



**MATERIAL SAFETY DATA SHEET: ARTHEEK® ANESTHETIC
ARTICAINE HYDROCHLORIDE 4%, EPINEPHRINE 1:100.000
PRANFS-004**

1 IDENTIFICATION

- 1.1 Chemical name: Methyl - 4 - methyl - 3 - ((2RS) - 2 - (propylamino)propanoyl) amino) thiophene - 2 - carboxylic hydrochloride.
- 1.2 Generic Name: Articaine Hydrochloride with epinephrine
- 1.3 Synonym: Epinephrine is known as adrenaline.

2 COMPOSITION INFORMATION

- 2.1 Hazardous components: Articaine Hydrochloride
- 2.2 Non Hazardous component: N.A.

3 IDENTIFICATION OF DANGERS

- 3.1 Characteristic of the material: Translucent liquid free of particulate matter.
- 3.2 Appearance in case of emergency: Pink solution with particulate matter.
- 3.3 Potential adverse health effects: Toxic in high concentrations.

4 FIRST AID MEASURES

- 4.1 First aid and emergency procedures in case of:
 - Inhalation: No evidence of intoxication.
 - Contact with eyes: Must wash with plenty of water.
 - Contact with the skin: There is no evidence of negative toxic implications when in contact with the skin
 - Ingestion: The treatment of the patients with toxic manifestation consists of:

Laying the patient face up and lifting the legs in a 30°- 45° angle above the horizontal level, secure in place and make sure to keep proper oxygenation. If ventilation is inadequate, provide patient with oxygen if possible.

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If heart rate is low (< 40) or does not register, commence external cardio massage. If patients is unconscious and/or the ventilation is inadequate after taking all the

previous measures, proceed with treatment for convulsions and apply mechanical ventilation.

For convulsions: The treatment of the convulsion consists in making sure that there is a proper oxygenation and stopping the convulsions. If the convulsions persist in spite of proper ventilation, a benzodiazepine must be administered such as diazepam (in increased 2.5 mg) or a very short term intravenously barbiturate such as sodium thiopental (in increased 50 to 100 mg) every 2 to 3 minutes to stop convulsions. The agents, especially barbiturates can cause circulatory depression when administered intravenously. According to the clinical situation, the circulatory depression can be treated with i.v. solutions and a vasopressor if necessary (such as ephedrine)

This treatment may also produce respiratory depression; means for mechanical ventilation must be available. The use of neuromuscular blocking agents may also be used to decrease the manifestation of persistent muscular convulsions. The use of artificial respiration is obligatory when using the agents.

For methemoglobinemia: If it does not response to the administration of oxygen, administer methylene blue (intravenously 1 to 2 mg per Kg of corporal weight (mg/Kg) of a 1% solution for a period of 5 minutes).

4.2 Antidote: Does not apply.

4.3 Information for doctors: Does not apply.

5 ACTION IN CASE OF FIRE

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- 5.1 Flammable Properties: None Determined.
- 5.2 Means of extinguishing: Fire may be extinguished with fire extinguishers type CO₂, ABC, BC, Solkaflan.
- 5.3 Instructions for firefighting: Use full respiratory equipment and protective clothes

6 ACTION IN CASE OF ACCIDENTAL SPILL

- 6.1 Techniques, procedures and materials in case of:
 - Small spills: Put on gloves, prevent any spills down drains or canals, pick up with absorbent cloths.
 - Large Spills: prevent any spills down drains or canals, pick up in airtight plastic containers.
- 6.2 Other considerations: The residues of the local anesthetic, articaine, must be disposed of by incineration in treatment plants or according to the acting regulations of each country.

7 HANDLING AND STORAGE OF THE PRODUCT

- 7.1 Handling: The indicated for a pharmaceutical product, according to the acting regulations of each country
- 7.2 Storage: Must be stored in a dry, fresh, place, protected from direct light and heat or intense lighting. It should be stored at a temperature below 30.0 °C (111.6°F).
Keep out of the reach of children

The injectable product Artheek® Articaine with Epinephrine must be transported protected from direct light and heat and intense lighting. It is recommended to transport it between 15 °C y 30,0 °C (84.6 °F y 111.6 °F).

