

XXXX Pharmacy Name

LOGO

XXXX Address

Phone: XXX Fax: XXX

INFORMED CONSENT AND WAIVER OF LIABILITY FOR ABILIFY MAINTENA® (ARIPRAZOLE) INJECTIONS

This Informed Consent and Waiver of Liability (this “**Consent and Waiver**”) has been prepared to provide you with information regarding the risks and side effects of Abilify Maintena® (“**Abilify**”) injections. It is important that you read this information carefully and completely. Please discuss any questions you may have with, or request any additional information you need from, the pharmacist, nurse or your physician. Once you have read and understand this information, and had any questions addressed to your satisfaction, please sign and date this Consent and Waiver. **Do not sign this Consent and Waiver and do not receive an Abilify injection if you have questions about or do not understand the information you have received or are not comfortable assuming the risks that may be associated with Abilify.**

Patient’s Name _____ DOB ____/____/____
Street Address _____
City _____ State _____ Zip Code _____

PROPOSED TREATMENT

Abilify is a prescription medicine given by injection by a healthcare professional and used to treat schizophrenia.

SIDE EFFECTS AND COMPLICATIONS

Abilify may cause serious side effects, including:

- Increased risk of death in elderly people with dementia-related psychosis.** Abilify is not for the treatment of people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia).
- Neuroleptic malignant syndrome (NMS) a serious condition that can lead to death.** Call your physician or go to the nearest emergency room right away if you have any of these symptoms:
 - high fever
 - sweating
 - stiff muscles
 - changes in pulse, heart rate, and blood pressure
 - confusion
- Uncontrolled body movements (tardive dyskinesia).** Abilify may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop receiving Abilify. Tardive dyskinesia may also start after you stop receiving Abilify.
- Problems with your metabolism such as high blood sugar (hyperglycemia).**
 - Increases in blood sugar can happen in some people who take Abilify. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes

(such as being overweight or a family history of diabetes), your physician should check your blood sugar before you start receiving Abilify and during your treatment. Call your physician if you have any of these symptoms of high blood sugar while receiving Abilify:

- feel very thirsty
- need to urinate more than usual
- feel very hungry
- feel weak or tired
- feel sick to your stomach
- feel confused, or your breath smells fruity
- increased fat levels (cholesterol and triglycerides) in your blood.
- weight gain. You and your physician should check your weight regularly.
- Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- Low white blood cell count**
- Seizures (convulsions)**
- Problems controlling your body temperature so that you feel too warm**
- Difficulty swallowing**
- Feeling like you need to move to stop unpleasant feelings in your legs (restless leg syndrome or akathisia)**
- Injection site pain**
- Sleepiness (sedation)**

The above list is not meant to be inclusive of all possible risks associated with Abilify, as there are both known and unknown side effects associated with any medication. Call your physician for medical advice about side effects.

PATIENTS WHO SHOULD NOT USE ABILIFY

Do not receive Abilify if you are allergic to aripiprazole or any of the ingredients in Abilify. Active ingredients include aripiprazole monohydrate. Inactive ingredients include carboxymethyl cellulose sodium, mannitol, sodium phosphate monobasic monohydrate, and sodium hydroxide.

THINGS TO TELL YOUR PRACTITIONER

Before you receive Abilify, tell the pharmacist, nurse, and your physician if you:

- have never taken Abilify (aripiprazole) before
- have diabetes or high blood sugar or a family history of diabetes or high blood sugar
- have or had seizures (convulsions)
- have or had low or high blood pressure
- have or had heart problems or a stroke
- have or had a low white blood cell count
- have any other medical problems, including problems that may affect you receiving an injection in your arm or buttocks
- are pregnant or plan to become pregnant. It is not known if Abilify will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Abilify can pass into your milk and may harm your baby.

Tell the pharmacist, nurse and your physician about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Abilify and other medicines may affect each other causing possible serious side effects. Do not start or stop any medicines while taking Abilify without talking to your physician first.

THINGS TO AVOID WHILE TAKING ABILIFY

- Do not drive, operate machinery, or do other dangerous activities until you know how Abilify affects you. Abilify may make you feel drowsy.
- Do not drink alcohol while you receive Abilify.
- Do not become too hot or dehydrated while you receive Abilify.
 - o Do not exercise too much.
 - o In hot weather, stay inside in a cool place if possible.
 - o Stay out of the sun.
 - o Do not wear too much clothing or heavy clothing.
 - o Drink plenty of water.

PATIENT CONSENT AND WAIVER OF LIABILITY

I acknowledge that I have carefully and fully read this Consent and Waiver and I understand the potential risks and side effects related to the use of Abilify Maintena listed above and explained by my physician. I have been given the opportunity to ask questions and I have had all of my questions answered.

I acknowledge that PHARMACY NAME did not prescribe the medicine and is only performing the Abilify injections through the pharmacist and/or a nurse at my request and with my authorization, which is hereby being given.

In acknowledgement of the foregoing, I, for myself, my heirs, assigns, and anyone acting on my behalf, hereby waive any and all claims against PHARMACY NAME and its principals, agents, and employees, and agree to hold each them harmless from any and all liability whatsoever, arising out of, in connection with, or in any way related to the use or administration of Abilify Maintena.

I agree that this Consent and Waiver will be valid for each repeated Abilify injection.

Patient Signature

Date

Signature of Practitioner who Conducted
the Informed Consent Discussion

Name