

COMPARISON OF FDA-APPROVED PHARMACOTHERAPIES FOR ALCOHOL DEPENDENCE

Generic Name	Marketed As	Indication	Purpose	Dosage	Mechanism of Action	Abstinence Requirements	Recommended Length of Treatment	Counseling Recommendations	Common Side Effects	Contraindications	Possible Drug Interactions	Special Precautions	Populations
disulfiram	Antabuse®	an aid in the management of selected chronic alcohol patients who want to remain in a state of enforced sobriety so that supportive and psychotherapeutic treatment may be applied to best advantage	to discourage drinking by making the patient physically sick when alcohol is consumed	one tablet once a day by mouth – can be crushed, diluted or mixed with food	<i>aldehyde dehydrogenase inhibitor</i> - blocks the metabolism of alcohol and causes a build-up of acetaldehyde and a severe reaction called the “disulfiram-alcohol reaction” if a patient drinks alcohol	must be abstinent from alcohol for at least 12 hours prior to treatment initiation	the FDA has not limited the treatment time	should be used in conjunction with a comprehensive psychosocial treatment program	acneform eruption, eye pain, headache, hepatic failure, hepatitis, impotence, metallic or garlic-like aftertaste, mild drowsiness, mild fatigue, peripheral neuritis, peripheral neuropathy, polyneuritis, skin rash	use of alcohol or alcohol-containing preparations; coronary artery disease; severe myocardial disease; psychosis; previous sensitivity to disulfiram or other thiuram derivatives; recently taken metronidazole or paraldehyde	alcohol; oral anticoagulants; nitrite; isoniazid; phenytoin; any nonprescription medication containing alcohol	do not breathe ethylene dibromide or its vapors, paint fumes, paint thinner, varnish or shellac; exercise extreme caution with applying aftershave, mouthwash, lotions, colognes and rubbing alcohol; do not drink alcoholic beverages, medications that contain alcohol or sauces, vinegars or foods that contain alcohol	FDA-approved for ages 18 to 65 years old; not been adequately tested for use with the elderly, adolescents or polysubstance abuse populations; Pregnancy Category C designation (use only when the potential benefits justifies the potential risk to the fetus)
naltrexone hydrochloride	ReVia®/ Depade®	in the treatment of alcohol dependence and for the blockade of the effects of exogenous administered opioids	to discourage drinking by decreasing the pleasurable effects from consuming alcohol	one tablet once a day by mouth – can be crushed, diluted or mixed with food	<i>opioid receptor antagonist</i> - by blocking opioid receptors, the “reward” and acute reinforcing effects from dopamine are blocked, and drinking is reduced	must be abstinent from opioids for at least seven to ten days prior to treatment initiation; abstinence from alcohol is not required	the FDA has not limited the treatment time	should be used in conjunction with a comprehensive psychosocial treatment program	anxiety, dizziness, fatigue, headache, insomnia, nausea, nervousness, vomiting	opioid physical dependence or undergoing acute opiate withdrawal; opioid analgesics; previous sensitivity to naltrexone or any other components of the medication; acute hepatitis or liver failure	opioid-containing medications; opiates; thioridazine	if opioid analgesia is required during an emergency, patient may necessitate greater than usual amounts of opioids to achieve desired effect and the resulting respiratory depression may be deeper and more prolonged	FDA-approved for ages 18 to 65 years old; not been adequately tested for use with the elderly, adolescents or polysubstance abuse populations; Pregnancy Category C designation (use only when the potential benefits justifies the potential risk to the fetus)
acamprosate calcium	Campral®	for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation	to encourage sobriety by reducing post-acute withdrawal symptoms from alcohol dependence	two tablets three times a day by mouth – cannot be crushed or diluted, but can be mixed with food	<i>glutamate receptor modulator</i> - reduces the activity of glutamate and decreases post-acute withdrawal symptoms from alcohol dependence	must be abstinent from alcohol at treatment initiation and have completed the medical detoxification process	approved by the FDA for use up to one year	should be used in conjunction with a comprehensive psychosocial treatment program	accidental injury, anxiety, depression, diarrhea, dizziness, dry mouth, flatulence, insomnia, itching, loss of appetite, nausea, pain, sweating, skin sensations, weakness	previous sensitivity to acamprosate calcium or any of its components, severe renal impairment (creatinine clearance level of ≤ 30 mL/min)	none known	does not prevent acute withdrawal symptoms from alcohol dependence; patient should be monitored closely for suicidal thoughts or attempts	FDA-approved for ages 18 to 65 years old; not been adequately tested for use with the elderly, adolescents or polysubstance abuse populations; Pregnancy Category C designation (use only when the potential benefits justifies the potential risk to the fetus)
naltrexone for extended-release injectable suspension	Vivitrol®	for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment	to reduce drinking and maintain abstinence in patients who are abstinent prior to treatment	one injection into buttock deep muscle, administered once a month by a healthcare professional	<i>opioid receptor antagonist</i> - by blocking opioid receptors, the “reward” and acute reinforcing effects from dopamine are blocked, and drinking is reduced	must be abstinent from opioids for at least seven to ten days prior to treatment initiation and not actively drinking at treatment initiation	the FDA has not limited the treatment time	should be used in conjunction with a comprehensive psychosocial treatment program	abdominal pain, anxiety, back pain/stiffness, depression, diarrhea, dizziness, drowsiness, dry mouth, headache, injection site reaction, joint stiffness, loss of appetite, muscle cramps, nausea, pharyngitis, rash, sleep disorder, upper respiratory infection, vomiting	opioid physical dependence or undergoing acute opiate withdrawal; opioid analgesics; previous sensitivity to naltrexone, PLG, carboxymethylcellulose or any other components of the diluent; acute hepatitis or liver failure	opioid-containing medications; opiates; not adequately tested	patient should be monitored closely for suicidal thoughts or attempts; if opioid analgesia is required during an emergency, patient may necessitate greater than usual amounts of opioids to achieve desired effect and the resulting respiratory depression may be deeper and more prolonged; diagnosis of eosinophilic pneumonia should be considered if pneumonia develops; caution exercised with patients with thrombocytopenia or coagulation disorder	FDA-approved for ages 18 to 65 years old; not been adequately tested for use with the elderly, adolescents or polysubstance abuse populations; Pregnancy Category C designation (use only when the potential benefits justifies the potential risk to the fetus)

This chart was developed by NAADAC, the Association for Addiction Professionals, and produced from Odyssey Pharmaceuticals, Inc. (2005). *Antabuse (disulfiram, USP)* [package insert]. East Hanover, NJ: Author.; Duramed Pharmaceuticals, Inc. (2005). *ReVia (naltrexone hydrochloride)* [package insert]. Pomona, NY: Author.; Forest Pharmaceuticals, Inc. (2005). *Depade (naltrexone hydrochloride tablets, USP)* [package insert]. St. Louis, MO: Author.; Mallinckrodt, Inc. (2003). *Depade (naltrexone hydrochloride tablets, USP)* [package insert]. St. Louis, MO: Author.; Mallinckrodt, Inc. (2003). *Depade (naltrexone hydrochloride tablets, USP)* [package insert]. St. Louis, MO: Author. and Alkermes, Inc. (2006). *Vivitrol (naltrexone for extended-release injectable suspension)* [package insert]. Cambridge, MA: Author. For further explanation and information, please consult a prescriber or pharmaceutical representative. Printed 08/07.