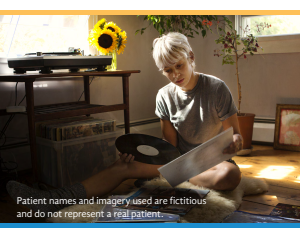
ONCE-MONTHLY

400mg

Abilify Maintena

(aripiprazole) prolonged-release suspension for injection

In the EU and UK, Abilify Maintena® (aripiprazole once-monthly) is indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.[1]
This document is intended to be viewed online only. Prescribing information can be found at the end of this document. This material is intended for healthcare professionals only. Prescribing information may vary depending on local approval in each country. Before prescribing any product always refer to local materials such as the prescribing information and Summary of Product Characteristics (SmPC). This material has been produced by Otsuka Pharmaceutical Europe Ltd. and H. Lundbeck A/S.



Nadia's big passion is music. She loves spending the weekend at her dad's house listening to all his favourite records. Nadia's dad keeps a huge record collection – she would look forward to flipping through them, playing ones that caught her eye and discovering new music she has not heard before.

After being diagnosed with schizophrenia, listening to music can be a demanding task for Nadia. She has been experiencing some positive and negative symptoms, and has struggled to spend enough time with her dad.

Recently, Nadia's doctor suggested switching her medication from oral aripiprazole to Abilify Maintena® (aripiprazole once-monthly) to provide more control of her positive and negative symptoms.[2]

Abilify Maintena® Two Injection Start*† is an alternative initiation option, allowing patients to start directly with Abilify Maintena® without the need for the 14-day oral supplement vs. one injection start.[1]*

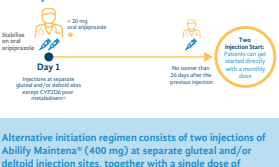
Nadia is now well enough to spend more time with her dad and looks forward to discovering more new music.

Consider starting your suitable patients on the Abilify Maintena® Two Injection Start[1] and help patients like Nadia take small steps to bring achievable moments back into their lives. Please see Abilify Maintena® SmPC for more information.[1]

With Two Injection Start the 14-day oral supplement is no longer required compared to one injection start[1]

ONE injection start

TWO injection start



*Abilify Maintena® injection is given on day 1 as a Two Injection Start and an additional dose of 20 mg oral aripiprazole. The second dose is scheduled no sooner than 26 days after initiation. For patients who have never taken aripiprazole, tolerability with oral aripiprazole must occur prior to initiating treatment with Abilify Maintena®.

†Two Injection Start is two aripiprazole once-monthly 400 mg intramuscular injections at separate gluteal and/or deltoid sites with a single 20 mg oral dose of aripiprazol on the first day of treatment. Two Injection Start is not suitable for all patients. Starting and maintenance doses and site of administration may need adjustment. Please refer to the summary of product characteristics (SmPC) for further information.[1]

‡For known CYP2D6 poor metabolisers the starting dose should be two 300 mg injections administered in either two separate deltoid muscles or one deltoid and one gluteal muscle along with one single dose of the previous prescribed dose of aripiprazole. Dose DO NOT fall into two gluteal muscles. Two injection start is not to be used in known CYP2D6 poor metabolisers concomitantly using a strong CYP3A4 inhibitor.[1]

§Based on the study conducted to investigate safety and tolerability of a single high dose formulation of aripiprazole LAI administered to the gluteal site of administration. Dose not statement as it is higher than licensed doses.[3–5]

CYP, cytochrome P; **EU**, European Union; **UK**, United Kingdom; **LAIs**, long acting injectables.

References:
1. Abilify Maintena® (aripiprazole once-monthly) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/abilify-maintena-epar-product-information_en.pdf and https://www.medicines.org.uk/emc/product/7962/smpc#gref [Accessed: August 2022].
2. Fleischhacker WW, *et al. Br J Psychiatry* 2014;205:135–144.
3. Wang Y, *et al. Curr Med Res Opin* 2021;37:1961–1972
4. Data on file. Otsuka UK/Pharma Europe Ltd. The Alternative Initiation Regimen With Prior Oral Aripiprazole Stabilization. Safety. OPE-AM-2100011. March 2021.
5. Data on file. Otsuka UK/Pharma Europe Ltd. The Alternative Initiation Regimen With Prior Oral Aripiprazole Stabilization. Efficacy. OPE-AM-2100010. March 2021.

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OPE-AM-2200037 HQ-ABIM-0751

except CYP2D6 poor metabolisers*†

Alternative initiation regimen consists of two injections of Abilify Maintena® (400 mg) at separate gluteal and/or deltoid injection sites, together with a single dose of 20 mg oral aripiprazole, on the first day of treatment. Based on pharmacokinetic assessments, the new initiation regimen is expected to be similar in safety profile compared to one injection start[1,3,4]

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References:
1. Abilify Maintena® (aripiprazole once-monthly) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/abilify-maintena-epar-product-information_en.pdf and https://www.medicines.org.uk/emc/product/7962/smpc#gref [Accessed: August 2022].
2. Fleischhacker WW, *et al. Br J Psychiatry* 2014;205:135–144.
3. Wang Y, *et al. Curr Med Res Opin* 2021;37:1961–1972
4. Data on file. Otsuka UK/Pharma Europe Ltd. The Alternative Initiation Regimen With Prior Oral Aripiprazole Stabilization. Safety. OPE-AM-2100011. March 2021.
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Prescribing information

ABILIFY® (**aripiprazole**) PRESCRIBING INFORMATION – ABILIFY® TABLETS, ABILIFY® ORODISPERSIBLE TABLETS, ABILIFY® ORAL SOLUTION, ABILIFY® SOLUTION FOR INJECTION (INTRAMUSCULAR (IM)), ABILIFY MAINTENA® POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION, ABILIFY MAINTENA® POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE.

