

Bristol-Myers Squibb
ABILIFY APA tour script
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VIDEO

AUDIO

Welcome Option for continuing attendees from ABILIFY

Tour guide appears on tablet screen. He's a doctor-type, a peer of the APA doctors, credible and authoritative but also empathetic, 40-something, dressed business casual, sport jacket or sweater

He remains on-screen during tutorial with ABILIFY logo

Welcome Option for continuing attendees from ABILIFY. Facilitator will opt them in and with their feedback, select Bipolar I Disorder (BP) or Schizophrenia (SZ) tour paths. This part of the tour occurs just inside the ABILIFY area before Station One. The Tour guide says—

TOUR GUIDE: Welcome back. I'm glad you decided to continue. This tour operates the same way as the last one. You'll go from station to station to learn about ABILIFY. Over 80,000 health care providers in the United States like you have chosen ABILIFY to help over one million of their patients.

The demonstrated symptom improvement, maintenance of efficacy and safety profile of ABILIFY are among the reasons why so many health care providers have prescribed ABILIFY for people diagnosed with Bipolar I Disorder or schizophrenia.

The makers of ABILIFY recognize, as you do, that patients are more than just a collection of symptoms. We'd like to help you see the person behind the symptoms.

So let's proceed to Station One, where I'll introduce you to an actual patient. Tour Station One looks like this...

(Moves to Station One)

(WELCOME/OPT-IN) for new attendees

Tour guide appears on tablet screen. He's a doctor-type, a peer of the APA doctors, credible and authoritative but also empathetic, 40-something, wears a sweater, a Stone Phillips type

TOUR GUIDE: (Welcome One for

Doctors)—Hello, Doctor. Welcome to SmartTour. I'll be your tour guide today. This tour is self-guided, and to show you how that's done, please step forward to the guide station (there to your left) and place the tablet within the guide. As soon as the screen changes, step back and I'll return with a few more instructions.

(Welcome Two for everyone else)—

Hello! And welcome to SmartTour. I'll be your tour guide today. This tour is self-guided, and to show you how that is done, please step forward to the guide station (there to your left) and place the tablet within the guide. As soon as the screen changes, step back and I'll return with a few more instructions.

(Welcome 1 & 2 Continues)—Along the tour path, you'll be asked to proceed to five guide locations. They look like this. At each one, as directed, you'll place the tablet

within the guide and, just like you saw here, when the screen changes, step back to enjoy the tour. There are lean rails for your convenience. And this is important -- Each tablet has a security chip inside that tracks it's location, so...to avoid setting off an alarm, please stay within the confines of the tour area with the tablet.

Opt-in screen with boxes appears

Now, one more preliminary and then we'll get started. This is an interactive tour. You'll be asked to answer questions related to your experience in the field, and to comment on your knowledge of the product presented in this tour. This will enable us to learn about your preferences and interests as they pertain to the use of atypical antipsychotic medications. You can use the attached stylus to indicate your answers and preferences throughout the tour. Are you willing to participate? Just tap the stylus on your answer.

Link button appears on screen:
Please see IMPORTANT SAFETY INFORMATION, including **Bolded WARNING**, and INDICATION

Button appears large for explanation, then shrinks to small size in lower corner. Button will appear from time to time during the tour

Throughout this tour, you'll also be able to select the "ISI" button to see Important Safety Information and Indications for ABILIFY.

Complete ISI text is at the very end of this script

Tour guide returns

Now that we've finished with the preliminaries, welcome to the ABILIFY tour . Over 80,000 health care providers in the United States like you have chosen ABILIFY to help over one million of their patients.

Animated logo:

ABILIFY[®]
(aripiprazole)
5,10,15, 20, 30 mg Tablets

The demonstrated symptom improvement, maintenance of efficacy and safety profile of ABILIFY are among the reasons why so many health care providers have prescribed ABILIFY for people diagnosed with Bipolar I Disorder or schizophrenia.

Animated "A" with road graphic

The makers of ABILIFY recognize, as you do, that patients are more than just a collection of symptoms. We'd like to help you to see the person behind the symptoms.

SUPER:

Although the patients in this video are not representative of every patient taking ABILIFY[®], their experiences suggest how ABILIFY[®] may work for some patients.

Individual results may vary.

The patients you'll see in this video aren't representative of every patient taking ABILIFY. But their experiences suggest how ABILIFY may work for some people. Remember, as with any medication, individual results may vary.

The safety and efficacy of ABILIFY in patients younger than 18 have not been established. Bristol-Myers Squibb and Otsuka America Pharmaceutical do not promote the use of ABILIFY in a manner that is inconsistent with the approved product labeling.

Link buttons for “Bipolar I Disorder,” “Schizophrenia” & “Both” appear on screen

END OF WELCOME/OPT-IN SEGMENT

BEGINNING OF TOUR STATION 1
BIPOLAR

Images representative of mania (consider using images from Picture Painting Flashcard)

The safety and efficacy of ABILIFY in patients younger than 18 have not been established. Bristol-Myers Squibb and Otsuka America Pharmaceutical do not promote the use of ABILIFY in a manner that is inconsistent with the approved product labeling.

