

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

ABILIFY 5 mg, 10 mg or 15 mg tablets

Aripiprazole

ABILIFY 5 mg contains sugar: 67 mg lactose (as monohydrate) per tablet

ABILIFY 10 mg contains sugar: 62,18 mg lactose (as monohydrate) per tablet

ABILIFY 15 mg contains sugar: 57 mg lactose (as monohydrate) per tablet

Read all of this leaflet carefully before you start taking ABILIFY

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist, nurse or other health care provider
- ABILIFY 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 ABILIFY is and what it is used for
2. What you need to know before you take ABILIFY
3. How to take ABILIFY
4. Possible side effects

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

5. How to store ABILIFY

6. Contents of the pack and other information

1. What ABILIFY is and what it is used for

Schizophrenia

ABILIFY is indicated for the treatment of schizophrenia and for the maintenance of clinical

improvement in adults.

ABILIFY is one of a group of medicines called antipsychotics. 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:

ABILIFY 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 ABILIFY treatment.

ABILIFY 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 ABILIFY

Do not take ABILIFY:

- if you are allergic to aripiprazole or any of the other ingredients in ABILIFY

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

(listed in section 6).

- If you are under 18 years of age.

Warnings and precautions

Take special care with ABILIFY:

Before treatment with ABILIFY, tell your doctor if you suffer from:

- 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
- Seizure
- Muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat
- Involuntary, irregular muscle movement, especially in the face
- Cardiovascular disease, family history of cardiovascular disease, stroke or “mini” stroke, abnormal blood pressure
- blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots

Tell your health care provider if you:

- Notice you are gaining weight, develop unusual movements, experience sleepiness that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms.
- If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your caregiver/relative should tell your doctor if you have ever had a stroke or “mini” stroke.
- Suicidal thoughts and behaviour have been reported during ABILIFY treatment.

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself.

- Past experience with excessive gambling or other impulsive behaviours, such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings.
- ABILIFY may cause difficulty controlling core body temperature or overheating, take appropriate care when taking ABILIFY if you will be experiencing conditions which may contribute to an elevation in core body temperature, e.g. exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.
- ABILIFY 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.

Children and adolescents.

ABILIFY is not for use in children and adolescents as it has not been studied in patients under 18 years. Ask your doctor or pharmacist for advice before taking ABILIFY.

Other medicines and ABILIFY

Always tell your health care provider if you are taking any other medicine.

This includes complementary or traditional medicines.

Blood pressure-lowering medicine: ABILIFY may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

to keep your blood pressure under control.

Taking ABILIFY with some medicines may need to change your dose of ABILIFY.

It is especially important to mention the following to your doctor:

- 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 agents (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, phenobarbitone)
- Certain antibiotics used to treat tuberculosis (rifabutin, rifampicin)

Medicines that increase the level of serotonin are typically used in conditions including depression, generalised anxiety disorder, obsessive- compulsive disorder (OCD) and social phobia as well as migraine and pain:

- 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
- 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
- St John's Wort (*Hypericum perforatum*) used as a herbal remedy for mild

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

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 ABILIFY, you should see your doctor.

ABILIFY with food and drink and alcohol

ABILIFY can be administered regardless of meals. Alcohol should be avoided when taking ABILIFY.

Pregnancy, breast-feeding and fertility

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

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 healthcare professional for advice before taking ABILIFY.

The following symptoms may occur in newborn babies, of mothers that have used ABILIFY 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.

Be sure to tell your doctor immediately if you are breastfeeding.

If you are taking ABILIFY, you should not breastfeed.

Driving and using machines

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

Dizziness and vision problems may occur during treatment with ABILIFY (see section 4).

This should be considered in cases where full alertness is required, e.g. when driving a car or handling machines. Do not drive or use tools or machines if you feel drowsy after receiving ABILIFY.

ABILIFY contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ABILIFY.

3. How to take ABILIFY

ABILIFY tablets:

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

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

For Schizophrenia:

ABILIFY 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.

For Bipolar Mania:

ABILIFY is started at a dose of 15 mg/day, once a day. The dose can be adjusted at intervals of not less than 24 hours. Your doctor will prescribe the dose recommended for you up to a maximum of 30 mg once per day.

If you have the impression that the effect of ABILIFY is too strong or too weak, talk to your doctor or pharmacist.

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

Try to take the ABILIFY 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 ABILIFY without first consulting your doctor.

If you take more ABILIFY than you should

Patients who have taken too much ABILIFY have experienced the following symptoms:

- rapid heartbeat, agitation/aggressiveness, problems with speech
- unusual movements (especially of the face or tongue) and reduced level of consciousness

Other symptoms may include:

- acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating
- muscle stiffness, and drowsiness or sleepiness, slower breathing, choking, high or low blood pressure, abnormal rhythms of the heart.

