and a sudden headache with nausea. These may be signs of a stroke and you may need urgent medical attention,

- yellow eyes or skin, dark urine, stomach pain,
- tightening of the neck muscles, difficulty swallowing,
- very painful and stiff muscles together with dark urine, passing small amounts of urine and feeling weak,
- problems urinating or controlling the bladder,
- an erection that lasts longer than normal,
- high fever,
- bloating or swelling of face, arms, hands, lower legs or feet with rapid weight gain.

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

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- difficulty sleeping, drowsiness, sedation, restlessness, anxiousness, agitation,
- headache, dizziness, light-headedness, inability to sit still, trembling,
- vomiting, nausea (feeling sick), indigestion, stomach discomfort, constipation, increased saliva,
- feeling weak and tired,
- blurred vision,
- fast heartbeat,
- feeling dizzy when you suddenly stand up (a type of low blood pressure),
- stiff muscles,
- high blood sugar condition (diabetes mellitus),

- weight gain.

*Less frequent side effects:*

- hiccups,
- higher-than-normal levels of the hormone prolactin in the blood, decreased prolactin levels,
- high blood sugar (hyperglycaemia),
- depression, altered or increased sexual interest,
- uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia), muscle disorder causing twisting movements (dystonia),
- seizures (fits),
- restless legs,
- double vision, eye sensitivity to light,
- inflammation of the pancreas, difficulty swallowing foods and liquids, loose watery stool (diarrhoea),
- swelling of hands and feet.

*Frequency unknown:*

- low levels of white blood cells, low levels of blood platelets, low sodium levels in the blood,
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, hives),
- diabetic ketoacidosis (ketones in the blood and urine) or coma,
- weight loss, loss of appetite (anorexia),
- nervousness, not being able to control gambling habits, impulsive behaviour,

- thoughts of suicide, suicide attempt and suicide, feeling aggressive, binge eating, compulsive shopping, tendency to wander away,
- problems speaking clearly, movement disorder with muscles contracting uncontrollably,
- combination of fever, muscle stiffness, faster breathing, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome), serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk),
- spasmodic movement of the eyeballs into fixed position, usually upward,
- sudden unexplained death,
- life-threatening irregular heartbeat,
- heart attack,
- abnormal heart rhythm, irregular slow heart rate,
- 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,
- high blood pressure, stroke,
- fainting,
- accidental inhalation of food with risk of pneumonia (lung infection),
- spasm of the muscles around the voice box, cough,
- abdominal discomfort, dry mouth,
- liver failure, inflammation of the liver, yellowing of the skin and white part of eyes, reports of abnormal liver tests values,

- skin rash and sensitivity to light, unusual hair loss or thinning, excessive sweating,
- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia),
- pain in muscles, abnormal muscle breakdown which can lead to kidney problems,
- involuntary loss of urine (incontinence),
- difficulty in passing urine,
- withdrawal symptoms in newborn babies in case of exposure during pregnancy (see **Pregnancy, and breastfeeding and fertility)**,
- prolonged and/or painful erection,
- difficulty controlling core body temperature or overheating,
- chest pain,
- in blood tests: increased or fluctuating blood sugar, increased glycosylated haemoglobin, increased creatine phosphokinase.

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

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ABIPIP.

## 5. How to store ABIPIP

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the blisters in the carton until required for use and keep the HDPE bottle well-closed. Protect from moisture.

Do not use ABIPIP after the expiry date which is stated on the blister and on the carton/HDPE bottle.

Return all unused medicine to your pharmacist.

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

## 6. Contents of the pack and other information

### What ABIPIP contains

The active substance is aripiprazole.

ABIPIP 5 tablets contain 5 mg of aripiprazole.

ABIPIP 10 tablets contain 10 mg of aripiprazole.

ABIPIP 15 tablets contain 15 mg of aripiprazole.

ABIPIP 30 tablets contain 30 mg of aripiprazole.

The other ingredients are:  Croscarmellose sodium, crystalline maltose, magnesium

stearate, microcrystalline cellulose, pregelatinised starch. The colourants are: indigo carmine (E132) (5 mg tablet), iron oxide red (E172) (10 mg and 30 mg tablets), iron oxide yellow (E172) (15 mg tablet).

**What ABIPIP looks like and contents of the pack**

ABIPIP 5: Light blue to blue, mottled, round, biconvex tablets, engraved with “5” on one side.

ABIPIP 10: Pink, round, biconvex tablets, engraved with “10” on one side.

ABIPIP 15: Yellow, round, biconvex tablets, engraved with “15” on one side.

ABIPIP 30: Pink, oval, biconvex tablets, engraved with “30” on one side.

ABIPIP 5, 10, 15 and 30 are packed in either of the following:

- A cardboard box containing 28, 30, 96 or 100 tablets, packed in silver PA/ALL/PVC-aluminium foil blisters (alu-alu blister).
- A white opaque high density polyethylene (HDPE) bottle with a child resistant polypropylene (PP) screw cap with a mounted desiccant, containing 28, 30, 96 or 100 tablets.

Not all packing systems or sizes may be marketed.

**Holder of certificate of registration**

**CIPLA MEDPRO (PTY) LTD.**

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Namibia: NS3 20/2.6/0037

ABIPIP 30: 51/2.6.5/0670

Namibia: NS3 20/2.6/0038

**Access to the corresponding Professional Information**

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to

be generated and included after approval.