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8 EXPOSURE CONTROLS AND PERSONAL PROTECTION

Conditions for control of exposure: Use adequate gloves. The most adequate gloves depend on a series of factors such as physical resistance, sensibility level, and level of impermeability of the material of the glove. For this case surgical latex gloves provide a proper protection. The gloves must be replaced regularly being careful not to tear them.

8.1 Personal protection equipment: Does not apply.

- Respiratory Equipment: Does not apply.
- Eye Protection: Goggles.

8.2 Exposure Parameters: None reported.

9 PHYSICAL AND CHEMICAL PROPERTIES OF THE PRODUCT

- Appearance or shape: Translucent liquid free of particulate matter
- Odor: odorless
- Physical State: Liquid
- pH:3.3 - 5.5
- Vapor Pressure: Does not apply
- Vapor Density: Does not apply
- Boiling Point: None determined
- Freezing or Fusion Point (Specify which): Does not apply
- Solubility in water: Solvable
- Specific Gravity or Density: 1.0 approximately.
- Size of particle: Does not apply
- Content of Volatile Organic Components: Does not apply
- Softening Point: Does not apply
- Speed of evaporation: Does not apply
- Viscosity: Does not apply
- Gross Density (bulk density): Does not apply
- Volatility Percentage: Does not apply
- Partition coefficient octanol/water: None Determined
- Concentration of saturated vapor: Does not apply
- Molecular weight
- Articaine: 320.836
- Epinephrine: 183.20

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10 STABILITY AND REACTIVITY

- 10.1 Chemical stability: Strong oxidizing substances must be avoided.
- 10.2 Conditions to avoid: This product decomposes at temperatures of 35 °C (120.6 °F).
- 10.3 Incompatibility with other materials: No evidence.
- 10.4 Dangerous decompositions products: None reported.
- 10.5 Dangerous polymerization: Does not apply.

11. TOXICOLOGICAL INFORMATION

- 11.1 Acute toxicity: In excessive doses, high concentration of plasma, depression of the cardiovascular system (hypotension, irregular or slow heart rate, paleness, increased sweating) may occur. It may lead to heart arrest, toxicity of the central nervous system (double or blurred vision, confusion, dizziness, excitation, nervousness and anxiety). In patients with acidosis or hypoxia, the risk of severe allergic reactions is greater. These reactions involve the central nervousness and cardiovascular systems. The local anesthetics must be administered carefully in patients with anemia, severe heart diseases or insufficient circulation of any sort. Local anesthetics must be avoided when there is inflammation in the area where the injection was applied.
- 11.2 Chronic Toxicity: None Reported.
- 11.3 Other Information: Does not apply.

12. ECOLOGICAL INFORMATION

The residues of the local anesthetic Artheek® must be destroyed by incineration in treatment plants or according to the acting regulations of each country.

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13. DISPOSAL CONSIDERATIONS

The residues of the anesthetic Artheek® must be disposed of according to the acting local regulations

WARNING: The local laws regulations and restrictions may change or be subject to different interpretations and differ from national laws, due to this the disposal of the materials and their packaging may vary from those in this document.

14. TRANSPORT INFORMATION

- 14.1 Dangerous Materials: None
- 14.2 Type of Risk: Non Hazardous Material
- 14.3 UN: Number: None available
- 14.4 IATA Classification: Non Hazardous Material.

The injectable product Artheek® must be transported protected by direct light, heat and strong lighting. It is recommended to be transported between 15 and 30 °C. (84.6 °F and 111.6 °F).

15. REGULATION INFORMATION

15.1 In Colombia: Must be stored in a fresh, dry place and protected from direct light heat and strong lighting. It should be stored at a temperature below 30.0 °C (111.6°F).

- 15.1 Keep out of the reach of children.
- 15.2 International: According to the acting regulations of each country.

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16. OTHER IMPORTANT INFORMATION

In case of an emergency contact the Section of Physical and Industrial Safety at (574) 550 00 00.

The information provided in this safety data sheet is based in our current knowledge. No responsibility for the miss use of the product is assumed.

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