DEHYDRATED ALCOHOL- alcohol injection
Solupharm Pharmazeutische Erzeugnisse GmbH

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DEHYDRATED ALCOHOL INJECTION safely and effectively. See full prescribing information for DEHYDRATED ALCOHOL INJECTION.

DEHYDRATED ALCOHOL Injection, for cardiac septal branch intra-arterial use

Initial U.S. Approval: 1946

INDICATIONS AND USAGE

Dehydrated alcohol injection is an ablative agent indicated to induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy. (1)

DOSAGE AND ADMINISTRATION

- Inject small volumes over 1 to 2 minutes percutaneously into septal arterial branches, using the minimal dose necessary to achieve the desired reduction in peak left ventricular outflow tract pressure gradient. (2.1)
- In most situations, a dose of 1 mL to 2 mL is sufficient. The maximum dose that should be used in a single procedure is 5 mL. (2.1)

DOSAGE FORMS AND STRENGTHS

- Injection: 1 mL or 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass ampule. (3)

CONTRAINDICATIONS

- None (4)

WARNINGS AND PRECAUTIONS

- Transient heart block: Transient heart block is common at the time of injection. A temporary pacing wire is routinely inserted to mitigate transient heart block. (5.1)
- Persistent heart block: Approximately 10% of complete heart block events become permanent and require placement of a permanent pacemaker. (5.1)
- Remove the temporary pacemaker lead if no episode of high-degree atrioventricular block occurs. (5.1)
- Monitor the patient for heart failure, chest pain, and arrhythmias several days after the procedure. (5.1, 5.2, 5.3)

ADVERSE REACTIONS

Adverse reactions include arrhythmias, including ventricular tachycardia and/or ventricular fibrillation. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Avenacy at 1-855-283-6229 or FDA at 1-800-FDA-1088 orwww.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Dehydrated alcohol injection is not recommended during pregnancy. Maternal use is not expected to result in fetal exposure to the drug. (8.1)
- The rate of heart blocks and dysrhythmia increased with age. (8.5)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dehydrated alcohol injection is indicated to induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Use the minimum dose necessary to achieve the desired reduction in peak left ventricular outflow tract pressure gradient. Inject small volumes over 1 to 2 minutes percutaneously into septal arterial branches, guided by assessment of the gradient. In most situations, a dose of 1 mL to 2 mL is sufficient. The maximum dose of dehydrated alcohol injection that should be used in a single procedure is 5 mL.

2.2 Administration

Dehydrated alcohol injection should only be administered under the supervision of a qualified interventional cardiologist experienced in the percutaneous transluminal septal myocardial ablation procedure.

Inspect visually for particulate matter and discoloration prior to administration. Dehydrated Alcohol Injection should appear as a clear, colorless solution.

3 DOSAGE FORMS AND STRENGTHS

Injection: 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass vial. (3)

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Heart Block

Transient Heart Block
Transient heart block is common at the time of dehydrated alcohol, such as dehydrated alcohol injection into a septal artery. Prior to the injection, a temporary pacing wire is routinely inserted into the apex of the right ventricle, usually via the femoral vein, to treat transient heart block. The pacing lead can be removed if no episode of high-degree atrioventricular block occurs, usually after several hours of observation following percutaneous transluminal septal myocardial ablation.

Persistent Heart Block
Approximately 10% of complete heart block events become permanent and require placement of a permanent pacemaker following percutaneous transluminal septal myocardial ablation. Risk factors for permanent pacemaker dependency after septal ablation include a baseline PQ interval > 160 ms, baseline minimum heart rate < 50 bpm, baseline left ventricular outflow gradient > 70 mmHg, maximum QRS during the first 48 hours > 155 ms, 3rd degree atrio-ventricular block occurring during the procedure, and no clinical recovery between 12-48 hours after the procedure.

5.2 Myocardial Infarction

Injection of dehydrated alcohol is intended to create a controlled myocardial infarction for therapeutic purposes. However, excessive myocardial necrosis and subsequent heart failure have been reported. Factors increasing the risk of excessive tissue necrosis include higher volume of alcohol used and a higher number of septal branches injected to reduce the left ventricular outflow tract gradient.

