ARIAN TABLETS

Consumer Medication Information Leaflet (RiMUP)

Aripiprazole (10mg, 15mg, 20mg)

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What ARIAN is used for

ARIAN is one of a group of medicines called antipsychotics. It is used to treat schizophrenia and related manic disorders in patients who suffer from a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behavior and emotional flatness. People with this conditions may also feel depressed, guilty, anxious or tense.

How ARIAN works

ARIAN works by acting on various receptors in the brain, particularly dopamine receptors and serotonin (5HT) receptors. Dopamine and serotonin are natural compounds called neurotransmitters, and are involved in transmitting messages between brain cells. Psychotic illness is considered to be caused by disturbances in the activity of neurotransmitters (mainly dopamine) in the brain. Aripiprazole is thought to work mainly by stabilising the dopamine activity in the brain.

Before you use ARIAN

- *When you must not use it*

Do not take ARIAN:

If you are allergic (hypersensitive) to ARIAN or any of the other ingredients of ARIAN.

Pregnancy and lactation

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Be sure to tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

Breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are taking ARIAN, you should not breast-feed.

-Before you start use it

Tell your doctor if you suffer from:

- High blood sugar (characterized by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, feeling weak) or family history of diabetes
- Seizure
- Involuntary, irregular muscle movement, especially in the face
- Cardiovascular disease, family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- Bloods clots, family history of blood clots, as antipsychotics have been associated with formation of blood clots.

If you notice you are gaining weight, experience any difficulty in swallowing or allergic symptoms, please tell your doctor.

If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

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

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

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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

Taking ARIAN with some medicines may need to change your dose of ARIAN. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy

How to use ARIAN

- *How much to use*

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

Schizophrenia: The recommended starting and target dose is 10mg or 15mg once a day schedule without regard to meals . However your doctor may prescribe a lower or higher dose to maximum of 30mg once a day.

Bipolar Mania: The recommended starting dose is at 15mg to 30mg once a day schedule without regard to meals. However your doctor may prescribe a lower or higher dose to maximum of 30mg once a day.

ARIAN is not for use in children and adolescent under 18 years. Ask your doctor or pharmacist for advice before taking ARIAN.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking ARIAN until your doctor tells you to stop. You should not stop taking this medicine without medical advice.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it
- *Things you must do*

Take your medicine with a glass of water exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking ARIAN.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ARIAN to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, ARIAN can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Tell your doctor or pharmacist if you notice any of the following side effects:

Common side effects: uncontrollable twitching or jerking movement, headache, tiredness, nausea, vomiting, an uncomfortable feeling in the stomach, constipation, increased production of saliva, lightheadedness, trouble sleeping, restlessness feeling anxious, sleepiness, shaking and blurred vision.

Uncommon side effects: some people may feel dizzy, especially when getting up from a lying or sitting position, or may experience a fast heart rate.
Some people may feel depressed

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of ARIAN
- *Storage*

Keep this medicine out of the sight and reach of children.

Store below 30 °C

Do not use this medicine after the expiry date which is stated on the blister and on the carton.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- *What it looks like*

ARIAN 10 mg tablets are white, uncoated, oval shaped beveled edged tablets.
ARIAN 15 mg tablets are white, uncoated, round, biconvex, beveled edged tablets
ARIAN 20 mg tablets are white, uncoated, round, biconvex tablets.

- *Ingredients*
- Active ingredient(s)
  Aripiprazole

- Inactive ingredients
  Maize Starch (Unipure F), Lactose monohydrate (Pharmatose 200M) Hydroxy propyl cellulose (Klucel EF) Microcrystalline Cellulose (Avicel pH101), Magnesium Stearate, purified water

- *MAL number(s):*

ARIAN 10MG:

ARIAN 15MG:

ARIAN 20MG:

Manufacturer
Indoco Remedies Limited
L-14, Verna Industrial Estate,
Verna-Goa 403 722,
India.

Product Registration Holder
UNIMED SDN BHD
No. 53, Jalan Tembaga SD5/2B
Bandar Sri Damansara
52200 Kuala Lumpur

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22/01/2015