Long-Acting Injectables: Pharmacological Information

J Code/ Medication	Storage and Medication Considerations	Appointment and Patient Considerations	Follow-Up Considerations	Notes
J2315 INJECTION NALTREXONE DEPOT FORM 1 MG | Injection, naltrexone, depot form, 1 mg [Vivitrol®] VIVITROL (naltrexone for extended-release injectable suspension) is supplied in single-use cartons. Each carton contains one 380-mg vial of VIVITROL microspheres, one vial containing 4 mL (to deliver 3.4 mL) of diluent for the suspension of VIVITROL, one 5-mL prepackaged syringe, one 1-inch 20-gauge needle, two 1.5-inch 20-gauge needles and two 2-inch 20-gauge needles with needle protection devices: NDC 65757-300-01.	• Should be stored in the refrigerator (2-8°C, 36-46°F). Unrefrigerated, can be stored at temperatures not exceeding 77°F for no more than 7 days prior to administration • The microspheres, diluent, preparation needle, and an administration needle with needle protection device are required for preparation and administration • Must be suspended only in the diluent supplied in the carton • Prior to preparation, allow the drug to reach room temperature (approx. 45 min) • Visually inspect for particulate matter and discoloration • Properly mixed suspensions will be milky white, will contain no clumps, and will move freely down the wall of the vial • Must use one of the needles provided in the carton (1.5 inch for very lean patients or 2 inch for larger amount of subcutaneous tissue) • Consider alternate treatment for patients whose body habitus precludes an IM gluteal injection with one of the provided needles. • Remove carton from refrigeration, allow to reach room temperature • To ease mixing, firmly tap the Vivitrol microspheres vial on a hard surface, ensuring powder moves freely • Remove flip-off caps from both vials • Wipe the vial tops with an alcohol swab • Place the 1-inch preparation needle on the syringe and withdraw 3.4 mL of diluent • Inject diluent into the microsphere vial • Mix the powder by vigorously shaking the vial for approx. 1 minute. Ensure dose is thoroughly suspended. • Immediately after suspension, withdraw 4.2 mL of the suspension into the syringe using the same preparation needle • Select the appropriate needle (1.5 or 2 inch) for an IM injection based on patient's body habitus • Replace the preparation needle with the selected administration needle • Tap the syringe to release any air bubbles, push gently on plunger until 4 mL of the suspension remains in the syringe • Suspension is now ready for immediate administration	• Should be opioid free for a minimum of 7-10 days • Patients transitioning from buprenorphine or methadone may be vulnerable to precipitation of withdrawal symptoms for as long as two weeks. • Monitor for s/sx of acute opioid withdrawal • Should be used with caution in patients with hepatic or renal disease	• Advise patients that they may experience nausea following the initial injection. It should be mild and subside within a few days. Less likely to occur in subsequent injections • Patients may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps • Monitor for injection site reactions (Reactions include pain, tenderness, induration, swelling, erythema, bruising, or pruritus) • Patients exhibiting signs of abscess, cellulitis, necrosis, or extensive swelling should be evaluated • Monitor for symptoms of opioid withdrawal • Families and caregivers should monitor for the emergence of symptoms of depression or suicidality • Advise patients that if they previously used opioids, they may be more sensitive to lower doses of opioids and at risk of accidental overdose should they use opioids when their next dose is due • Advise patients that because VIVITROL can block the effects of opioids, patients will not perceive any effect if they attempt to self-administer heroin or any other opioid drug in small doses while on VIVITROL	• Administered every 4 weeks or 1x/month • Administered as an IM gluteal injection, alternating buttocks for each subsequent injection • Pretreatment with oral naltrexone is not required prior to using Vivitrol • Contraindicated in patients with a history of hypersensitivity to naltrexone, PLG, carboxymethyl-cellulose, or any other components of the diluent • Please refer to the package insert for additional information

BH4509a_12/2022
ph_rev 5/2019

