

Medicaid Patients Now Have Access to Atopiclair® Nonsteroidal Cream on the Florida Medicaid Preferred Drug List

Dear Doctor:

Atopiclair – a steroid-free therapeutic option for the management of itching, burning, and pain associated with atopic dermatitis (AD) – is now available on Florida's Preferred Drug List for your Medicaid patients.

Use of Atopiclair for mild to moderate AD is supported by well-controlled clinical trials in adults and children.¹⁻⁴ Atopiclair has been studied in children as young as 1 month of age.⁵

Efficacy summary: 77% of pediatric patients were rated as clear or almost clear by day 22, with significant improvement in itch vs vehicle as early as day 3 ($P < .0001$).² In another study, 94% of Atopiclair-treated adult patients required no steroid rescue medication during the 50-day study period.¹

Safety summary: Atopiclair has no restriction on duration of use. Safety has been demonstrated in both children and adults.¹⁻⁴ In a pediatric study, frequently reported adverse events (AEs) in Atopiclair-treated and vehicle-treated patients were stinging (8.3% vs 2.8%) and burning (6.9% vs 7.1%).^{2,5} In adults, frequently reported AEs in Atopiclair-treated and vehicle-treated patients were common cold (5.5% vs 6.8%), influenza (2.8% vs 4.1%), and rash (2.1% vs 5.5%).¹

Atopiclair is for external use only; avoid contact with eyes. Under the supervision of a health care professional, Atopiclair nonsteroidal cream is indicated to manage and relieve the itching, burning, and pain experienced with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis. Atopiclair nonsteroidal cream helps to relieve dry, waxy skin by maintaining a moist skin environment, which is beneficial to the healing process.

Atopiclair nonsteroidal cream does not contain milk, wheat, peanut or animal derivatives. Atopiclair nonsteroidal cream does contain shea butter (*Butyrospermum parkii*), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

If you need additional samples, call Graceway Pharmaceuticals at 1-877-287-2080.

Please see enclosed full Prescribing Information for Atopiclair.

Sincerely,



Marisa Desideri
Product Manager

References: 1. Abramovits W, Boguniewicz M. A multicenter, randomized, vehicle-controlled clinical study to examine the efficacy and safety of MAS063DP (Atopiclair) in the management of mild to moderate atopic dermatitis in adults. *J Drugs Dermatol.* 2006;5(3):236-244. 2. Boguniewicz M, Zeichner JA, Eichenfield LF, et al. MAS063DP is effective monotherapy for mild to moderate atopic dermatitis in infants and children: a multicenter, randomized, vehicle-controlled study. *J Pediatr.* In press. 3. Belloni G, Pinelli S, Veraldi S. A randomised, double-blind, vehicle-controlled study to evaluate the efficacy and safety of MAS063D (Atopiclair) in the treatment of mild to moderate atopic dermatitis. *Eur J Dermatol.* 2005;15(1):31-36. 4. Patrizi A, Capitanio B, Neri I, Giacomini F, et al. A double-blind, randomized, vehicle-controlled clinical study to evaluate the efficacy and safety of MAS063DP (Atopiclair) in the management of atopic dermatitis in paediatric patients. *Pediatr Allergy Immunol.* 2008. In press. 5. Data on file. Graceway Pharmaceuticals, LLC.



Atopiclair[®]

NONSTEROIDAL CREAM

Symptom Relief for Atopic Dermatitis

FOR TOPICAL DERMATOLOGICAL AND EXTERNAL USE ONLY.

AVOID CONTACT WITH EYES.

Indications for Use: Under the supervision of a healthcare professional, Atopiclair nonsteroidal cream is indicated to manage and relieve the itching, burning, and pain experienced with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis. Atopiclair nonsteroidal cream helps to relieve dry, waxy skin by maintaining a moist skin environment, which is beneficial to the healing process.

Directions for Use: Apply Atopiclair nonsteroidal cream to the affected skin areas 2 to 3 times a day (or as needed), and massage gently into the skin. If the skin is broken, cover Atopiclair nonsteroidal cream with a dressing of choice.


Ingredients: Atopiclair is an off-white, nonsteroidal cream comprised of Deionized water, Ethylhexyl palmitate, Pentylene glycol, Butyrospermum parkii, Capryloyl glycine, Glyceryl stearate, PEG-100 stearate, Arachidyl glucoside, Behenyl alcohol, Arachidyl alcohol, Bisabolol, Tocopheryl acetate (antioxidant), Glycyrrhetic acid, Carbomer, Ethylhexylglycerin, Piroctone olamine, Sodium hydroxide, Allantoin, DMDM hydantoin, Vitis vinifera, Disodium EDTA, Ascorbyl tetraisopalmitate, Sodium hyaluronate, Propyl gallate, Telmesteine, and Butylene glycol.


Cautions: The use of Atopiclair nonsteroidal cream is contraindicated in any patient with a known history of hypersensitivity to any of the ingredients. Atopiclair nonsteroidal cream does not contain milk, wheat, peanut or animal derivatives. Atopiclair nonsteroidal cream does contain shea butter (*Butyrospermum parkii*), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

Other Patient Information: The formulation contains no dyes or fragrances and is well tolerated and safe for patients of all ages.

How Supplied: 100g tube.

Precautions: Do not use the product if the packaging is damaged or after expiration date. Store at room temperature up to 25°C (77°F). Do not freeze.

Manufactured in Italy under license from
 Sinclair Pharmaceuticals Ltd.
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Distributed by

 Bristol, TN 37620

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