

LAI

Long-Acting Injection

Schizophrenia

Guidance

for patients using ABILIFY and their families



Supervisor: *Hirohisa Hida*
Director of Medical Corporation Soramugikai Hida Clinic



● Q 1	Are you taking medicine regularly?	3
● Q 2	What is ABILIFY "LAI"?	4
● Q 3	What are the advantages of ABILIFY LAI?	6
● Q 4	How will your life change with ABILIFY LAI?	11
● Q 5	Is the oral medicine no longer necessary after switching to ABILIFY LAI?	12
● Q 6	Where is ABILIFY LAI injected?	14
● Q 7	Is ABILIFY LAI safe? Are there any adverse effects?	15
● Q 8	Can anyone use ABILIFY LAI?	16
● Q 9	What should you do if you would like to use ABILIFY LAI?	18
●	Follow your doctor's instructions even after the symptoms have improved.	19

Q1 Are you taking medicine regularly?

Your medicine of your choice

In the treatment of schizophrenia, drug therapy is essential to stabilize the symptoms and prevent relapse. However, it is not easy to continue taking your medicine regularly. You may feel bothered to take the medicine every day or may unintentionally miss a dose. To continue proper treatment, check if you have any trouble taking the medicine.

CHECK

Do you have any trouble?

- Sometimes miss a dose
- Feel bothered to take the medicine every day
- Feel uncomfortable to take the medicine in public
- Sometimes adjust the amount of the medicine by yourself
- Sometimes get annoyed by your family or caregiver checking if you have taken the medicine
- Sometimes refrain from activities because of worrying about the time to take the medicine
- Very concerned about relapse



If you have any trouble taking the medicine every day, you may consider using a non-oral dosage form, the long-acting injection (LAI). Let us learn about ABILIFY LAI with this booklet. You are the central player in the treatment. Select the dosage form with which you can easily continue treatment while living your own life.

Q2 What is ABILIFY "LAI"?

LAI is one of the various dosage forms.

The dosage forms of the atypical antipsychotic ABILIFY include various oral medicines as well as the long-acting injection (LAI). The dosage form can be selected based on the ease, comfort, and purpose of use.

Oral medicine

Take every day at prescribed times with a glass of water or lukewarm water.

Tablets



ABILIFY tablets 1mg



ABILIFY tablets 3mg



ABILIFY tablets 6mg



ABILIFY tablets 12mg

Powder



ABILIFY powder 1%

There are various dosage forms !



Atypical Antipsychotic kun

Oral medicine

Take every day at prescribed times without water.

Oral solution



ABILIFY oral solution 0.1% 1mL



ABILIFY oral solution 0.1% 3mL



ABILIFY oral solution 0.1% 6mL



ABILIFY oral solution 0.1% 12mL

Orally Disintegrating Tablets(OD Tablets)



ABILIFY OD Tablets 3mg



ABILIFY OD Tablets 6mg



ABILIFY OD Tablets 12mg



ABILIFY OD Tablets 24mg

Injection

Get injected at a medical institution once every 4 weeks.

Long-acting injection



ABILIFY LAI 300mg (vial)



ABILIFY LAI 400mg (vial)



ABILIFY LAI 300mg (syringe)



ABILIFY LAI 400mg (syringe)

LAI is an injection type of medicine.



LAI kun

Q3 What are the advantages of ABILIFY LAI?

ABILIFY LAI is injected once every 4 weeks.

Oral medicines should be taken every day in the amount prescribed by the doctor at the prescribed time. As ABILIFY LAI remains at the injection site (in the muscle) until gradually taken into the blood, it has long-lasting effects once injected. If you visit the medical institution once every 4 weeks for an injection, you can expect the same therapeutic effect as with taking the oral medicine every day without fail.



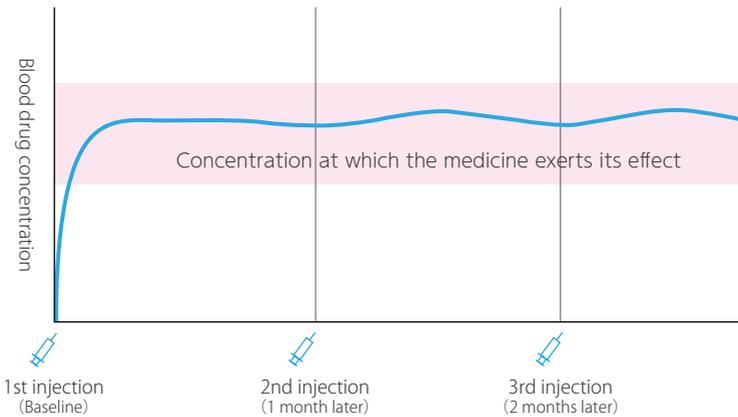
ABILIFY LAI stabilizes the blood drug concentration.