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(Unclassified) Sublocade (Buprenorphine extended-release subcutaneous) SUBLOCADE is available as a clear, viscous, colorless to yellow to amber, solution for subcutaneous injection only , in dose strengths of 100mg/0.5mL and 300mg/1.5ml buprenorphine hydrochloride extended-release solution in a pre-filled syringe with a 19 gauge 5/8 inch needle attached.	• Store the unopened prefilled syringes in the refrigerator between 35 to 46 degrees F in the original packaging; do not freeze • Once outside the refrigerator this product may be stored in its original packaging at room temperature, 15 to 30 degrees C (59 to 86 degrees F), for up to 7 days prior to administration • Discard product if it contains particulate matter, is cloudy, or discolored or if product that has been exposed to conditions other than those recommended, or if left outside the refrigerator for more than 7 days • Only use the syringe and safety needle included with the product for administration. Do not attach the needle until the time of administration • Visually inspect parenteral products for particulate matter and discoloration before administration whenever solution and container permit • Each dose is a clear, colorless to yellow to amber viscous solution	• Only a healthcare professional should prepare and administer this injection • Healthcare settings and pharmacies that order and dispense this injection must be certified in the Sublocade REMS program and comply with the REMS requirements. The REMS Medication Guide must be provided to each patient before starting Sublocade and each time they receive Sublocade • Inform patients that they may have detectable levels of buprenorphine for a prolonged period of time after treatment with SUBLOCADE. Considerations of drug-drug interactions, buprenorphine effects, and analgesia may continue to be relevant for several months after the last injection	• Administer monthly with a minimum of 26 days between doses • Do not rub the injection area after the injection. If bleeding occurs, use a gauze pad or bandage but only use minimal pressure and advise the patient that there may be a lump for several weeks after the injection that will decrease in size over time • The injection site should be examined for infection, evidence of tampering, or attempts to remove the depot • Review medication interactions at each visit as Sublocade can cause serious life-threatening interactions when taken with certain other medications including anxiety medications, benzodiazepines, sleeping pills, tranquilizers, muscle relaxants, antidepressants, sedatives, antihistamines or alcohol	• Approved for use in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for at least 7 days, and are transitioning to this injection for maintenance treatment
J1631 INJ HALOPERIDOL DECANOATE PER 50 MG HALDOL (haloperidol) Decanoate 50 for IM injection, 50 mg haloperidol as 70.52 mg per mL haloperidol decanoate: NDC 50458-253-03 - 3 × 1 mL ampules. HALDOL (haloperidol) Decanoate 100 for IM injection, 100 mg haloperidol as 141.04 mg per mL haloperidol decanoate: NDC 50458-254-14 - 5 × 1 mL ampules.	• Store at controlled room temperature (15-30°C, 59-86°F) • Protect from light • Before breaking the ampule, lightly tap the top of the ampule with your finger until all fluid moves to the bottom portion of the ampule • Hold the ampule between thumb and index finder with the colored point facing you • Position the index finger of the other hand to support the neck of the ampule. Position the thumb so that it covers the colored point and is parallel to the colored ring(s) • Keeping the thumb on the colored point and with the index fingers close together, apply firm pressure on the colored point in the direction of the arrow to snap the ampule open • Should be administered by deep intramuscular injection • A 21-gauge needle is recommended • Maximum volume per injection site should not exceed 3 mL • Inspect visually for particulate matter and discoloration prior to administration	• Patients should be previously stabilized on oral antipsychotic medications (specifically haloperidol)	• Monitor for the need for dose adjustment • Haloperidol decanoate may impair the mental and/or physical abilities required for the performance of hazardous tasks • The use of alcohol should be avoided due to possible additive effects and hypotension • Antipsychotics such as haloperidol are not FDA approved for the treatment of dementia-related psychosis in geriatric patients and there is a boxed warning to this effect in the drug labels	• Typically administered at monthly intervals • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)

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J2680 INJ FLUPHENAZINE DECANOATE TO 25 MG Fluphenazine Decanoate Injection, USP 25 mg/mL, 5 mL multiple doses, flip-top vials individually packaged. Fluphenazine Decanoate Injection, USP is available as a clear, pale-yellow solution for intramuscular (IM) or subcutaneous (SC) use providing 25 mg fluphenazine decanoate per mL in a sesame oil vehicle with 12 mg benzyl alcohol as a preservative.	