

LAI

Long-Acting Injection

Bipolar Disorder

Guidance

for patients using ABILIFY and their families



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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"?

ABILIFY long-acting injection (LAI) is an atypical antipsychotic injection that remains effective for 4 weeks.

ABILIFY is one of the atypical antipsychotics used for the treatment of bipolar disorder, similar to mood stabilizers. ABILIFY LAI is indicated for the suppression of relapse of mood episodes in bipolar I disorder. It is injected once every 4 weeks.

ABILIFY is also available in various oral forms, which are indicated for improving the manic symptoms of bipolar disorder.

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.

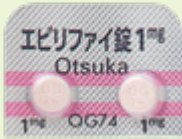


LAI kun

Oral medicine

Take once a day 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 !



Atipical Antipsychotic kun

Take every day 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



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.



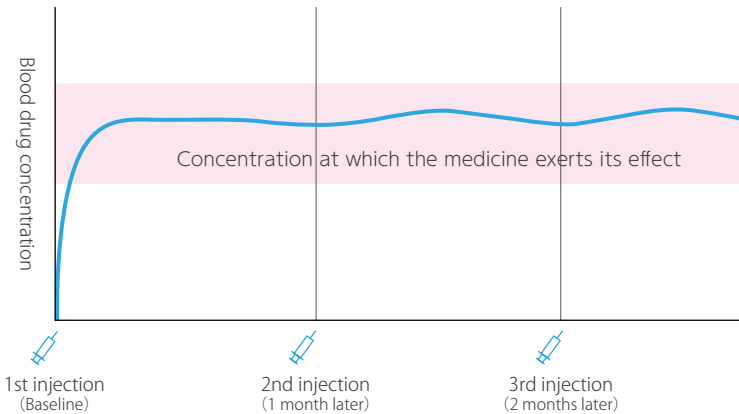
ABILIFY LAI stabilizes the blood drug concentration.

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.



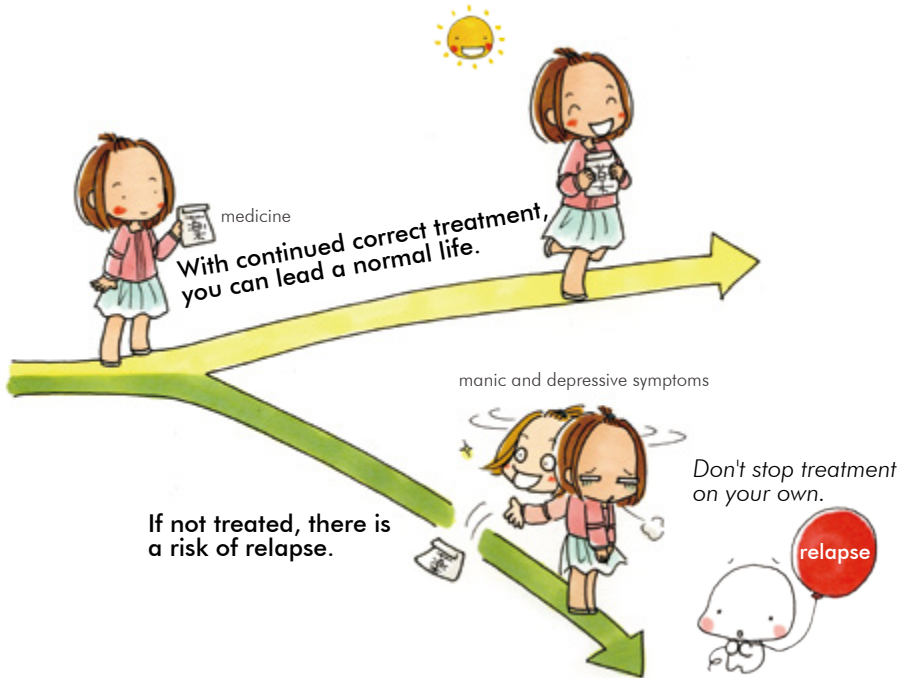
Change in blood concentration of aripiprazole (assumption)



ABILIFY LAI can be effective in preventing relapse.

