



For Topical Dermatological Use Only

50000013

INSTRUCTIONS FOR USE

**ATRAPRO™ Dermal Spray with Preservatives
For Topical Dermatological Use Only**

Rx Only – Prescription Medical Device –

Caution: Federal Law restricts this device to sale by, or on the order of a licensed healthcare practitioner.

DESCRIPTION

ATRAPRO™ Dermal Spray with Preservatives is a non-oily, non-foaming pH neutral formulation indicated for use as described below.

INGREDIENTS

Electrolyzed Water, Sodium Chloride, and preservatives: Sodium Hypochlorite (0.004%), Hypochlorous Acid (0.003%)

INDICATIONS FOR USE

ATRAPRO™ Dermal Spray with Preservatives is intended to be used by health care professionals in the management via debridement of wounds such as stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot ulcers, post surgical wounds, first- and second-degree burns, grafted and donor sites.

STABILITY PERFORMANCE TESTING: ATRAPRO™

Dermal Spray with Preservatives has been evaluated by the USP<51> Antimicrobial Effectiveness Test and in Time-Kill studies for preservative effectiveness.

Name of Organism	Log Reduction (30 sec.)	Time to Kill	Percent Reduction
<i>Staphylococcus aureus MRSA</i>	6.34	30 seconds	99.9999%
<i>Enterococcus faecalis VRE</i>	6.36	30 seconds	99.9999%
<i>Staphylococcus aureus</i>	6.23	30 seconds	99.9999%
<i>Escherichia coli</i>	5.70	30 seconds	99.9997%
<i>Acinetobacter baumannii</i>	6.37	30 seconds	99.9999%
<i>Bacteroides fragilis</i>	7.64	30 seconds	99.9999%
<i>Candida albicans</i>	6.33	30 seconds	99.9999%
<i>Enterobacter aerogenes</i>	6.09	30 seconds	99.9999%
<i>Enterococcus faecium VRE - MDR</i>	6.51	30 seconds	99.9999%
<i>Haemophilus influenzae</i>	5.18	30 seconds	99.9993%
<i>Klebsiella oxytoca MDR</i>	6.05	30 seconds	99.9999%
<i>Klebsiella pneumoniae</i>	6.14	30 seconds	99.9999%
<i>Micrococcus luteus</i>	5.84	30 seconds	99.9999%
<i>Proteus mirabilis</i>	6.20	30 seconds	99.9999%
<i>Pseudomonas aeruginosa</i>	5.81	30 seconds	99.9998%
<i>Serratia marcescens</i>	6.00	30 seconds	99.9999%
<i>Staphylococcus epidermidis</i>	5.64	30 seconds	99.9998%
<i>Staphylococcus haemolyticus</i>	5.91	30 seconds	99.9999%
<i>Staphylococcus hominis</i>	5.45	30 seconds	99.9996%
<i>Staphylococcus saprophyticus</i>	5.96	30 seconds	99.9999%
<i>Streptococcus pyogenes</i>	6.72	30 seconds	99.9999%

CONTRAINDICATIONS

Known hypersensitivity to any of the ingredients in ATRAPRO™ Dermal Spray with Preservatives.

PRECAUTIONS

ATRAPRO™ Dermal Spray with Preservatives is to be used only as directed by a licensed healthcare practitioner. Do not use to treat any condition other than that for which it is prescribed. Avoid contact with the eyes.

If a reaction to ATRAPRO™ Dermal Spray with Preservatives suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued and the prescribing healthcare practitioner consulted.

WARNINGS

For topical external use only. **Not for injection.**

There may be a temporary burning or stinging sensation when first applied to broken skin.

KEEP THIS AND ALL OTHER MEDICATIONS OUT OF THE REACH OF CHILDREN.

DIRECTIONS FOR USE

Unless otherwise directed by a prescribing healthcare practitioner, ATRAPRO™ Dermal Spray with Preservatives should be applied to affected area three times a day (or as needed).

STORAGE

Store with cap closed tightly after each use in its original container. Store at controlled room temperature 59° to 75°F (15° to 24°C), and away from direct sunlight and heat sources. Do not freeze.

HANDLING & DISPOSAL

ATRAPRO™ Dermal Spray with Preservatives is non-irritating, non-cytotoxic and non-sensitizing to skin and eyes. Special handling or disposal precautions are not required.

HOW SUPPLIED

ATRAPRO™ Dermal Spray with Preservatives is supplied in an 8 fluid ounce (236 mL) spray bottle bearing the NDC number 23710-065-08.

Manufactured in the USA for
Quinnova Pharmaceuticals, Inc., Newtown, PA 18940
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