Now please use your stylus to touch the screen on your tablet and choose which disease you would like to focus on -- [Bipolar I Disorder](#) or [Schizophrenia](#). At the end of your tour, you’ll have a chance to go back and focus on the other disease. Please make your choice now and proceed to Tour Station One when signaled by the facilitator.

[\(BIPOLAR I DISORDER TOUR PATH\)](#)

1BP A TOUR GUIDE (V.O.) : As you know, Bipolar I Disorder often means living with extreme mood swings or “episodes.” These can include manic, depressive and mixed episodes. Today, we’ll meet a patient named Gwen, with manic symptoms of Bipolar I Disorder.

Prerecorded interview soundbite, Gwen
(02:24:24)

SUPER:

Gwen

Diagnosed with Bipolar I Disorder

Symptoms of Manic Episode, Young Mania
Rating Scale (Y-MRS):

- Irritability
- Disruptive/aggressive behavior
- Sleep
- Elevated mood
- Speech
- Increased activity
- Sexual interest
- Language/thought disorder
- Thought content
- Appearance
- Insight

Prerecorded interview soundbite, Gwen,
Bipolar I Disorder patient (02:18:22)

B-roll, Gwen engaged in daily activities

Prerecorded interview soundbite, Gwen
(03:15:13)

[1BP E GWEN](#): I had a heightened sense of energy when I was in that manic mode, and two hours of sleep was the max for me.

[1BP D TOUR GUIDE \(V.O.\)](#): The symptoms of a manic episode, as measured by the Young Mania Rating Scale, often include elevated mood -- extreme irritability and anxiety -- talking too fast and too much -- and having an unusual increase in energy and a reduced need for sleep.

[1BP C GWEN](#): And the mood swings would come and be rather drastic, and I would wind up in the hospital about every six months.

[1BP F TOUR GUIDE \(V.O.\)](#): Patients with Bipolar I Disorder may act impulsively and engage in behaviors that are risky or that they may later regret -- like going on spending sprees, for example.

[1BP G GWEN](#): I would spend money on anything that I wanted, and I'm not quite sure why I would want the things that I wanted, be it jewelry or even things like furniture polish that I didn't need at the time.

B-roll, Gwen engaged in daily activities

[1BP H TOUR GUIDE \(V.O.\):](#) With Bipolar I Disorder, a person's illness often takes center stage. Others don't see beyond the symptoms and the acting-out. They don't realize that the individual still has normal desires and goals.

Prerecorded interview soundbite, Gwen
(03:10:21)

[1BP K GWEN:](#) In terms of my mother and my sister, I must have hurt them terribly when I was in my manic modes, and I don't know if saying I'm sorry would make an effect.

Tour guide appears on screen

[1BP M TOUR GUIDE:](#) We'll continue our tour at Station Two, where you'll find out about the efficacy of ABILIFY. So please proceed to the next tour station, place the tablet within the guide area, step back, and we'll continue.

Visuals on screen direct viewer to tour station #2

END OF TOUR STATION ONE
BIPOLAR
BEGINNING OF TOUR STATION ONE
SCHIZOPHRENIA

[\(SCHIZOPHRENIA TOUR TRACK,
STATION #1\)](#)

Tour guide appears on screen

[1SZ-A TOUR GUIDE:](#) Schizophrenia causes great distress to patients and their families, and has a considerable social and economic impact.

Intercut Tour Guide footage with B-roll of Andrea engaged in daily activities

1SZ-B To people afflicted with it, schizophrenia can mean an impaired ability to think clearly, make decisions, manage emotions, relate to other people, and distinguish reality from hallucinations and delusions.

1SZ-C. People often view those with schizophrenia in a marginalizing way, based on the effect that their symptoms have on them as individuals.

SUPER:

Positive Symptoms of Schizophrenia:

- Delusions
- Unusual thoughts
- Hallucinations
- Hearing voices
- Seeing things

1SZ-D TOUR GUIDE (V.O.): Positive symptoms are things that schizophrenia “adds on” -- such as delusions, unusual thoughts, hallucinations, hearing voices, or seeing things that aren’t actually there. These symptoms tend to marginalize the individuals.

SUPER:

Negative Symptoms of Schizophrenia

- Lack of motivation or interest in normal activities, e.g.: getting up and taking a shower in the morning

1SZ-E Negative symptoms are things that schizophrenia “takes away” from people-- such as motivation or interest in activities that one normally would do, like getting up and taking a shower in the morning. These symptoms tend to keep patients from expressing themselves, and often prevent engagement of their interests and their loved ones. They may be referred to as “silent symptoms” – meaning withdrawal

Link button labeled “PANSS™” appears on screen

SUPER (scroll):
 PANSS™ Positive Score Items:

- Hostility
- Excitement
- Delusions
- Suspiciousness/Persecution
- Hallucinatory Behavior
- Conceptual Disorganization
- Grandiosity

PANSS™ Negative Score Items:

- Emotional Withdrawal
- Passive Apathetic Withdrawal
- Difficulty in Abstract Thinking
- Blunted Affect
- Lack of Spontaneity/Flow of Conversation
- Stereotyped Thinking
- Poor Rapport

B-roll, Andrea engaged in daily activities

and lack of interest, as if the person is in a fog.