ABILIFY has the same effect regardless of the dosage form, such as oral medicine or LAI. ABILIFY LAI, however, has a characteristic that the active ingredient (aripiprazole) is slowly absorbed into the body after injection to maintain concentration in the blood. Therefore, it is expected to stabilize the symptoms.

After reaching a stable concentration in the blood, the medicine can help stabilize the symptoms.



Change in blood concentration of aripiprazole (assumption)



ABILIFY LAI can be effective in preventing relapse.

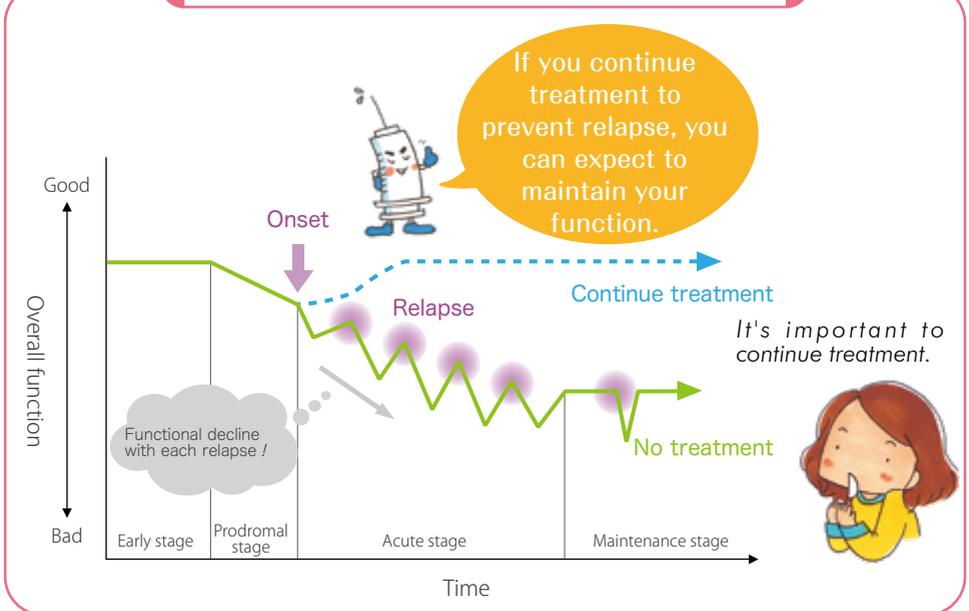
Schizophrenia is a highly recurrent psychiatric disorder, and repeated relapses are associated with the risks described on the right. The most important goal of schizophrenia treatment is to prevent relapse.

If you continue treatment with ABILIFY LAI, the medicine will constantly be maintained in your body, and thus you can expect to stabilize the symptoms and prevent relapse.

If the disease recurs repeatedly...

- Mental and social functions decline, and you may no longer be able to do what you have been able to do.
- The medicine becomes less effective, and you may need a longer time to recover.
- Many patients are readmitted to the hospital.

Course and treatment goal of schizophrenia



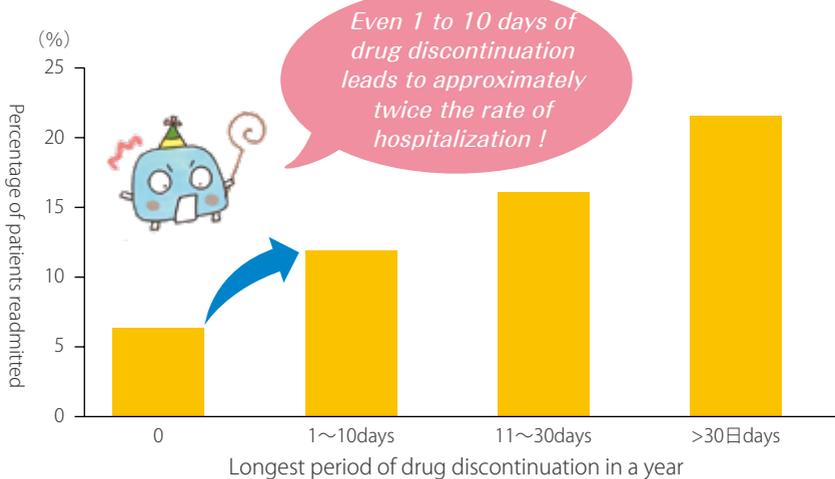
ABILIFY LAI reduces your concern about missing a dose.