5.3 Ventricular Arrhythmia

Ventricular tachycardia and ventricular fibrillation requiring electrocardioversion occurred

at a frequency of approximately 1%. Perform continuous electrocardiographic monitoring for 48 hours after the procedure.

6 ADVERSE REACTIONS

Heart block [*see Warnings and precautions*(5.1)]

The following other adverse reactions associated with percutaneous transluminal septal myocardial ablation with the use of dehydrated alcohol, such as dehydrated alcohol injection, were identified in the literature: Ventricular tachycardia and ventricular fibrillation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
The concentrations of alcohol in blood after PTSMA were not measured, but dehydrated alcohol injection, is not expected to increase significantly the systemic concentrations of endogenous alcohol following administration into a septal artery during percutaneous transluminal septal myocardial ablation. Maternal use is not expected to result in fetal exposure to the drug.

Clinical Considerations
Dehydrated alcohol injection for percutaneous transluminal septal myocardial ablation has not been evaluated in pregnant women and is not recommended during pregnancy. When possible, the percutaneous transluminal septal myocardial ablation procedure should be postponed in women until the postpartum period.

Data
Animal reproduction studies have shown an adverse effect on the fetus and chronic fetal alcohol exposure is known to cause developmental defects in human. The developmental effects of acute ethanol exposure, such as from percutaneous transluminal septal myocardial ablation, have not been studied in pregnant or lactating women.

8.2 Lactation

Dehydrated alcohol injection is not expected to increase significantly the systemic concentrations of endogenous alcohol following administration into a septal artery during percutaneous transluminal septal myocardial ablation and breastfeeding is not expected to result in exposure of the child to the drug.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

A comparison of the outcomes in patients with hypertrophic obstructive cardiomyopathy in patients < 60 years old and in patients ≥ 60 years old showed similar improvement in exercise capacity after ablation. The rate of heart blocks and

dysrhythmia increased with age. Permanent pacemaker dependency increased to 34% in patients > 60 years old.

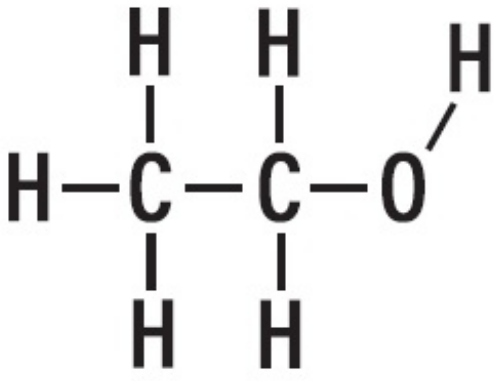
10 OVERDOSAGE

There is a direct correlation between the volume of alcohol and size of iatrogenic myocardial infarction. Stop the procedure if there is failure to reduce the left ventricular outflow tract pressure gradient to less than 10 mmHg when reaching a total dose of 5 mL.

11 DESCRIPTION

Dehydrated alcohol injection, USP is a sterile, preservative free solution of ≥ 99% by volume ethyl alcohol and no excipients. Dehydrated alcohol injection, USP is for cardiac septal branch intra-arterial use. It has a molecular formula of C_2H_6O and a molecular weight of 46.07.

Dehydrated alcohol injection, USP is a potent tissue toxin. Ethanol is a clear, colorless, volatile, and flammable liquid miscible with water and with practically all organic solvents. It has the following structural formula:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dehydrated alcohol is a tissue toxin that produces a myocardial infarction when injected through an intra-arterial catheter into a target septal vessel, which causes the hypertrophied septum to thin.

12.2 Pharmacodynamics

A dose independent, approximate 70% reduction of the peak pressure gradient across left ventricular outflow tract is observed after injection of alcohol volumes in the range of 1 to 4 mL. Remodeling contributes about 20% to the 70% total reduction in peak pressure gradient across the left ventricular outflow tract measured 12 months after septal ablation. Other markers, such as infarct size or peak concentration of creatine kinase-MB (CK-MB), in contrast to peak pressure gradient across the left ventricular outflow tract, vary in proportion to the injected alcohol volume in the 1 to 4 mL range.