1SZ-F The Positive and Negative Syndrome Scale, or PANSS, lists positive and negative symptoms of schizophrenia in a way that can be measured . If you’d like more information on the PANSS scale, click on the link button.

1SZ-G (SHORT SEGMENT FOR THOSE WHO CHOOSE “PANSS”)

(MUSIC UP FOR SCROLL OF ON-SCREEN TEXT)

(SCHIZOPHRENIA TOUR CONTINUES)

1SZ-H TOUR GUIDE (V.O.): Now let’s meet Andrea. Her experience with schizophrenia included hallucinations.

Prerecorded interview soundbite, Linda
(16:06:08:14)

SUPER:

Linda
Andrea's friend & caregiver

1SZ-J LINDA: She was suffering three different types of hallucination. The visual, where she was seeing things, tactile, where she was feeling things, and audio, where she was hearing things. I mean, she had it all.

Prerecorded interview soundbite, Andrea
(13:04:03:26)

SUPER:

Andrea
Diagnosed with schizophrenia

B-roll, Andrea engaged in daily activities

1SZ-M ANDREA: A lot of the negative symptoms that I experienced were lack of wanting to socialize with people.

(13:07:39:05) I became very isolated, I wanted to be away from people. I felt like people didn't understand and I didn't understand them.

Prerecorded interview soundbite, Linda
(16:01:37:13)

B-roll, Andrea engaged in daily activities

1SZ-N LINDA: So I decided to go on the Internet, you know, and I just start navigating around and after about a week of this, I remember saying to my husband, "Honey, I think I know what's wrong with Andrea." He says "What?" I said, "I think she's a schizophrenic, a paranoid schizophrenic."

(16:04:04:15) The doctor confirmed, and I remember looking at the piece of paper he gave me to send in to the social security office, or the disability office, and I looked at it, Chronic Paranoid Schizophrenia.

Prerecorded interview soundbite, Andrea
(13:20:37:16)

1SZ-O ANDREA: I remember looking at that just reading those three words just dumbfounded that this was a chronic thing and it was a paranoid thing and it was a schizophrenia thing. It was very overwhelming and I didn't, I never thought that there would be a light at the end of that tunnel.

Tour guide appears on screen, along with answer buttons:

- Efficacy
- Safety
- Tolerability
- Dosage
- All of these

(BOTH BIPOLAR & SCHIZOPHRENIA TOUR PATHS, FOR THOSE WHO HAVE OPTED IN TO ANSWERING QUESTIONS)

TOUR GUIDE: Before we move on to the next stop on our tour, please take a moment to answer this question: What is your top treatment criterion when prescribing an antipsychotic medication?

(AFTER THEY ANSWER:) Thank you for your answer.

Tour guide appears on screen

Visuals on screen direct viewer to tour station #2

1SZ-Q TOUR GUIDE: We'll continue at tour station two, where you'll find out about the efficacy of ABILIFY.

So please proceed to the next tour station, place the tablet within the guide area, step back, and we'll continue.

END OF TOUR STATION ONE
SCHIZOPHRENIA

BEGINNING OF TOUR STATION #2
BIPOLAR

Tour guide appears on screen

Animation, graph, “Y-MRS Total Score”
(from visual aid, p.4, “Imagine where this
might lead”)

Animation, graph, “Y-MRS Total Score”
(from visual aid, p.4, “Imagine where this
might lead”)

Animation, graph, “CGI BP Severity of
Illness (Mania) Score,” (from visual aid, p.
5, “Imagine where this might lead”)

Prerecorded interview soundbites, Gwen
(05:04:07)

SUPER:

Although the patients in this video are not
representative of every patient taking
ABILIFY®, their experiences suggest how
ABILIFY® may work for some patients.

Individual results may vary.

(BIPOLAR I DISORDER TOUR TRACK)

2BP-A

TOUR GUIDE: The efficacy of ABILIFY
in the treatment of acute manic and mixed
episodes of Bipolar I Disorder was
established in two 3-week, placebo-
controlled trials.

2BP-B

TOUR GUIDE (V.O.): In a second 3-
week, placebo-controlled trial, there was
significant symptom improvement in
hospitalized patients with manic or mixed
episodes. ABILIFY was superior to a
placebo in reduction of Y-MRS Total
Score.

2BP-D

TOUR GUIDE (V.O.): ABILIFY also
demonstrated a significant improvement in
the CGI BP score compared to placebo.

2BP-E

GWEN: And I realize that it’s not going to
be the same way for everybody, but I’m
grateful for what the ABILIFY has been
able to do for me.