To prevent relapse, it is necessary to take the medicine every day without fail. However, have you ever unintentionally missed a dose or adjusted the dose at your own discretion?

Data shows that people who discontinue the medicine even for 1 to 10 days have approximately twice the rate of readmission compared with those who do not miss a dose.

ABILIFY LAI is injected at a medical institution once every 4 weeks. It frees you from the daily concern about missing a dose. If you do not visit your doctor as scheduled, the medical staff can notice and encourage you to visit, which helps you continue treatment.

Period of drug discontinuation and risk of hospitalization



Weiden, P. J. et al. : Psychiatr. Serv. 2004 ; 55(8) : 886-891.

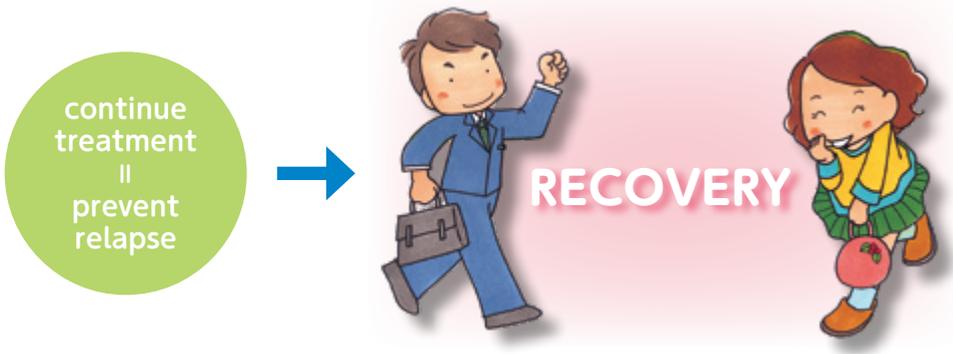
ABILIFY LAI supports your recovery.

The treatment goal of schizophrenia is to stabilize the symptoms and help you "regain your own life and take a step toward your goal in life and your future (dream)", which is called "recovery". Recovery varies from person to person; some people resume their studies and jobs, which they discontinued due to the disease, and others try something new.



The essential aspect in aiming for recovery is to continue treatment properly to prevent relapse. ABILIFY LAI is a dosage form that enables you to work towards recovery without worrying about the medicine. It relieves you from the burden of taking the medicine and is highly effective in preventing relapse.

Regain your confidence by starting with what you can do without trying too hard, for example, increasing the number of days you visit a day care center and building up your physical strength.



Q4 How will your life change with ABILIFY LAI?

Advantages and disadvantages of ABILIFY LAI

Advantages (good points / what can be expected)

It ensures intake of the medicine.

- Eases your concern about relapse and hospitalization
- Stabilizes the symptoms
- Eliminates your concern about missing a dose

It decreases (eliminates) the burden of taking the medicine.

- Allows you to remain active without worrying about the time to take the medicine
- Enables you to not care about what others think about you

It is an easy-to-take dosage form, but you must visit your hospital once every 4 weeks !



Disadvantages (weak points)

Injection involves pain.

It may also cause "injection-related adverse effects" (see P15).

Any adverse effect may result in prolonged symptoms.

If you feel that something is different, tell your doctor or pharmacist immediately.

It takes time to have an effect.

Oral medicine will be used in combination for 2 weeks until the efficacy is confirmed.

Consult your doctor if you have any questions !



*ABILIFY LAI may cause sleepiness, decreased attention/concentration, and delayed reactions, which are also caused by the oral medicine. Avoid operating dangerous machinery, including driving a car during use.

*If you consume alcohol while using ABILIFY LAI, adverse effects such as dizziness and lightheadedness are more likely to occur. Avoid alcohol consumption during use.

Q5

Is the oral medicine no longer necessary after switching to ABILIFY LAI?

It depends on the symptoms and the patient.

If you start treatment with ABILIFY LAI, the antipsychotic oral medicine also needs to be taken until the blood drug concentration becomes stable. If the symptoms stabilize or adverse effects decrease, the amount and type of medicine that is being taken may be decreased, and some patients may no longer need the oral medicine. However, there are individual differences.

Periodical hospital visit is necessary.

Even after starting treatment with LAI and the symptoms stabilize, if you discontinue treatment at your own discretion, it may lead to exacerbation and relapse of the disease. Periodically visit your hospital once every 4 weeks to continue treatment. Tell your doctor if you have any adverse effects and other worrisome symptoms.

With both LAI and the oral medicine...