12.3 Pharmacokinetics

Because injection of dehydrated alcohol injection during septal ablation is not expected to increase the systemic concentrations of endogenous alcohol significantly, the pharmacokinetics of dehydrated alcohol are not expected to be clinically significant.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Ethanol (of alcohol beverages) was added to Group 1 International Agency for Research on Cancer (IARC) Carcinogenicity Ratings (IARC monographs). Substances in this group are either carcinogenic to humans, or there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the substance acts through a relevant mechanism of carcinogenicity. Alcohol consumption has been associated with various cancers, including liver, esophageal, breast, prostate, and colorectal cancer. Since dehydrated alcohol injection is not expected to reach the systemic circulation following administration into a septal artery during percutaneous transluminal septal myocardial ablation, the recommended clinical use of the drug product is not expected to have carcinogenic risk in patients.

Literature reports suggest that ethanol is not mutagenic in the in vitro bacterial reverse mutation (Ames) assay or in *vitro* chromosomal aberration assays. Ethanol is metabolized to acetaldehyde, which is a known mutagen.

There are no data from either animal or human studies regarding potential for the impairment of fertility.

13.2 Animal Toxicology and/or Pharmacology

The median lethal dose (LD_{50}) values for ethyl alcohol given by intravenous and oral routes are 1440 and 7060 mg/kg in rats and 1973 and 3450 mg/kg in mice, respectively. The LD_{50} for ethyl alcohol given by subcutaneous injection is 8285 mg/kg in mice.

14 CLINICAL STUDIES

Evidence of the effectiveness of ethanol on exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy was obtained from literature involving over 4000 patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

Dehydrated alcohol injection, USP is a clear, colorless liquid supplied in clear, glass, single-dose vials. Each mL contains ≥ 99% by volume ethyl alcohol, supplied as follows:

Dehydrated Alcohol Injection, USP

NDC	(Volume)	Package Factor
83634-306-05	5 mL Single-Dose Vial	5 Vials per carton

Storage Conditions

Store at room temperature, between 20°C and 25°C (68°F and 77°F).

Do not refrigerate or freeze.

Highly flammable, store away from any heat source.

Sterile, Nonpyrogenic, Preservative-free.

The container closure is not made with natural rubber latex.

AVENACY

Mfd. for Avenacy

Schaumburg, IL 60173 (USA)

Made in Germany

April 2025

XXXXXXXXX

Package Labeling:


04.2028.
2025.00
Dehydrated Alcohol
Injection, USP
5 mL of ≥99% by volume ethyl alcohol
5 x 5 mL Single-Dose Vials
℞ only
For Cardiac Septal Branch Intra-Arterial Use
Discard unused portion
HIGHLY FLAMMABLE
09-JS-01
plm
GTIN:
SN:
EXP.:
LOT:
Data Matrix Code
NDC 83634-306-05
Sterile, Nonpyrogenic, Preservative-free.
The container closure is not made with natural rubber latex.
Each mL contains: ≥99% by volume ethyl alcohol.
WARNING: Do not use if discolored or precipitated.
Usual Dosage: See prescribing information.
Store at room temperature, between 20°C and 25°C (68°F and 77°F).
Do not refrigerate or freeze.
Highly flammable, store away from any heat source.
AVENACY
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Schaumburg, IL 60173 (USA)
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(01)20383634306057
052881-00
58526-1
A Sterile, Preservative-free Solution

DEHYDRATED ALCOHOL

alcohol injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55579-306
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55579-306-41	5 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product	01/08/2025	
2	NDC:55579-306-05	5 mL in 1 BOX; Type 0: Not a Combination Product	01/08/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA219569	01/08/2025	

Labeler - Solupharm Pharmazeutische Erzeugnisse GmbH (316875129)

Registrant - Solupharm Pharmazeutische Erzeugnisse GmbH (316875129)

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