

FINAL PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S5

ARIPIPRAZOLE 5 mg ACCORD (Tablets)

ARIPIPRAZOLE 10 mg ACCORD (Tablets)

ARIPIPRAZOLE 15 mg ACCORD (Tablets)

ARIPIPRAZOLE 30 mg ACCORD (Tablets)

Aripiprazole

Contains sugar:

ARIPIPRAZOLE 5 mg ACCORD: 66,43 mg lactose monohydrate per tablet.

ARIPIPRAZOLE 10 mg ACCORD: 62,00 mg lactose monohydrate per tablet.

ARIPIPRAZOLE 15 mg ACCORD: 93,00 mg lactose monohydrate per tablet.

ARIPIPRAZOLE 30 mg ACCORD: 186,00 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking ARIPIPRAZOLE ACCORD

- 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.
- ARIPIPRAZOLE ACCORD 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 ARIPIPRAZOLE ACCORD is and what it is used for
2. What you need to know before you take ARIPIPRAZOLE ACCORD
3. How to take ARIPIPRAZOLE ACCORD

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4. Possible side effects
5. How to store ARIPIPRAZOLE ACCORD
6. Contents of the pack and other information

1. What ARIPIPRAZOLE ACCORD is and what it is used for

- ARIPIPRAZOLE ACCORD belongs to a group of medicines called antipsychotics. It is used to treat adults suffering from a disease called schizophrenia, which is 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.
- ARIPIPRAZOLE ACCORD is also used to treat adults who suffer from a condition called bipolar mania, 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 ARIPIPRAZOLE ACCORD

Do not take ARIPIPRAZOLE ACCORD:

- if you are hypersensitive (allergic) to aripiprazole or any of the other ingredients of ARIPIPRAZOLE ACCORD (listed in section 6)

Warnings and precautions

Special care should be taken with ARIPIPRAZOLE ACCORD:

- If you have heart disease, family history of heart disease, stroke or “mini” stroke, abnormal blood pressure, especially low blood pressure as ARIPIPRAZOLE ACCORD can cause orthostatic hypotension (feeling lightheaded or dizzy when you stand up from a sitting or lying down position).
- Blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots.
- If you have a history of seizures.

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- If you are elderly and suffer from other age-related memory or mental function issues.
- ARIPIPRAZOLE ACCORD may cause difficulty controlling core body temperature or overheating. 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 certain types of medicines, or being subject to dehydration, take appropriate care when taking ARIPIPRAZOLE ACCORD.
- As it 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.

Tell your doctor or health care provider:

- If you start having thoughts of hurting yourself.
- If you start to experience involuntary or repetitive movements, like blinking rapidly or smacking your lips.
- If you experience muscle stiffness, a high fever, faster heartbeat or faster breathing
- If you are a diabetic patient and notice any signs of increased sugar levels such as tiredness, increased thirst, dry mouth, needing to pee often or blurred vision.
- If you notice that you are gaining weight.
- If you experience an increased urge to gamble, eat or spend money excessively or other impulsive behaviours, such as an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings.
- If you experience heartburn, regurgitation, chest pain, difficulty swallowing or the feeling that food is stuck in the throat or chest.

Children and adolescents

ARIPIPRAZOLE ACCORD is not for use in children and adolescents under the age of 18 years.

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Other medicines and ARIPIPRAZOLE ACCORD

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

Please talk to your doctor or pharmacist if you are taking any of the following medicines as your dosage of ARIPIPRAZOLE ACCORD or other medicines may have to be adjusted:

- Medicines to control your blood pressure as ARIPIPRAZOLE ACCORD may increase the effect of these medicines.
- Quinidine, which is used to correct heart rhythm
- Antifungal medicines like ketoconazole and itraconazole
- Medicines used to treat HIV infection, 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
 - 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 experience any unusual symptoms while taking any

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of these medicines together with ARIPIPRAZOLE ACCORD, you should see your doctor.

ARIPIPRAZOLE ACCORD with food, drink and alcohol

Avoid alcohol while taking ARIPIPRAZOLE ACCORD.

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 healthcare provider for advice before taking this medicine.

You should not use this medicine during pregnancy or while you are breastfeeding.

Driving and using machines

- It is not always possible to predict to what extent ARIPIPRAZOLE ACCORD may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ARIPIPRAZOLE ACCORD affects you.
- ARIPIPRAZOLE ACCORD may cause sleepiness or changes to your vision. Do not drive or use machinery if you experience any of these effects.

ARIPIPRAZOLE ACCORD contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this medicine.

3. How to take ARIPIPRAZOLE ACCORD

- Do not share medicines prescribed for you with any other person.
- Always take ARIPIPRAZOLE ACCORD exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 10 or 15 mg a day. The maximum dose is 30 mg per day.

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- If you have the impression that the effect of ARIPIPRAZOLE ACCORD is too strong or too weak, tell your doctor or pharmacist.
- Try to take your tablet at around the same time every day.
- This medicine can be taken regardless of meals.