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Animation, graph, “Time to Combined Affective Relapses (manic plus depressive)” (from visual aid, p. 6 , “Imagine where this might lead)

SUPER:

The majority of relapses were due to manic rather than depressive symptoms. There are insufficient data to know whether ABILIFY is effective in delaying the time to occurrence of depression in patients with Bipolar I Disorder.

Animation, bar graph, “Total Combined Affective Relapses (Manic Plus Depressive)” (from visual aid, p. 7 , “Imagine where this might lead”)

Tour Guide appears on screen

Visuals on screen guide viewer to tour station #3

END OF TOUR STATION TWO

[2BP-F](#)

TOUR GUIDE (V.O.): According to the results of clinical trials, the efficacy of ABILIFY goes beyond the acute phase. ABILIFY demonstrated maintenance of efficacy in patients with Bipolar I Disorder. ABILIFY was superior to a placebo in delaying the time to relapse.

Health care providers who elect to use ABILIFY for extended periods – that is, longer than six weeks – should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

[2BP-H](#) TOUR GUIDE (V.O.): In a clinical trial, patients taking ABILIFY also experienced fewer relapses compared to placebo.

[2BP-L](#) TOUR GUIDE: In the next stop on our tour, we’ll talk about adverse events. So please proceed to the next tour station, place the tablet within the guide area, step back, and we’ll continue.

BIPOLAR

BEGINNING OF TOUR STATION #2
SCHIZOPHRENIA

Animation, graph, “PANSS™ Positive Score” (p. 8, Vis-aid, “Imagine where this might lead)

Animation, graph, “PANSS™ Negative Score” (p. 9, Vis-aid, “Imagine where this might lead”)

Prerecorded interview soundbite, Andrea (14:10:17:24)

(SCHIZOPHRENIA TOUR TRACK,
STATION #2)

2SZ-A TOUR GUIDE: ABILIFY has demonstrated its efficacy in a variety of short and long-term clinical trials.

2SZ-B TOUR GUIDE (V.O.): In both short and long-term clinical schizophrenia trials, ABILIFY has demonstrated efficacy. In an acute schizophrenia trial, ABILIFY demonstrated rapid and significant improvement in the PANSS Total Score compared to a placebo. Significant improvement in positive symptoms was demonstrated as early as week one.

2SZ-C ABILIFY also demonstrated significant improvement in negative symptoms as early as week one.

ANDREA: I went to a mental health conference, and they had a booth there, with information on ABILIFY, and after reading the information, my doctor and I discussed it and he was, we were both, we both agreed to go ahead and give it a try.

Prerecorded interview soundbite, Linda
(16:05:37:01)

SUPER: Individual results may vary

LINDA: And as she started taking medication, she didn't get better right away, but some of the symptoms she had did disappear. She wasn't having those seizures that she was before. And slowly, it's like the Andrea that I knew was inside there started coming out.

(16:11:32:19) By the second week I remember her coming in the kitchen and she says "You know what, I think this is going to work."

Prerecorded interview soundbite, Andrea
(14:11:58:25)

ANDREA: I was told that ABILIFY would help with the positive and negative symptoms of schizophrenia, and that to me was really important because my positive symptoms felt like they were being dealt with, but my negative symptoms were what was really stopping me

Prerecorded interview soundbite, Linda
(16:12:20:17)

SUPER: Individual results may vary

LINDA: My husband and I both slowly noticed a change in her social skills. The same woman that as soon as the doorbell rang would go to her room started staying out in the living room and chatting with our guest. And I remember our guest even saying, "Oh Andrea's doing well, isn't she?"

Animation, PANSS Total Score graph, (P.11, “Imagine” vis-aid)

2SZ-F TOUR GUIDE (V.O.): ABILIFY has also demonstrated efficacy with staying power, providing continuing relief of schizophrenia symptoms, according to the PANSS Total Score. In a 26-week schizophrenia trial, ABILIFY demonstrated maintenance of stability. So ABILIFY has been shown to address both positive and negative symptoms of schizophrenia.

Animation, “Time to Relapse” graph, (p. 10, “Imagine” vis-aid)

2SZ-G ABILIFY also reduced the relative risk of relapse by half, compared to a placebo.

Prerecorded interview soundbite, Linda (16:14:00:09)

SUPER: Individual results may vary

LINDA : Andrea came to me and asked me if I thought it would be okay if she went back to college. Now this was a young woman that couldn’t even stay focused for 30 minutes to watch a TV program.

Prerecorded interview soundbite, Andrea (14:23:36:24)

SUPER: Individual results may vary

ANDREA: I still have symptoms of schizophrenia, but my negative symptoms and my positive symptoms don’t interfere with my life. I’m still able to function and get out and do things where I had, I wasn’t able to do before ABILIFY.

