Module 1.3.2: Patient Information Leaflet

for ABIPIP 5 / 10 / 15 / 30 (Tablets)

SCHEDULING STATUS

S5

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM

ABIPIP 5 tablets

ABIPIP 10 tablets

ABIPIP 15 tablets

ABIPIP 30 tablets

Read this leaflet carefully before you start taking ABIPIP

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

The active ingredient 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 (5 mg tablet); iron oxide red (10 mg and 30 mg tablets), iron oxide yellow (15 mg tablet).

Contains sugar: (crystalline maltose).

	Maltose content:
5 mg tablet:	28 mg/tablet
10 mg tablet:	56 mg/tablet
15 mg tablet:	84 mg/tablet
30 mg tablet:	168 mg/tablet

WHAT ABIPIP IS USED FOR

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).

BEFORE YOU TAKE ABIPIP

Do not take ABIPIP

- if you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of **ABIPIP**
- 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.

Take special care with ABIPIP

Before you start taking **ABIPIP**, tell your doctor:

- **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 **POSSIBLE SIDE EFFECTS**);
- 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 or if you or a family member has a history of diabetes (see **POSSIBLE SIDE EFFECTS**);
- if you have high blood cholesterol;

- if you have a thyroid gland disorder;
- 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**.

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. 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 **Taking other medicines with ABIPIP**.

You may need regular weight checks while taking **ABIPIP** as it may cause weight gain in some patients. See **POSSIBLE SIDE EFFECTS**.

Taking ABIPIP with food and drink

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 and breastfeeding

If you are pregnant or breastfeeding your baby please consult with your doctor, pharmacist or other healthcare professional.

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.

Tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

If you are taking **ABIPIP**, you should not breastfeed your baby.

Driving and using machinery

ABIPIP may make you feel drowsy, light-headed and may also cause blurred vision

or double vision. If this happens, do not drive or use any tools or machines until you are feeling well again.

Important information about some of the ingredients of ABIPIP

ABIPIP contains a sweetener (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**.

Taking other medicines with ABIPIP

Always tell your doctor or healthcare professional 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)
- 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)
- 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)
- 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**.

HOW TO TAKE ABIPIP

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

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

Your doctor will also 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, talk to 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.

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 control 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 forgot 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.

Effects when treatment with ABIPIP is stopped

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.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional 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

If you have these symptoms, you may have had a serious allergic reaction to **ABIPIP** and will need urgent medical attention.

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 **Take special care with ABIPIP**)
- 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 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, irritability
- headache, dizziness, light-headedness, inability to sit still, trembling
- vomiting, nausea (feeling sick), indigestion, constipation, increased saliva
- feeling weak and tired
- weight gain.

Less frequent side effects

- feeling dizzy when you suddenly stand up (a type of low blood pressure)
- hiccups

- higher-than-normal levels of the hormone prolactin in the blood.

Frequency unknown

- weight loss, loss of appetite
- nervousness, not being able to control gambling habits
- problems speaking clearly, movement disorder with muscles contracting uncontrollably
- diarrhoea, stomach pain, dry mouth
- skin rash and sensitivity to light, unusual hair loss or thinning, excessive sweating
- stiff muscles, pain in muscles, especially in the arms, legs, or joints.

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

STORING AND DISPOSING OF 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.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF ABIPIP

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 necessarily be marketed.

IDENTIFICATION OF ABIPIP

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

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

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

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

REGISTRATION NUMBERS

ABIPIP 5: 51/2.6.5/0667

ABIPIP 10: 51/2.6.5/0668

ABIPIP 15: 51/2.6.5/0669

ABIPIP 30: 51/2.6.5/0670

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION

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MANNER OF GAINING ACCESS TO THE PROFESSIONAL INFORMATION

The professional information is available with each pack size.