In addition to the drug therapy, there are various psychosocial methods to treat schizophrenia, which are expected to have synergistic effect when combined with drug therapy. Taking care of your usual lifestyle, such as maintaining a healthy daily rhythm and trying



to sleep and exercise well, is also important to stabilize the symptoms. The same is true with both the oral medicine and LAI.

Main medicines used for the treatment of schizophrenia

The following medicines, primarily antipsychotics, are used for the treatment of schizophrenia:

Medicines playing a central role

Antipsychotics: Used to improve symptoms such as hallucination/delusion, agitation, having trouble putting thoughts together, having difficulty in expressing your feelings and feeling unmotivated, and to prevent relapse.

Medicines that control the symptoms

Anxiolytics: Used to relieve strong anxiety and tension.

Antidepressants: Used to relieve depressed mood and increase motivation.

Sleeping pills: A medicine with the right duration of action for the symptom is used to control sleeping patterns, such as inability to sleep well, having difficulty falling asleep, waking up early in the morning, and sleeping during the day and being awake at night.

Medicines to suppress the adverse effects of antipsychotics

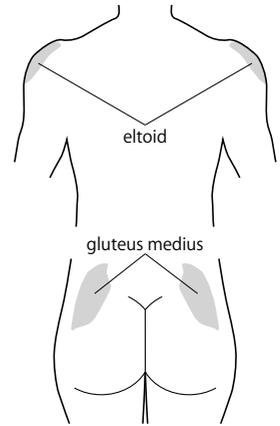
Antiparkinsonian agents: Used to suppress extrapyramidal symptoms, such as hand tremor, body stiffness, and numb legs.

Laxatives: Used to improve bowel movements.

Q6 Where is ABILIFY LAI injected?

ABILIFY LAI is injected into your buttock or shoulder muscle.

ABILIFY LAI is injected into the muscle on the outer side of the buttocks called "gluteus medius" or the muscle on the outer side of the shoulders called "eltoid". While both sites are suitable for the safe use of LAI, your doctor will select the injection site that suits you to avoid damaging important nerves and blood vessels, as there are individual differences in physique and muscle mass. If you want to request either one, tell your doctor.



LAI will be injected avoiding the previous site of injection. After injection, be careful not to rub the injection site. If you feel strong pain or discomfort during or after the injection, tell your doctor or the medical staff immediately. It is reported that the injection site pain is milder at the gluteus medius than at the eltoid.

Tell what you think !

Some people may be concerned about the injection pain and injection into the buttocks. ABILIFY LAI is water-soluble and designed to reduce pain during injection. It is injected at the relatively upper side of the buttocks, and your doctor will respect your privacy during the injection by covering with blankets and towels.

If you have any concerns about the injection, tell your medical staff what you think.

Talk to your medical staff if you have any concerns !

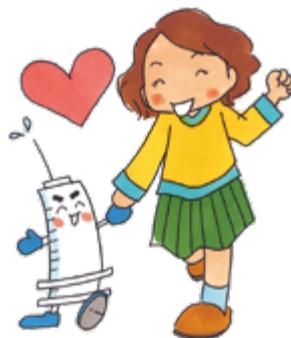


Q7 Is ABILIFY LAI safe? Are there any adverse effects?

ABILIFY LAI is used after confirming that it is suitable for you.

ABILIFY LAI is intended for use to prevent exacerbation or relapse of psychiatric symptoms. It cannot be used for patients with severe symptoms in the acute stage and for patients with unstable symptoms.

Before using ABILIFY LAI, your doctor will give you the ABILIFY oral medicine to see if it is appropriate for your condition (to confirm efficacy and safety). While the long-acting effect of LAI is an advantage, it is also a disadvantage as there is no way to remove the medicine from your body immediately in the event of adverse effects. Discuss this thoroughly with your doctor before use.



LAI-specific adverse effects

The adverse effects seen with ABILIFY oral medicine are also seen with ABILIFY LAI. In addition, LAI may cause the symptoms described on the right as injection-related adverse effects.

Injection-related adverse effects

Injection site has...