Bipolar disorder is considered to be a disease that mostly recurs if not treated properly¹⁾. With repeated relapse, some patients lose their social credit, properties, and jobs and may also have troubled relationship with their families. However, starting an appropriate treatment from an early stage can prevent such social damage. Repeated relapse of the disease shortens the time to the next onset and induces rapid cycling, which may result in almost no period of good health (remission period).

If you continue treatment with ABILIFY LAI, you can maintain the medicine regularly in your body, and thus you can expect to stabilize the symptoms and prevent relapse.



- 1) Goodwin, F.K. et al.: Manic-depressive illness. Bipolar disorders and recurrent depression. 2nd edition. Oxford University Press; 2007.

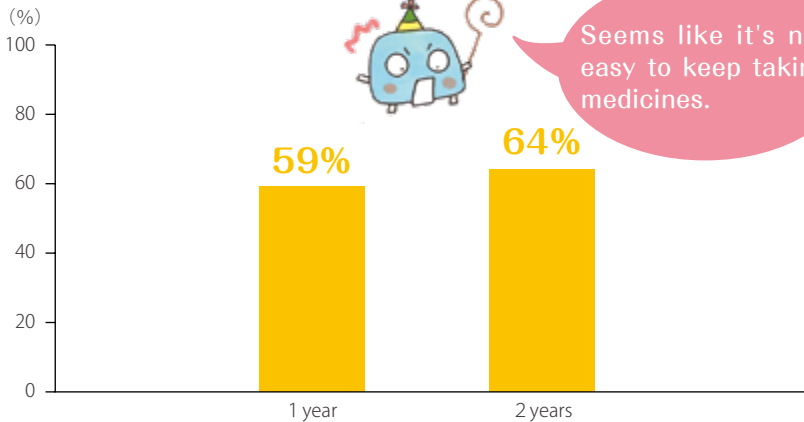
ABILIFY LAI reduces your concern about missing a dose.

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?

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.

Percentage of patients with bipolar disorder who do not take medicines regularly*

* Less than 80% of the total number of actual medication days in the study period



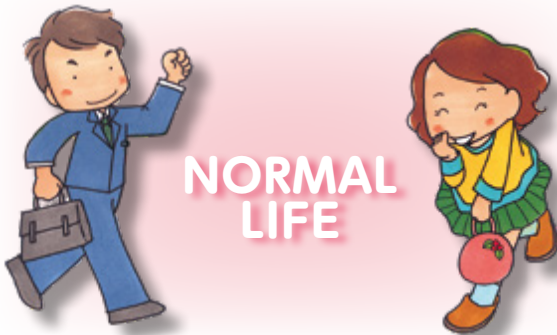
Li, C. et al. : Psychiatry Res. 2014; 218(1-2), 75-78.

ABILIFY LAI supports continued treatment.

The treatment goal of bipolar disorder is to resolve manic and depressive symptoms and prevent relapse. Once injected, ABILIFY LAI remains effective for 4 weeks, and the therapeutic effect is expected to be the same as that with daily medicine use. Therefore, it relieves you from the burden of taking the medicine and the concern about missing a dose. By continuing proper treatment, you may be able to live your daily life while controlling the symptoms.



continue
treatment
||
prevent
relapse



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 bipolar disorder

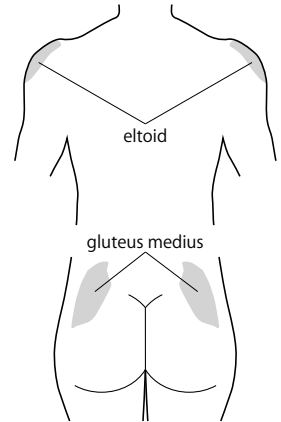
The following medicines are used for the treatment of bipolar disorder:

Mood stabilizers	Basic treatment for bipolar disorder that is effective in the treatment and prevention of manic and depressive symptoms.
Atypical antipsychotics	Atypical antipsychotics, including ABILIFY, block neurotransmitters, such as dopamine, and are effectively used for the treatment of schizophrenia as well as bipolar disorder.
Sleeping pills	Temporarily used to relieve symptoms of insomnia, such as having difficulty falling asleep and waking up early in the morning.

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.