• Store at room temperature (20-25°C, 68-77°F) • Protect from light • Retain vial in carton until ready for use • May be given IM or SC • A dry syringe and needle of at least 21 gauge should be used. Use of a wet needle or syringe may cause the solution to become cloudy • Inspect visually for particulate matter and discoloration prior to administration	• It may be advisable that patients who have no history of taking phenothiazines should be treated initially with a shorter-acting form of fluphenazine before administering the decanoate to determine the patient's response to fluphenazine and to establish appropriate dosage • Contraindicated in patients with suspected or established subcortical brain damage, comatose or severely depressed states • Should not be used in patients receiving large doses of hypnotics, with blood dyscrasia or liver damage	• Monitor for the need for dose adjustment • The use of this drug may impair the mental and physical abilities required for driving a car or operating heavy machinery • Physicians should be alert to the possibility that severe adverse reactions may occur which require immediate medical attention • Potentiation of the effects of alcohol may occur with the use of this drug • Antipsychotics, including fluphenazine, are not FDA-approved for the treatment of dementia-related psychosis in geriatric patients	• The onset of action generally appears between 24 and 72 hours after injection and the effects of the drug on psychotic symptoms becomes significant within 48 to 96 hours. • Subsequent injections and the dosage interval are determined in accordance with the patient's response. When administered as maintenance therapy, a single injection may be effective in controlling schizophrenic symptoms up to four weeks or longer. • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)
J2794 INJ RISPERIDONE LONG ACTING RISPERDAL CONSTA (risperidone) is available in dosage strengths of 12.5 mg, 25 mg, 37.5 mg, or 50 mg risperidone. It is provided as a dose pack, consisting of a vial containing the risperidone microspheres, a pre-filled syringe containing 2 mL of diluent for RISPERDAL CONSTA , a West-Medimop Vial Adapter , and two Terumo SurGuard 3 Needles for intramuscular injection (a 21 G UTW 1-inch needle with needle protection device	• The entire dose pack should be stored in the refrigerator (2-8°C, 36-46°F) and protected from light • If refrigeration is unavailable, Risperdal Consta can be stored at temperatures not exceeding 77°F (25°C) for no more than 7 days prior to administration • Must be reconstituted only in the diluent supplied in the dose pack • Do not store suspension after reconstitution • The entire contents of the vial must be administered to ensure intended dose of Risperdal Consta is delivered • Single use device. Do not reuse • Remove dose pack from the refrigerator and allow to sit at room temperature for at least 30 minutes before reconstituting • Remove cap from vial. Wipe top with an alcohol swab. Allow to air dry • Using the packaging, connect vial adapter to vial securely (should not be at an angle). Discard blister packaging • Snap white cap off of syringe. Connect syringe to vial adapter with a firm clockwise twisting motion until it feel snug • Inject diluent from syringe into vial • Holding plunger rod, shake vigorously for at least 10 seconds • When mixed properly, the suspension appears uniform, thick and milky in color • Invert vial completely. Slowly pull plunger	• Tolerability should be established with oral risperidone prior to initiating treatment with Risperdal Consta	• Advise patients regarding risk for orthostatic hypotension, as well as interference with cognitive and motor performance. • Patients should be advised to avoid alcohol during treatment • Antipsychotics, like risperidone, are not approved for the treatment of dementia-related psychosis in geriatric patients	• Oral risperidone should be given with the first injection and continued for 3 weeks to ensure that adequate therapeutic concentrations are maintained prior to the main release phase of risperidone from the injection site. • Administered every 2 weeks • Maximum dose should not exceed 50 mg every 2 weeks • Recommended to use at the lowest dose needed • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)

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for deltoid administration and a 20 G TW 2-inch needle with needle protection device for gluteal administration).	rod down to withdraw entire contents from the vial into the syringe • Follow instructions for injection			
J2426 INJECTION PALIPERIDONE PALMITATE INVEGA SUSTENNA is available as a white to off-white sterile aqueous extended-release suspension for intramuscular injection in dose strengths of 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg paliperidone palmitate. The kit contains a prefilled syringe and 2 safety needles (a 1 ½-inch 22 gauge safety needle and a 1-inch 23-gauge safety needle).	• Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted • Inspect visually for foreign matter and discoloration prior to administration • Intended for IM use only • Recommended needle size for administration into the deltoid muscle is determined by patient's weight. 