Prerecorded interview soundbite, Linda
(16:16:33:16)

SUPER: Individual results may vary

Tour guide appears on screen, along with
answer buttons: 5,4,3,2,1, with 5 labeled
Extremely Comfortable and 1 labeled
Extremely Uncomfortable

Tour Guide appears on screen

Visuals on screen guide viewer to tour
station #3

END OF TOUR STATION TWO
SCHIZOPHRENIA

LINDA : She just had so much going on in
her head she couldn't concentrate, and I
mean, I look at her today and the young
woman you see today, it's a miracle, it's
just a miracle.

(BOTH BIPOLAR & SCHIZOPHRENIA
TOUR PATHS, FOR THOSE WHO
HAVE OPTED IN TO ANSWERING
QUESTIONS)

TOUR GUIDE: Now that we're at the end
of this stop on our tour, please take a
moment to answer this question: Based on
what you've just seen, on a scale of 1 to 5,
5 being the highest, how comfortable are
you that ABILIFY has a similar efficacy
profile to other antipsychotic medications?
(AFTER THEY ANSWER:) Thank you.

2SZ-J TOUR GUIDE: In the next stop on
our tour, we'll talk about adverse events.
So please proceed to the next tour station,
place the tablet within the guide area, step
back, and we'll continue.

BEGINNING OF TOUR STATION #3

Tour Guide appears on screen

Tour guide on screen

SUPER TITLE: Somnolence

Animation, pie chart, “88% of ABILIFY-treated patients reported no somnolence” (Vis-aid, “Imagine,” p. 16)

3-A TOUR GUIDE: Now that we’ve seen some of the information supporting the efficacy of ABILIFY, we’d like to show you some information about ABILIFY and adverse events.

3-C TOUR GUIDE: Many people with Bipolar I Disorder or schizophrenia worry that medicine will make them feel sleepy or “flat,” or cause them to lose their “edge” and be less productive. When you’re initiating treatment with ABILIFY, early sedation may be desirable to calm the patient. But once the patient is stabilized, sedation can have an undesirable impact. A low incidence of sedation may be misinterpreted as a lack of efficacy. You may not be accustomed to using agents like ABILIFY, that have a low incidence of sedation.

3-D TOUR GUIDE (V.O.): In clinical trials, ABILIFY demonstrated a low incidence of sedation. Somnolence with ABILIFY was comparable to placebo -- with 12% of Bipolar I Disorder patients on ABILIFY feeling sleepy or tired, compared to 8% for placebo. In other words, 88% of patients treated with ABILIFY reported no somnolence.

Previous shot remains on screen

3-E In short-term, placebo-controlled trials, somnolence led to discontinuation in only 0.1% patients with schizophrenia on ABILIFY. It did not lead to discontinuation by any patients with bipolar mania.

SUPER TITLE: Extrapyraxidal Syndrome

SUPER TEXT:

Bipolar mania & schizophrenia trials
EPS

6% ABILIFY vs. 4% placebo

(Reference: "Imagine" Vis Aid, p. 17)

3-F TOUR GUIDE (V.O.): In bipolar mania and schizophrenia trials, 6% of patients treated with ABILIFY reported extrapyramidal syndrome, compared with 4% for those who were given a placebo.

In 3-week bipolar mania trials, the incidence of EPS-related events excluding events related to akathisia was 17% for ABILIFY versus 12% for placebo. The incidence of Akathisia-related events was 15% for ABILIFY versus 4% for placebo.

As with all antipsychotic medications, prescribing of ABILIFY should be consistent with the need to minimize the risk of tardive dyskinesia, or TD.

The rate of discontinuation due to akathisia was 2.3% for ABILIFY versus 0.5% for placebo.

Animation, bar graph, "Change in Weight at 26 Weeks" (Vis-aid, "Imagine where this might lead," p. 18)

3-G TOUR GUIDE (V.O.): In a 26-week schizophrenia trial, weight change averaged less than 1.3 kilograms for ABILIFY-treated patients.

SUPER TITLE: Weight Gain

Animation, bar graph, “Change in Weight at 52 Weeks” (Vis-aid, “Imagine where this might lead,” p. 19)

“DETAILS” link button appears, linking to SUPERED TEXT:

A prospective, 52-week trial in patients with **schizophrenia**

SUPER:

Glucose: mean change comparable to placebo in schizophrenia trials

Animation, bar graph, “Fasting Serum Lipids, mean change from baseline in a 26-week trial” (From visual aid, “My Life . . . is more than my illness,” p.21, D6-A0384C)

SUPER TITLE: **Lipids**

Animation, bar graph, “Mean serum levels at baseline and at 26 weeks” (From visual aid, “My Life . . . is more than my illness,” D6-A0384C)

SUPER TITLE: **Prolactin**

In a 52-week schizophrenia trial, weight change averaged 1 kilogram for ABILIFY-treated patients.