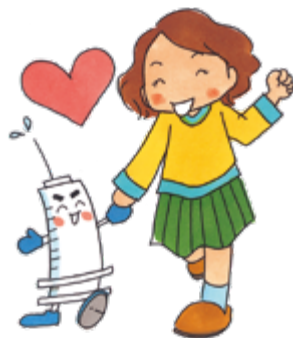
Talk to your medical staff if you have any concerns !



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 indicated for the suppression of relapse of mood episodes. It cannot be used for patients with severe symptoms in the acute stage and for those 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...

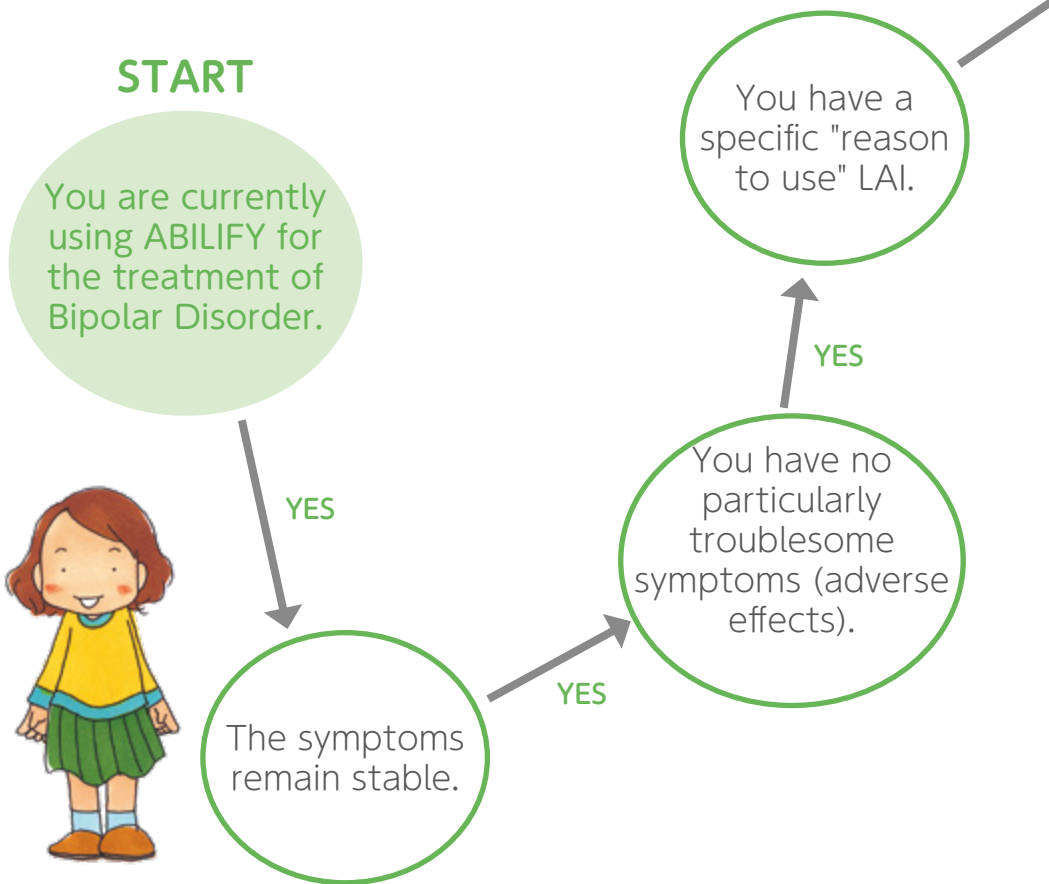
- | | |
|------------------------------------|-----------------------------------|
| <input type="checkbox"/> pain | <input type="checkbox"/> redness |
| <input type="checkbox"/> stiffness | <input type="checkbox"/> swelling |

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
1	/ /	/ /	shoulder (L, R) buttock (L, R)
2	/ /	/ /	shoulder (L, R) buttock (L, R)
3	/ /	/ /	shoulder (L, R) buttock (L, R)
4	/ /	/ /	shoulder (L, R) buttock (L, R)

"Dosage Schedule Card" for ABILIFY LAI

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





Otsuka Pharmaceutical Co., Ltd.

Emergency contact

Name of the medical institution

Contact details

Your doctor

Your medical staff