Aripiprazole 1mg/ml Oral Solution

1. What is Aripiprazole Oral Solution and what is it used for?

Aripiprazole Oral Solution contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics. In adults and adolescents aged 15 years and older who suffer from a disease characterized by symptoms such as: hearing or seeing things which are not there, suspiciousness, mistaken belief, incorrect speech and behaviour and unusual and unpleasant feelings. People with this condition may feel distressed and anxious. Aripiprazole Oral Solution is used to treat adults and adolescents aged 15 years and older who suffer from a condition with symptoms such as: hearing or seeing things which are not there, suspiciousness, mistaken belief, incorrect speech and behaviour and unusual and unpleasant feelings. People with this condition may feel distressed and anxious.

2. What do I need to know before you take Aripiprazole Oral Solution?

Do not take Aripiprazole Oral Solution:

- if you are allergic to aripiprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before taking Aripiprazole Oral Solution if you suffer from:

- liver or kidney disease with symptoms such as excessive tiredness, large amounts of urine, increase in appetite and feeling cold or feverish medical history of diabetes.
- seizure.
- irregular muscle movements, especially in the face.
- heart problems or high blood pressure.
- anticoagulants.
- any medicines to correct heart rhythm.
- medicines that increase the level of serotonin: triptans, tramadol, 5HT1A agonists (corresponding to 5HT2A antagonists) or 5HT2A antagonists.
- medicines that increase serotonin (listed in section 6) and have been associated with formation of blood clots.
- certain medicines to treat HIV infection.

If you notice any gain in weight, develop unusual movements, experience unsteadiness with normal daily activities, any difficulty in walking 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 should tell your doctor if you have ever had a stroke or "mini" stroke.

Tell your doctor immediately if you have any thoughts or feelings such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly or sometimes severe irritability. In adults it also appears this condition from returning in patients who have responded to the treatment with Aripiprazole Oral Solution.

3. How to take Aripiprazole Oral Solution

Aripiprazole Oral Solution contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics. Open the bottle and make sure that the syringe is firmly inserted into the adapter (Figure 1).

Push the plunger down and fill the syringe up to the prescribed dose (Figure 2).

If any bubbles appear in the syringe, keep the bottle upside down and slightly push in the plunger and pull it back again. Repeat until there are no more bubbles in the syringe (Figure 4).

Turn the bottle the right way up and remove the syringe (Figure 6).
Aripiprazole 1mg/ml 150ml Oral Solution PIL - UK

Proof Round

* Please note that only Artwork Studio is permitted to make changes to the above artwork. No changes are permitted by any 3rd party other than added notes and mark ups for required changes.

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Version 2

3

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4.

Possible side effects

4. Possible side effects

- agitation
- excessive gambling
- suicide
- weight gain
- weight loss
- loss of appetite (anorexia)
- not enough sodium in the blood
- worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma

The following side effects have been reported since the marketing of oral aripiprazole but the frequency for them is not known (frequency cannot be estimated from available data):

- double vision
- altered or increased sexual interest
- tremor
- sensitivity to light
- excessive sweating
- not enough food
- increased heart rate
- high blood pressure
- anxiety
- altered or uncontrolled eating
- changes in sexual drive
- intense menses
- increased breast size
- low mood
- itching of the skin (with raised lumps) or rash
- feeling sick
- feeling anxious
- tremor
- increased heart rate
- feeling dizzy, especially when getting up from bed or a chair
- nausea
- sadness
- dizziness, light-headedness or fainting
- feeling unusually tired
- restlessness
- feeling of being drunk, sweating or breathing heavily
- uncontrolled movements of the limbs, and feeling dizzy, especially when getting up from a long sitting position, were considered by the manufacturer to be serious side effects of oral aripiprazole and should be reported to your doctor.

- sensitivity to light
- anxiety
- altered or uncontrolled eating
- tremor
- sleeplessness
- sweating, dark urine or a lowered level of sugar in the blood (hypoglycaemia)

4. Possible side effects

Further side effects may occur when aripiprazole is used less often (for example, every two or three days):

- difficulty in swallowing or breathing
- nervousness
- speech disorder
- inflammation of the pancreas
- high blood pressure
- sudden unexplained death
- lung infection
- speech disorder
- nervousness
- inflammation of the pancreas
- high blood pressure
- sudden unexplained death

In elderly patients with dementia, more fatal cases have been reported while taking antipsychotic medicine, in cases of stroke or in “stroke” have been reported.

Additional side effects in children and adolescents

Adolescents aged 11 years and older and experienced side effects were similar in frequency and magnitude to those in adults except that sleepiness, uncontrollable twitching or jerking movements, restlessness, and tiredness were more common in adolescents under 16 years old, and frequent changes in appetite were more common in adolescents than in adults. Additional side effects seen in children and adolescents included:

- agitation
- excessive gambling
- suicide
- weight gain
- weight loss
- loss of appetite (anorexia)
- not enough sodium in the blood
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If you are styling, feel your doctor’s response by any of these behaviors; he/she will discuss ways of managing or reducing the symptoms.

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