[In schizophrenia trials, the mean change in glucose was comparable to placebo.](#)

[3-H TOUR GUIDE \(V.O.\):](#) In a 26-week schizophrenia trial, there were no medically important differences between ABILIFY and placebo patients in triglyceride, HDL, LDL, and total cholesterol measurements. [Fasting serum lipids were comparable to placebo in a 26-week trial.](#)

[3-I TOUR GUIDE \(V.O.\):](#) Some medicines for Bipolar I Disorder and schizophrenia can affect sexual function by raising prolactin levels. In a 26-week schizophrenia clinical study with ABILIFY, the mean change in prolactin levels was comparable to a placebo.

Tour Guide appears on screen

Link buttons showing adverse effects reappear from beginning of segment

Visuals appear showing viewers how to get to Tour Station #4

END OF TOUR STATION THREE

(TOUR STATION #4—BOTH CONDITIONS)

Tour guide appears on screen

Animation, photo of ABILIFY® bottle (Vis-aid “Setting expectations when treating with ABILIFY,” D6-A0517)

SUPER TEXT: The safety of doses of ABILIFY® above 30 mg/day has not been evaluated in clinical trials.

SUPER:

The safety of doses of ABILIFY above 30 mg/day has not been evaluated in clinical trials.

In institutions, 30 mg starting dose for

(CLOSING FOR TOUR STATION #3

BIPOLAR & SCHIZOPHRENIA)

3-J At the fourth and final stop on your ABILIFY tour, we’ll give you some tips on treating your patients with ABILIFY. So please proceed to the next tour station, place the tablet within the guide area, step back, and we’ll continue.

4-A TOUR GUIDE: Once you’ve decided to initiate ABILIFY for your patient, what factors should you consider? Here are some guidelines.

4-B TOUR GUIDE (V.O.): First, let’s talk about dosage. ABILIFY should be taken once a day, either with or without food.

4-D Prescriptions for ABILIFY should be written for the smallest quantity consistent with good patient management, to reduce the risk of overdose.

(BIPOLAR I DISORDER TOUR TRACK)

4BP- A TOUR GUIDE (V.O.): The therapeutic dose range is either 15mg or 30mg for Bipolar I Disorder. In Bipolar I

acute mania

Disorder clinical trials for acute mania, a starting dose of 30 milligrams was effective. Some patients had their dosage decreased to 15 milligrams for tolerability.

Animation, based on “Customize Treatment with Tablet or Oral Solution” (From visual aid, “Setting expectations when treating with ABILIFY”, D6-A0517)

4-C ABILIFY is available in a variety of strengths and formulations, so you can customize the dosage and adjust it based on the patient’s response.

Prerecorded interview soundbite, Gwen (05:17:48)

4BP- B GWEN: Every morning I put my pills in a little pill box and I take what medication I have to take in the morning, and when it’s time for me to take my medicine, I carry it with me and I take it, and it’s something that I’ve promised myself to do so that I can stay healthy.

SUPER: 10-30 mg starting dose recommended for schizophrenia patients.

(SCHIZOPHRENIA TOUR TRACK)
4SZ-A TOUR GUIDE (V.O.): The therapeutic dose range of ABILIFY for Schizophrenia is 10mg to 30mg.

Animation, based on “Customize Treatment with Tablet or Oral Solution” (From visual aid, “Setting expectations when treating with ABILIFY”, D6-A0517)

4-C ABILIFY is available in a variety of strengths and formulations, so you can customize the dosage and adjust it based on the patient’s response.

Prerecorded interview soundbite, Andrea
(14:30:53:08)

ANDREA: I definitely have to be med-compliant. Linda puts my medicine out every morning before she leaves for work. So when I get up in the morning and I come into the kitchen, I see it on the counter and I automatically know, take your meds. And at night, I have three alarms that go off. Two on my watch and, and another one in my room. So it's three times to remind me to take my medicine, and sometimes it takes me 'til the third one to get in there and actually take them, but, I always take my medicine in the morning and I all, and it's just something you've just got to do.

Tour guide appears on screen

4SZ-C TOUR GUIDE: Here's some guidance on initiating treatment with ABILIFY while transitioning to it from other medications.

Animation, graph, "Gradual discontinuation may be appropriate" (from p.3 of visual aid entitled "You've decided to initiate ABILIFY for your patient. What should you consider?")

4SZ-D TOUR GUIDE (V.O.): Gradual discontinuation of previous medication and titrating ABILIFY to an effective dose, based on clinical judgment, may be appropriate for most patients.

SUPER TEXT: The clinical significance of receptor-binding profiles is unknown

4SZ-E In formulating your initiation or transition plan, you may want to consider the receptor-binding profile of the previous medication.

Tour guide appears on screen

4SZ-F TOUR GUIDE): What's the receptor-binding profile of ABILIFY? Well, the exact way ABILIFY works is unknown. But it's believed to function something like a thermostat, adjusting the activity of the key neurotransmitters dopamine and serotonin.

"Partial agonism" link button appears on screen

4SZ-G TOUR GUIDE (V.O.): ABILIFY is the first and only available dopamine partial agonist. To learn more about Partial Agonism, touch the link button with your stylus.