23-gauge needle for patients weighing less than 90 kg and 22 gauge for patients weighing 90 kg or more • Recommended needle size for administration into the gluteal muscle is the 1 ½ inch, 22-gauge needle regardless of patient weight. Administer into the upper-outer quadrant of the gluteal muscle • Shake the syringe vigorously for a minimum of 10 seconds to ensure a homogeneous suspension • Select appropriate needle • While holding the syringe upright, remove the rubber tip cap with an easy clockwise twisting motion • Peel the safety needle pouch halfway open. Grasp the needle sheath using the plastic peel pouch. Attach the safety needle to the luer connection of the syringe with an easy clockwise twisting motion • Pull the needle sheath away from the needle with a straight pull • De-aerate the syringe • Inject the entire contents IM slowly, deep into the selected deltoid or gluteal muscle of the patient • Activate the needle protection system. Discard appropriately	• Tolerability with oral paliperidone or oral risperidone should be done prior to initiating treatment with Invega Sustenna	• Advise patients regarding risk for orthostatic hypotension, as well as interference with cognitive and motor performance • Patients should be advised regarding appropriate care in avoiding overheating and dehydration • Antipsychotics are not approved for the treatment of dementia-related psychosis in geriatric patients	• Recommended initiation with a dose of 234 mg on day 1 and 156 mg one week later, both administered in the deltoid muscle. Following the second initiation dose, monthly doses can be administered in either the deltoid or gluteal muscle • Not recommended in moderate to severe renal impairment • See dosing recommendations for mild renal impairment • Monthly maintenance dose should be administered 5 weeks after the first injection • Gluteal injections should be alternated between the two gluteal muscles. • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)
J0401 ARIPIPRAZOLE INJECTION ABILIFY MAINTENA: Pre-filled dual chamber syringe: (aripiprazole) pre-filled dual chamber syringe for extended-release injectable suspension in single-use syringes is available in 300 mg or 400 mg strength syringes.	• Pre-filled dual chamber syringe: Store below 30°C [86°F]. Do not freeze. Protect the syringe from light by storing in the original package until time of use • Vial: Store at 25°C (77°F), excursions permitted between 15°C and 30°C (59°F to 86°F) **<u>Instructions for Pre-filled Syringe</u>** • Reconstitute at room temperature • Push plunger rod slightly to engage threads. Rotate plunger rod until the rod stops rotating to release diluent. After plunger rod is at complete stop, middle stopper will be at the indicator line • Vertically shake the syringe vigorously for 20 seconds until drug is uniformly milky-white • Visually inspect the syringe for particulate	• Tolerability with oral aripiprazole should be established prior to initiating treatment with Abilify Maintena	• Do not massage the injection site • Advise patients regarding risk for orthostatic hypotension, as well as interference with cognitive and motor performance. • Advise patients with pre-existing low WBC count or a history of drug-induced leucopenia/neutropenia that they should have their CBC monitored while receiving Abilify Maintena • Patients should be advised regarding appropriate care in avoiding overheating and dehydration	• Recommended and maintenance dose is 400mg monthly (no sooner than 26 days after the previous injection). Reduce dose if adverse reactions. • After the first Abilify Maintena injection, administer oral aripiprazole (10 to 20 mg) for 14

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The pre-filled dual chamber syringe consists of a front chamber that contains the lyophilized powder of aripiprazole monohydrate and a rear chamber that contains sterile water for injection. Single-Use Vial: ABILIFY MAINTENA (aripiprazole) extended-release injectable suspension in single-use vials is available in 300 mg or 400 mg strength vials.	matter and discoloration prior to administration. The suspension should appear uniform, homogenous, opaque and milky-white in color • Twist and pull off over-cap and tip-cap. • Select appropriate needle. Non-obese deltoid (1 inch), non-obese gluteus (1.5 inch); obese deltoid (1.5 inch), obese gluteus (2 inch) • Follow directions for injection **Instructions for Vial Preparation** • Remove the cap of the vial of Sterile Water for Injection and Abilify Maintena lyophilized power and wipe tops with sterile alcohol swab • Using syringe with pre-attached hypodermic safety needle, withdraw the pre-determined Sterile Water for Injection volume • Slowly inject the Sterile Water for Injection into the vial containing Abilify Maintena lyophilized powder • Withdraw air to equalize the pressure in the vial by pulling back slightly on the plunger. Remove the needle from the vial. Engage needle safety device • Shake vial vigorously for 30 seconds until reconstituted suspension appears uniform. • Visually inspect suspension for particulate matter and discoloration prior to administration. Reconstituted Abilify Maintena is a uniform, homogenous suspension that is opaque and milky-white in color • If the injection is not performed immediately after reconstitution keep the vial at room temperature and shake the vial vigorously for at least 60 seconds to re-suspend prior to injection • Follow instructions for injection		• Antipsychotics, such as aripiprazole, are not approved for the treatment of dementia-related psychosis in elderly patients	consecutive days to achieve therapeutic concentrations during initiation of therapy. • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)