If you take more ARIPIPRAZOLE ACCORD than you should

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

You may experience the following symptoms if you take too much ARIPIPRAZOLE ACCORD:

- Lack of energy, sleepiness
- Raised blood pressure
- Increased heart rate
- Vomiting

If you forget to take ARIPIPRAZOLE ACCORD

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

If you stop taking ARIPIPRAZOLE ACCORD

Do not stop your treatment just because you feel better. It is important that you carry on taking ARIPIPRAZOLE ACCORD for as long as your doctor has told you to

4. Possible side effects

- ARIPIPRAZOLE ACCORD can have side effects.
- Not all side effects reported for ARIPIPRAZOLE ACCORD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARIPIPRAZOLE ACCORD, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking ARIPIPRAZOLE ACCORD and tell your doctor immediately or

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go to the casualty department at your nearest hospital:

- Swelling of face, tongue
- Difficulty breathing
- Severe skin rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to ARIPIPRAZOLE ACCORD. 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:

- You start having thoughts of hurting yourself.
- You experience an increased urge to gamble, spend money excessively or other impulsive behaviour.
- Muscle stiffness, a high fever, faster heartbeat or faster breathing – these could be signs of a serious condition called Neuroleptic malignant syndrome.
- If you are agitated, restless, experience insomnia, confusion and a rapid heart rate and high blood pressure – these may be signs of serotonin syndrome.
- Heart palpitations, dizziness, nausea, cold sweats and chest pain – these may be signs of a cardiac problem.
- Leg pain or tenderness, accompanied by swelling and reddish, warm skin – these could indicate a clot in a vein
- Fever, rash and swollen lymph nodes could indicate a condition called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms).

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
 - Increased thirst, needing to urinate more often, especially at night – these could be signs of diabetes

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- Difficulty sleeping, feeling anxious or restless
 - Tremors, headache, feeling sleepy, dizziness
 - Blurred vision
 - Constipation, abdominal discomfort, nausea, vomiting, increased saliva production
 - Fatigue, weakness or lack of energy
- Less frequent side effects
- Change in menstrual cycle, production of breast milk
 - Increased thirst, dry mouth, needing to urinate often, fatigue may indicate increased blood sugar levels
 - Depression
 - Involuntary facial movements or repetitive twisting movements, uncontrollable urge to move your legs
 - Double vision, sensitivity to light
 - Increased heart rate
 - Feeling light headed or dizzy when standing up from a sitting or lying down position
 - swelling of hands and feet
- Side effects with unknown frequency
- Eating disorder
 - Spasm of the eyeballs where they get into a fixed position
 - Difficulty speaking, feeling of something being stuck in your throat
 - Food, saliva or liquids are breathed into your lungs instead of being swallowed.
 - Difficulty swallowing, abdominal pain, diarrhoea
 - Yellowing skin and eyes – which may indicate liver problems
 - Skin rash when exposed to sun, loss of hair, increased sweating
 - Muscle stiffness, dark, reddish urine, weakness, muscle aches

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- Difficulty urinating completely, leakage of urine
 - Prolonged erection
 - Problems with regulating temperature, chest pain, swelling of hands and feet
 - Increase or decrease in your weight
 - compulsive sexual behaviour or sexual addiction
 - hiccups
-
- 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 ARIPIPRAZOLE ACCORD.

5. How to store ARIPIPRAZOLE ACCORD

- Store all medicines out of reach of children.
- Store at or below 25 °C.

6. Contents of the pack and other information

What ARIPIPRAZOLE ACCORD contains

- The active substance is aripiprazole.
- Each capsule contains 5 mg, 10 mg, 15 mg or 30 mg aripiprazole.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, maize starch, hydroxypropylcellulose, magnesium stearate
- Colorants used are indigo carmine aluminium lake (E132), ferric oxide red (E172) and ferric oxide yellow

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(E172)

What ARIPIPRAZOLE ACCORD looks like and contents of the pack

ARIPIPRAZOLE 5 mg ACCORD: Blue coloured, modified rectangle shaped, biconvex, uncoated tablets, debossed with "A5" on one side and another side is plain.

ARIPIPRAZOLE 10 mg ACCORD: Pink coloured, modified rectangle shaped, biconvex, uncoated tablets, debossed with "A10" on one side and another side is plain.

ARIPIPRAZOLE 15 mg ACCORD: Yellow coloured, round shaped, bevelled edge, biconvex, uncoated tablets, debossed with "A15" on one side and another side is plain.

ARIPIPRAZOLE 30 mg ACCORD: Pink coloured, round shaped, bevelled edge, biconvex, uncoated tablets, debossed with "A30" on one side and another side is plain.

ARIPIPRAZOLE ACCORD tablets are packed in :

- Alu-Alu blisters comprising lidding foil made of hard tempered aluminium foil, with HSL coating on bright side; and forming foil made of aluminium strip, soft temper, plain, one side bright, dull side lacquer laminated to OPA, bright side lacquer laminated to PVC. Pack sizes: 14, 28, 49, 56 or 98 tablets
- HDPE containers comprising wide mouth white opaque HDPE container fitted with white opaque polypropylene closure (with wad having induction sealing liner), desiccant canister and cotton coil. Pack sizes: 30 or 100 tablets

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Building 2, Tuscany Office Park,

6 Coombe Place

Rivonia

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Johannesburg

South Africa

This leaflet was last revised in

Registration number

ARIPIPRAZOLE 5 mg ACCORD (Tablets): 56/2.6.5/1169

ARIPIPRAZOLE 10 mg ACCORD (Tablets): 56/2.6.5/1169

ARIPIPRAZOLE 15 mg ACCORD (Tablets): 56/2.6.5/1169

ARIPIPRAZOLE 30 mg ACCORD (Tablets): 56/2.6.5/1169