Tour guide appears on screen

(FOR THOSE WHO CHOOSE TO SEE "PARTIAL AGONISM" SEGMENT)

4-E TOUR GUIDE: For a given receptor, a drug can act as a full agonist, producing a maximal pharmacological response, or as a full antagonist, producing no response.

Animation, based on illustration, “ABILIFY may help modulate dopamine activity under different conditions” (from visual aid, “Imagine where this might lead”)

SUPERED TEXT:

Concomitant medications (i.e. antiparkinson drugs, benzodiazepines, anticonvulsants, or antidepressants)

No clinically significant effects were seen on the pharmacokinetics of ABILIFY® when coadministered with: Valproate, Lithium, Famotidine, Warfarin, Dextromethorphan, Omeprazole.

Given the primary CNS effects of ABILIFY, caution should be used when ABILIFY is taken in combination with other centrally acting drugs and alcohol.

Animation, graph, “Immediate discontinuation of the previous antipsychotic treatment” (from p.3 of visual aid, “You’ve decided to initiate ABILIFY for your patient. What should you consider

A partial agonist has affinity for a receptor, but unlike a full agonist, it will produce only a small degree of pharmacological response, even if a high proportion of receptors are occupied by the compound.

TOUR GUIDE (V.O.): It’s thought that ABILIFY’s dopamine partial agonism may help modulate dopamine activity under different conditions.

(TOUR CONTINUES HERE FOR BOTH BIPOLAR AND SCHIZOPHRENIA)

4-F TOUR GUIDE (V.O.): There are no systematically collected data that specifically address switching patients from other antipsychotics to ABILIFY, or concerning concomitant administration with other antipsychotics. But in all cases, the period of overlapping antipsychotic administration should be minimized.

4-G Immediate discontinuation of the previous antipsychotic treatment may be acceptable for some patients. You should consider the potential for withdrawal reactions from the previous medication, along with the potential for adverse events.

Tour guide appears on screen

(MUSIC UP FOR TOUR'S CLOSING SEQUENCE)

Animated logo:

ABILIFY[®]

(aripiprazole)

5,10,15, 20, 30 mg Tablets

4-K TOUR GUIDE: With ABILIFY, your patients with Bipolar I Disorder or schizophrenia may be able to move ahead. ABILIFY helps people with Bipolar I Disorder and those with schizophrenia to emerge and be recognized as individuals with hope for regularity in their lives. Over 80,000 health care providers in the United States like you have chosen ABILIFY to help over one million of their patients.

(BIPOLAR I DISORDER TOUR TRACK)

(BIPOLAR I DISORDER TOUR TRACK)

Prerecorded interview soundbite, Gwen
(05:27:59)

SUPER: Individual results may vary

4BP- D GWEN: I'm feeling very good and I don't want to feel very bad. So I'll take my medicine. (05:09:56) It just makes me able to deal with everything that comes my way now.

Prerecorded interview soundbite, Linda
(16:20:08:29)

(SCHIZOPHRENIA TOUR PATH)

4SZ-I LINDA: It ain't fair that somebody has to deal with this kind of illness, but I also can look at you and tell you there's hope, there's hope, and as long as there's hope, we can move forward.

Tour guide appears on screen, along with answer buttons:

- Feel confident
- Not confident
- Need more information

Answer buttons labeled 5,4,3,2,1 appear. 5 is labeled Very Willing, with 1 labeled Unwilling

Screen grab, ABILIFY web site home page
SUPER: www.ABILIFY.com

Tour guide appears on screen, along with link buttons:

- Take schizophrenia tour
- Take EMSAM® tour
- Exit exhibit

(BOTH BIPOLAR & SCHIZOPHRENIA TOUR PATHS, FOR THOSE WHO HAVE OPTED IN TO ANSWERING QUESTIONS)

TOUR GUIDE: Now that we're at the end of our ABILIFY tour, please tell us whether you feel confident in your ability to initiate treatment with ABILIFY or transition to it from another antipsychotic medication.

(AFTER THEY ANSWER:) And one final question. On a scale of 1 to 5, 5 being the highest, how would you rate your overall willingness to prescribe ABILIFY for your patients? (AFTER THEY ANSWER) Thanks for taking the time to answer our questions today.

(BIPOLAR TOUR CLOSING)

[4BP- E TOUR GUIDE \(V.O.\)](#): For more information about ABILIFY and Bipolar I Disorder, visit the ABILIFY web site at www.Abilify.com.

[4BP- F TOUR GUIDE](#): If you would like to complete the ABILIFY tour and cross over to take the EMASAM tour, please proceed to the dome and see the representative near the main exit.

Otherwise, we thank you for taking the ABILIFY tour. To turn in your tablet, proceed to the exit.

If you'd like more information on anything you've seen today, ask one of the reps in the main booth area, and they'll be happy to assist you.