J2358 INJECTION OLANZAPINE LONG-ACTING 1 MG | Zyprexa Relprevv (Olanzapine Extended-Release Injectable Suspension) ZYPREXA RELPREVV convenience kit is supplied in single-use cartons. Each carton includes one vial of olanzapine pamoate monohydrate in dosage strengths that are equivalent to 210 mg olanzapine (483 mg olanzapine pamoate monohydrate), 300 mg olanzapine	• Store at room temperature not to exceed 30°C (86°F) • When the drug product is suspended in the solution for ZYPREXA RELPREVV, it may be held at room temperature for 24 hours. The vial should be agitated immediately prior to product withdrawal. Once the suspension is withdrawn into the syringe, it should be used immediately • For deep IM gluteal injection only • Inspect visually for particulate matter and discoloration prior to administration • Must be suspended in the diluent supplied in the convenience kit • Use gloves with reconstituting; may irritate the skin. Flush skin with water if needed • Loosen the powder by lightly tapping the vial • Open the prepackaged hypodermic needle-pro syringe with needle protection device • Withdraw the pre-determined diluent volume into the syringe • Inject the diluent into the powder vial • Withdraw air to equalize the pressure in the vial by pulling back slightly on the plunger in the syringe • Remove the needle from the vial. Engage	• Tolerability with oral olanzapine should be established prior to initiating treatment with Zyprexa Relprevv • Following insertion of the needle into the muscle, aspiration should be maintained for several seconds to ensure that no blood is drawn into the syringe. If any blood is aspirated into the syringe, it should be discarded and fresh drug should be prepared	• Do not massage injection site • Monitor patients at the healthcare facility for at least 3 hours for post-injection delirium/ sedation syndrome. Symptoms are consistent with olanzapine overdose and include sedation (ranging from mild in severity to coma) and/or delirium (including confusion, disorientation, agitation, anxiety, and other cognitive impairment). Other symptoms noted include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, and convulsion • The potential for onset of an event is greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however, the event has occurred after 3 hours.	• Administered every 2 to 4 weeks by deep IM gluteal injection using a 19-gauge, 1.5-ince needle (150 mg to 300mg every 2 weeks: 405 mg every 4 weeks) • Should only be administered in a registered healthcare facility with ready access to emergency response services • Periodic evaluation for movement disorders is recommended (e.g., AIMS test)

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(690 mg olanzapine pamoate monohydrate), and 405 mg olanzapine (931 mg olanzapine pamoate monohydrate) per vial; one vial of approximately 3 mL of diluent for ZYPREXA RELPREVV used to suspend the drug product: one 3-mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with needle protection device; and two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device.	needle safety device • Tap the vial firmly and repeatedly on a padded surface until no powder is visible • Visually check the vial for clumps. Additional tapping may be required if large clumps remain • Shake the vial vigorously until the suspension appears smooth and is consistent in color and texture. The suspended product will be yellow and opaque • If foam forms, let vial stand to allow foam to dissipate • If the product is not used right away, it should be shaken vigorously to re-suspend • Reconstituted Zyprexa Relprevv remains stable for up to 24 hours in the vial. • Follow instructions for injection		Following the 3-hour observation period, healthcare professionals must confirm that the patient is alert, oriented, and absent of any signs and symptoms of post-injection delirium/ sedation syndrome prior to being released. All patients must be accompanied to their destination upon leaving the facility • For the remainder of the day of each injection, patients should not drive or operate heavy machinery, and should be advised to be vigilant for symptoms of post-injection delirium/ sedation syndrome and be able to obtain medical assistance if needed. If post-injection delirium/sedation syndrome is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation • Antipsychotics, such as olanzapine, are not approved for the treatment of dementia-related psychosis in geriatric patients	