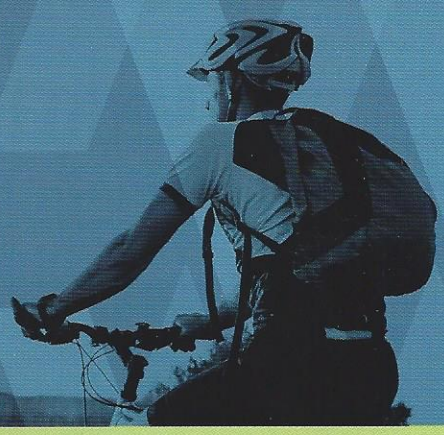
100% PURE AMNIO FLUID INJECTIONS



Repair Injuries Without Surgery

CelaPure AF is acellular, convenient, versatile and 100% pure amniotic fluid derived from donated human placental amniotic fluid. This liquid allograft uses a proprietary process and is FDA 361 compliant for homologous use.

CelaPure AF contains more than 300 growth factors, cytokines, proteins, and other naturally occurring nutrients which enable and maximize the potential of local endogenous cells. This, in turn, promotes cellular repair and regeneration. It's anti-inflammatory qualities have been shown to reduce pain and swelling at the site of the injury, while naturally occurring hyaluronic acid provides a cushioning and lubricating effect. CelaPure AF is a safe and drug-free alternative.

CelaPure AF is a chorion-free and membrane-free injectable that does not contain any stem cells or morselized dead tissue. It can be administered through as small as a 30 gauge needle for maximum patient comfort. A CelaPure AF injection may be administered multiple times without risk and there have been no adverse reactions reported to date.

All injections are frozen without any additives or chemical protectants and have a 2-year shelf life when maintained frozen at -80° centigrade.

Does not contain DMSO or Glycerol and is a stem cell free product

CelaPure AF Benefits

- 100% Pure Amniotic Fluid provides a higher concentration of growth factors compared to traditional amniotic fluid products
- Quick procedure time and ease of use
- Natural, non-steroidal solution to help reduce pain, inflammation, and encourage repair
- FDA 361 compliant as an unadulterated, cell-free, pure fluid product for homologous use

855.892.3872 info@carestreamamerica.com carestreamamerica.com

CAREstream AMERICA

Product distributed by CAREstream America, Inc.

100% PURE AMNIO FLUID INJECTIONS

Suspension for injection Amniotic Fluid Derived Solution

	ANTI-INFLAMMATORY	FAST TREATMENT TIME	PAIN-FREE TREATMENT	GROWTH FACTORS	ANTI-MICROBIAL
	Inflammation can cause pain, discomfort and stiffness depending on the severity.	Ability to return to normal activities quickly.	Some treatments create additional pain from inflammation or large needles.	Growth factors are proteins made by the body that stimulate tissue growth.	Anti-microbial agents kill microorganisms and inhibit their growth.
AMNIOTIC FLUID	✓	✓	✓	✓	✓
PLATELET-RICH PLASMA (PRP)	✗	✗	✗	✓	✗
CORTICOSTEROID	✓	✓	✗	✗	✗
HYALURONIC ACID	✗	✓	✗	✗	✗

All of our products are recovered in a sterile manner via a network of FDA and AATB registered facilities and are regulated under 21 CFR Part 1271 and section 361 of the Public Health and Service Act. The PDA-HAF injection is a versatile and convenient liquid allograft that is derived from donated human placental amnion fluid.

SAFETY INFORMATION

KEEP FROZEN UNTIL USE | STORE AT -20° C FOR EXTENDED STORAGE

CONTRAINDICATIONS

- Do not administer to patients that are immuno-compromised or taking immuno-suppressive drugs.
- CELAPURE AF injections are contraindicated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis.

WARNINGS

- Do not use for intravenous injection.
- Do not use if solution has a turbid appearance upon thaw.
- Once product is thawed, use immediately, or store at 4-8° C until injection. Do not maintain a thawed vial at room temperature for more than 24 hours.

HOW SUPPLIED

- CELAPURE AF is supplied in 0.5 ml, 1.0 ml, or 2.0 ml filled vials.

ADVERSE EVENTS

- Adverse events could include injection site pain and transient swelling.
- Adverse events should be communicated to CAREstream America.

SAFETY

- In order for the product to be considered safe, the incidence of severe swelling and pain consequent to injection should be less than 5%.

INFORMATION FOR PATIENTS

- Provide patient with a copy of the Patient Information prior use.
- Transient pain and/or swelling of an injected joint may occur after intra-articular injection of CELAPURE AF products.
- When used intra-articularly, it is recommended that the patient avoid any strenuous activities such as jogging or tennis within 48 hours following administration of the injection.

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