Screen grab, ABILIFY web site home page
SUPER: www.ABILIFY.com

(SCHIZOPHRENIA TOUR CLOSING)
4SZ-L TOUR GUIDE (V.O.): For more information about ABILIFY and schizophrenia, visit the ABILIFY web site at www.Abilify.com.

Tour guide appears on screen, along with link buttons:
- Take Bipolar I Disorder tour
- Take EMSAM® tour
- Exit exhibit

4SZ-M TOUR GUIDE: If you'd like to cross over and take the EMSAM tour, please proceed to the dome and confer with the rep near the main exit. Otherwise, we thank you for taking the EMSAM tour. To turn in your tablet, proceed to the exit.

If you'd like more information on anything you've seen today, ask one of the representatives in the main booth area, and they'll be happy to assist you.

BMS/OAPI logos and copyright

(CLOSING SHOT, FOR BOTH BIPOLAR & SCHIZOPHRENIA TOURS)

(CLOSING FOR THOSE THAT TOOK
EMSAM TOUR PREVIOUSLY)

4L TOUR GUIDE: Thank you for taking both tours today. Please proceed to the dome to turn in your tablet. If you'd like more information on anything you've seen today, ask one of the representatives in the main booth area, and they'll be happy to assist you.

(BELOW IS TEXT THAT DOCTORS
WILL SEE WHEN THEY CLICK ON
"ISI" AT ANY POINT IN THE TOUR)

SUPER (scroll):

**INDICATIONS and IMPORTANT SAFETY
INFORMATION for ABILIFY
(aripiprazole)**

INDICATIONS: ABILIFY is indicated for the treatment of:

? Acute manic and mixed episodes associated with Bipolar I Disorder

Maintaining efficacy in patients with Bipolar I Disorder with a recent manic or mixed episode who had been stabilized and then maintained for at least 6 weeks

GRAPHIC:

**INDICATIONS and IMPORTANT
SAFETY INFORMATION for
ABILIFY (aripiprazole)**

(MUSIC UP FOR INDICATIONS & ISI
TEXT SCROLL)

(Note: Substitute different ISI &
Indications text, either from pp. 22-23 of
"Imagine" vid-aid, or back cover of
"Seeing beyond current symptoms" mood
disorder questionnaire)

INDICATIONS: ABILIFY is indicated for the treatment of schizophrenia, including maintaining stability in patients who had been symptomatically stable on other antipsychotic medications for periods of 3 months or longer and observed for relapse during a period of up to 26 weeks.

IMPORTANT SAFETY INFORMATION:

Elderly patients, diagnosed with psychosis as a result of dementia (for example, an inability to perform daily activities as a result of increased memory loss), and who are treated with atypical antipsychotic medicines including ABILIFY, are at an increased risk of death when compared to patients who are treated with a placebo (sugar pill). ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

Serious side effects can occur with any antipsychotic medicine, including ABILIFY (aripiprazole).

Tell your healthcare provider right away if you have any conditions or side effects, including the following:

- ? Very high fever, rigid muscles, shaking, confusion, sweating, or increased heart rate and blood pressure. These may be signs of a condition called **neuroleptic malignant syndrome**, a rare but serious side effect which could be fatal
- ? Abnormal or uncontrollable movements. These may be signs of a serious condition called **tardive dyskinesia** which may be permanent
- ? **Elderly:** An **increased risk of stroke** and ministroke has been reported in a clinical study of elderly patients with dementia-related psychosis

? **Diabetes**, risk factors for diabetes (for example, obesity, family history of diabetes), or unexpected increases in thirst, urination, or hunger. **Increases in blood sugar levels** (hyperglycemia), in some cases serious and associated with coma or death, have been reported in patients taking medicines like ABILIFY®. Ask your healthcare provider about the need to monitor your blood sugar level before and during treatment.

Lightheadedness or faintness caused by a sudden change in heart rate and blood pressure when rising quickly from a sitting or lying position (orthostatic hypotension) has been reported with ABILIFY.

Medicines like ABILIFY can affect your judgment, thinking, or motor skills. You should not drive or operate hazardous machinery until you know how ABILIFY affects you.

Since medicines like ABILIFY can impact your body's ability to reduce **body temperature**, you should avoid overheating and dehydration.

Medicines like ABILIFY have been associated with **swallowing problems** (dysphagia). If you had or have swallowing problems, you should tell your healthcare provider.

If you have **suicidal thoughts**, you should tell your healthcare provider right away.

While taking ABILIFY, avoid:

? **Drinking alcohol**

? **Breast-feeding an infant**

Tell your healthcare provider if you have a history of **seizures**, or are **pregnant** or intend to become pregnant, and about all prescription and non-prescription medicines you are taking or plan to take.

Other common side effects include:

constipation, an inner sense of restlessness or need to move (akathisia), headache, nausea, upset stomach, vomiting, agitation, anxiety, insomnia, sleepiness, lightheadedness, and tremor.

For patients who must limit their sugar intake, **ABILIFY Oral Solution contains sugar.**

If you have questions about your health or medicines, talk to your healthcare provider.