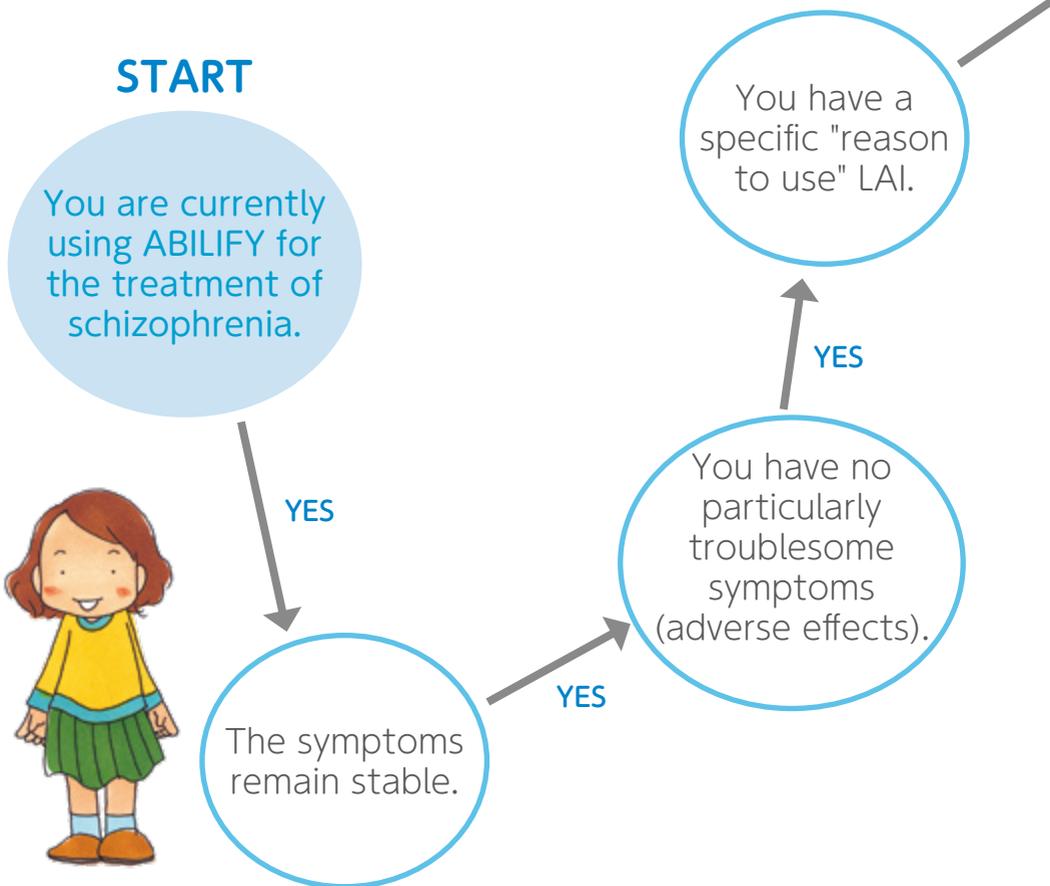
- pain
- redness
- stiffness
- swelling

If you feel that something is different or suspect adverse effects, consult your doctor or pharmacist as soon as possible.

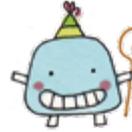
Q8 Can anyone use ABILIFY LAI?

Let's check !

Check if you can use ABILIFY LAI. Check whether the following conditions apply:



Consult your doctor if you have any questions or concerns about LAI.



You can visit a hospital once every 4 weeks.

YES

YES

You have understood the advantages and disadvantages of using LAI with this booklet.

YES



You have discussed with your doctor about the use of LAI.

YES



To Q9



Q9 What should you do if you would like to use ABILIFY LAI?

Tell your doctor about your intention.

If you fulfill the requirement for the use of ABILIFY LAI in Q8, tell your doctor that you want to use ABILIFY LAI. However, consult your doctor if any of the following applies to you:

- Under treatment (or have previously been treated) for other diseases
- Using other medicines
- Not under treatment but have some health concerns
- Have tried to commit suicide, sometimes feel like hurting yourself
- Being pregnant (potentially pregnant), breastfeeding
- Have had allergic symptoms after taking medicines
- Being elderly (65 years or older)



Follow your doctor's instructions even after the symptoms have improved.

Do not discontinue treatment at your own discretion.

ABILIFY LAI is a medicine that is injected at a medical institution once every 4 weeks. Even after the symptoms have improved, do not discontinue treatment at your own discretion and follow your doctor's instructions.

Efforts to more easily continue treatment with ABILIFY LAI

Bring the "Dosage Schedule Card" for ABILIFY when visiting a medical institution and enter the date of the hospital visit on your calendar at home so that you can continue the treatment more easily.



No.	Date of next injection	Date of injection	Site of injection	
 4 weeks	1	/ /	/ /	shoulder (L/R) buttock (L/R)
 4 weeks	2	/ /	/ /	shoulder (L/R) buttock (L/R)
 4 weeks	3	/ /	/ /	shoulder (L/R) buttock (L/R)
 4 weeks	4	/ /	/ /	shoulder (L/R) buttock (L/R)

"Dosage Schedule Card" for ABILIFY LAI

*The form can be downloaded from the QR code below.





Emergency contact

Name of the medical institution

Contact details

Your doctor

Your medical staff