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

PRESENTATIONS: Tablets: 5mg, 10mg, 15mg, 30mg; Orodispersible tablets: 10mg, 15mg, 30mg; Oral solution: 1mg/ml; Solution for injection (IM): Vial with 9.75mg aripiprazole (7.5mg/ml); Powder and solvent for prolonged-release suspension for injection: Vial with 300mg or 400mg aripiprazole; Pre-filled syringe with 300mg or 400mg aripiprazole. **INDICATIONS: Oral formulations:** Treatment of schizophrenia in adults and adolescents aged 15 years and older; **7.5mg/ml solution for injection (IM):** Rapid control of agitation and disturbed behaviours in adults with schizophrenia, when oral therapy is not appropriate. Treatment with aripiprazole solution for injection should be maintained as soon as clinically appropriate and use of oral aripiprazole should be initiated; **Prolonged-release suspension for injection:** Maintenance treatment of schizophrenia in adults stabilised with oral aripiprazole. **DOSAGE: Oral formulations:** Adults: Recommended starting dose 10 or 15mg once a day, maintenance dose 15mg once a day without regard to meals. Aripiprazole is effective in a dose range of 10 to 30mg once a day. Enhanced efficacy at doses higher than 15mg daily has not been demonstrated although individual patients may benefit from higher dose. Maximum daily dose should not exceed 30mg. Adolescents (>15 years old): Initiate at 2mg (using oral 1mg/ml solution) for 2 days, titrate to 5mg for 2 further days to reach recommended daily dose of 10mg. If needed, dose can be increased in 5mg increments, maximum daily dose 30mg. Enhanced efficacy at doses higher than 10mg daily has not been demonstrated although individual patients may benefit from higher dose. **7.5mg/ml solution for injection (IM):** Recommended initial dose 9.75mg (1.3ml), administered as single IM injection (deltoid or deep into gluteal muscle; gluteal muscle should be administered intravenously or subcutaneously). Effective dose range 5.25mg-15mg as a single injection, dose range 2.25mg-15mg may be given on basis of clinical status – which should include consideration of medicines already given either for maintenance or acute treatment. A second injection may be administered 2 hours after the first injection, based on clinical status. No more than 3 injections should be given in 24 hours. Maximum daily dose of aripiprazole is 30mg (including all Abilify® formulations). If continued treatment indicated with oral aripiprazole, see SmPC for oral aripiprazole preparations. **Prolonged-release suspension for injection:** For patients who have never taken aripiprazole, tolerability with oral aripiprazole must occur prior to initiation. Abilify Maintena® is only intended for IM use and should not be administered intravenously or subcutaneously. Starting dose can be administered as one injection or as two injections per start. **One injection start:** On the day of initiation, administer one injection of 400mg Abilify Maintena® and continue treatment with 10mg to 20mg oral aripiprazole per day for 14 consecutive days to maintain therapeutic aripiprazole concentration during initiation of therapy. Suspension should be injected slowly as a single injection (doses must not be divided) into gluteal or deltoid muscle (care should be taken to avoid inadvertent injection into a blood vessel). **Two injection start:** On the day of initiation, administer two aripiprazole injections of 400mg Abilify Maintena® at separate injection sites (see SmPCs for method of administration), along with one 20mg dose of oral aripiprazole. If initiating with the two injection start, inject into two different sites in two different muscles. DO NOT inject both injections concomitantly into the same deltoid or gluteal muscle. For known CYP2D6 poor metabolisers administer in either two separate deltoid muscles or one deltoid and one gluteal muscle. DO NOT inject into two gluteal muscles. After either the one or the two injection start, the recommended dose is one dose of Abilify Maintena® is 400mg once monthly as a single injection (no sooner than 26 days after the previous injection). Consider reducing dose to 300mg once monthly if adverse reaction experienced. **SPECIAL POPULATIONS:** Hepatic impairment: No dose adjustment required for mild-moderate hepatic impairment. Manage dose cautiously in severe hepatic impairment. **Oral formulations and 7.5mg/ml solution for injection (IM):** Maximum daily dose of 10mg should be used with caution in patients with severe hepatic impairment. **Prolonged-release suspension for injection:** Avoid oral formulation preferred in severe hepatic impairment. Renal impairment: No dose adjustment required. Elderly: Safety and efficacy not established in patients ≥ 65 years old. Consider a lower starting dose (oral formulations and 7.5 mg/ml solution for injection (IM)). Paediatrics: Not for children under 15 years. **Oral formulations, 7.5mg/ml solution for injection (IM) and prolonged-release suspension for injection:** Safety and efficacy in children and adolescents aged 15-17 years established. **Oral formulations:** For advice on known CYP2D6 inhibitors or CYP3A4 inhibitors or inducers see SmPCs. For Abilify Maintena®: see SmPC for instructions on reconstitution and administration and injection procedure. **CONTRAINDICATIONS:** Hypersensitivity to active substance or excipients. **WARNINGS/PRECAUTIONS:** Not recommended in children and adolescents for treatment, improvement in clinical condition may take days to weeks – monitor closely. Suicidal behaviour has been reported early after initiation or switch of medication. Oral formulations: Safety and efficacy below 15 years of age no

Prescribing information.

Click here for prescribing information in Austria.