

Atrapro™

ANTIPRURITIC HYDROGEL

For Topical Dermatological Use Only

50000031

INSTRUCTIONS FOR USE

ATRAPRO™ Antipruritic Hydrogel

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™ Antipruritic Hydrogel is a non-oily, pH neutral hydrogel dressing formulated for the relief of pain, burning and itching associated with various dermatoses, including atopic dermatitis and radiation dermatitis.

INGREDIENTS

Sodium lithium magnesium fluorosilicate, dimethicone, sodium phosphate, sodium bicarbonate, sodium chloride, sodium sulfate and water, with hypochlorous acid and sodium hypochlorite as gel preservatives.

* Hypochlorous acid and sodium hypochlorite are present only to preserve the hydrogel.

INDICATIONS FOR USE

Under the supervision of a health care professional, ATRAPRO™ Antipruritic Hydrogel is indicated to manage and relieve the pain, burning and itching experienced with various dermatoses, including atopic and radiation dermatitis.

ATRAPRO™ Antipruritic Hydrogel may be used also to relieve the pain of first and second degree burns. ATRAPRO™ Antipruritic Hydrogel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

Known hypersensitivity to any of the ATRAPRO™ Antipruritic Hydrogel ingredients.

PRECAUTIONS

ATRAPRO™ Antipruritic Hydrogel is to be used only as directed by a healthcare practitioner. Do not use to treat any condition other than that for which it is prescribed.

For external use only. Avoid contact with the eyes.

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

WARNINGS

Do not use if the inner seal is missing or damaged.

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

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

DIRECTIONS FOR USE

ATRAPRO™ Antipruritic Hydrogel should be applied to affected area three times a day (or as needed). Gently spread over the entire area to create a thin layer. Allow to dry. Bandage as needed.

Shake well before each use.

ATRAPRO™ Antipruritic Hydrogel is packaged in a specially designed package featuring a quality seal which must be removed before the first use.

SPECIALLY DESIGNED CAP – To open:



1. Unscrew cap



2. Flip cap over



3. Fit grooves on cap to tip of tube



4. Twist to open

STORAGE

Store with cap closed tightly after each use in its original container. Store at controlled room temperature 59° to 77°F (15° to 25°C). Keep away from direct sunlight and heat sources. Do not freeze.

HANDLING & DISPOSAL

ATRAPRO™ Antipruritic Hydrogel is non-irritating, non-cytotoxic and non-sensitizing to skin and eyes. Special handling or disposal precautions are not required.

HOW SUPPLIED

ATRAPRO™ Antipruritic Hydrogel is supplied in a 4 ounce (113 g) plastic tube bearing the NDC Number 23710-060-04, and a 1.5 ounce (42.5 g) professional sample tube bearing the NDC Number 23710-060-01.

Manufactured in the USA for QuinNova Pharmaceuticals, Inc.,
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Issue: Nov 2011, Rev 1

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