Contact your doctor or hospital immediately if you experience any of the above.

If you realise you have taken more ABILIFY tablets than your doctor has recommended (or if someone else has taken some of your ABILIFY tablets), contact your doctor right away.

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

If you forget to take ABILIFY

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day.

4. Possible side effects

ABILIFY can have side effects.

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

ABILIFY Tablets:

Schizophrenia:

Frequent side effects

- Insomnia (difficulty sleeping),
- headache,
- restlessness,
- dizziness,
- inability to sit or lie still,
- movement disorder,
- sedation,
- shaking,
- blurred vision,
- fast heart rate,
- constipation,
- dyspepsia (uncomfortable feeling in the stomach),

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

- nausea,
- vomiting,
- feeling dizzy when getting up from a lying or sitting position,
- fatigue.

Less frequent side effects

Increased or decreased blood levels of the hormone prolactin

Bipolar Mania:

Frequent side effects

- feeling anxious,
- restlessness,
- inability to sit or lie still,
- movement disorder,
- headache,
- tiredness,
- sleepiness,
- nausea,
- sedation,
- shaking,
- blurred vision,
- constipation,
- dyspepsia (uncomfortable feeling in the stomach),
- increase in salivary secretions,
- abdominal discomfort,
- stomach discomfort,
- vomiting,

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

- muscle stiffness.

Less frequent side effects

- Increased or decreased blood levels of the hormone prolactin,
- swelling of hands and feet,
- fast heart rate,
- feeling dizzy when getting up from a lying or sitting position.

If the condition continues or gets worse, contact your doctor as soon as possible.

Other findings

Combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, seizures and prolonged muscle contractions (of the neck muscles, tightness of the throat, difficulty swallowing, breathing difficulties and protrusion (bulging of the tongue). If this happens while you are taking ABILIFY, **contact your doctor immediately.**

The following side effects have been reported since the marketing of ABILIFY but the frequency of them to occur is not known.

- Changes in the levels of some blood cells,
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, rash),
- high blood sugar,
- onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma,
- low sodium level in the blood,
- decreased appetite.
- weight loss,
- weight gain,

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

- thoughts of suicide, suicide attempt and suicide,
- aggression,
- agitation,
- nervousness,
- seizures,
- serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles),
- speech disorder,
- fixation of the eyeballs in one position,
- sudden unexplained death,
- life-threatening irregular heartbeat, (including so called QT prolongation seen with ECG monitoring).
- heart attack,
- lower heartbeat,
- 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 (if you notice any of these symptoms, seek medical advice immediately),
- double vision,
- high blood pressure;
- fainting,
- accidental inhalation of food with risk of pneumonia,
- spasm of the muscles around the voice box,
- inflammation of the pancreas,

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

- difficulty in swallowing,
- diarrhoea,
- hiccups,
- liver failure,
- inflammation of the liver,
- yellowing of the skin and the white of the eyes;
- reports of abnormal liver test values,
- restless legs,
- 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),
- muscle pain,
- muscle stiffness,
- involuntary loss of urine,
- difficulty in passing urine,
- prolonged and or painful erection,
- feeling cold,
- high temperature,
- chest pain,
- swelling of the hands, ankles or feet,

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

- impulsive behavior,
- excessive gambling,
- increased sexual interest,
- compulsive 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.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ABILIFY.

5. How to store ABILIFY

Store ABILIFY tablets below 30 °C in the original container.

Store all medicines out of reach of children.

Return unused medicine to the pharmacy.

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

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

6. Contents of the pack and other information

What ABILIFY contains

ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

Active ingredient:

Each tablet contains aripiprazole 5, 10 or 15 mg

Inactive ingredients:

Colourants (iron oxide in the 10 and 15 mg tablets and indigo carmine in the 5 mg tablets), hydroxypropylcellulose, lactose, magnesium stearate, microcrystalline cellulose and starch.

What ABILIFY looks like and contents of the pack

ABILIFY 5 mg tablets are: blue, modified, rectangular, debossed on one side with “A-007” and “5”

ABILIFY 10 mg tablets are: pink, modified rectangular tablets, debossed on one side with “A- 008” and “10”

ABILIFY 15 mg tablets are: yellow, round tablets, debossed on one side with “A-009” and “15”

ABILIFY tablets are available in aluminium/aluminium blister packs containing 30 or 100 tablets.

Holder of Certificate of Registration

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ABILIFY 5, 10 and 15 MG TABLETS

PATIENT INFORMATION LEAFLET

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