

Pediatric Use

Safety and efficacy of HUMIRA in pediatric patients for uses other than juvenile idiopathic arthritis have not been established.

Juvenile Idiopathic Arthritis

In the juvenile idiopathic arthritis study, HUMIRA was shown to reduce signs and symptoms of active polyarticular juvenile idiopathic arthritis in patients 4 to 17 years of age. HUMIRA has not been studied in children less than 4 years of age, and there are limited data on HUMIRA treatment in children with weight <15 kg.

Safety of HUMIRA in pediatric patients was generally similar to that observed in adults with certain exceptions [see Adverse Reactions].

Geriatric Use

A total of 519 rheumatoid arthritis patients 65 years of age and older, including 107 patients 75 years of age and older, received HUMIRA in clinical studies RA-I through IV. No overall difference in effectiveness was observed between these subjects and younger subjects. The frequency of serious infection and malignancy among HUMIRA treated subjects over 65 years of age was higher than for those under 65 years of age. Because there is a higher incidence of infections and malignancies in the elderly population in general, caution should be used when treating the elderly.

OVERDOSAGE

Doses up to 10 mg/kg have been administered to patients in clinical trials without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

PATIENT COUNSELING INFORMATION

Patient Counseling

Patients should be advised of the potential benefits and risks of HUMIRA. Physicians should instruct their patients to read the Medication Guide before starting HUMIRA therapy and to reread each time the prescription is renewed.

Immunosuppression

Inform patients that HUMIRA may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections.

Allergic Reactions

Patients should be advised to seek immediate medical attention if they experience any symptoms of severe allergic reactions. Advise latex-sensitive patients that the needle cap of the prefilled syringe contains latex.

Other Medical Conditions

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

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PRODUCTS

Tattoo Care Products

The Tattoo Potion product line includes lotions that help maintain a tattoo’s longevity and prevent fading. Products include Tattoo Potion Number 1 SPF 30, for sun protection; Number 7, a lotion for everyday use that contains vitamins A, D, and E; and Number 9, a water-based aftercare treatment. For more information, contact Tattoo Potion by calling 800-770-9847.

Silver Soap

Cor soap contains silver nanoparticles that kill bacteria on the surface of the skin. It also contains silica, collagen, sericin, and chitosan to mitigate sun damage and age spots. A 120-g bar costs \$85, and a trial-size bar costs \$12. For more information, contact Cor by calling 617-440-5623.

Line Refining Solution

TNS Line Refine reduces the appearance of wrinkles and lines around the mouth and eyes by smoothing, tightening, and filling fine lines. For more information, contact SkinMedica Inc. by visiting www.skinmedicaaesthetics.com/products/nouricel-md/tns-line-refine.

Self-Tanning Lotion

Avène Moisturizing Self-Tanning Lotion is available only through physician office distribution. This lightweight lotion produces a tan plus hydration in an hour. It can be used on the face and body by people with all skin tones. The lotion is hypoallergenic and noncomedogenic, and is formulated with Avène thermal spring water. The 100-mL bottle retails for \$28. For more information, contact Pierre Fabre Dermo-Cosmétique USA by calling 866-412-8363.

Streak-Free Moisturizer

The Azur moisturizer and antiaging cream for face and eyes is designed to act as a moisturizer and makeup base that resists streaking from sweat or watery eyes dur-

ing outdoor activities. The cream also provides an SPF of 30 or 40 and contains vitamins A, C, and E to promote healthier skin. For more information about the moisturizer, contact Azur International by visiting www.azurskin.com.

Vectra 3D Imaging Photography

The Vectra 3D from Canfield Imaging Systems is a device that takes multiple photos to create continuous, rotatable views that facilitate comprehensive comparison of patient progress after treatment. For more information, visit www.canfieldsci.com/Imaging_Products_Vectra3D.asp.

Fruit-Infused Facial Lotions

Three new products from Antiqua Prima Inc. are derived from fruit and fruit extracts. Gratificatio Serum tightens the skin and reduces inflammation. Fulfillimente Cream is for after chemical peels or microdermabrasion. Purificatio Serum is for hyperpigmented or oily skin. For more information, visit [www.antiqua prima.com](http://www.antiquaprima.com).

Clinical Tool for Reimbursement

PPS Clinical Optimizer software provides the real-time details and automated data transfer that are necessary to optimize patient care, outcomes, case weight, and reimbursement to ease the adaption to the new 2008 Medicare prospective payment system algorithm. For more information, call OCS Inc. at 888-325-3396.

Locoid Lotion Available

Locoid lotion (hydrocortisone butyrate 0.1%) is available for the treatment of mild to moderate atopic dermatitis in patients as young as 3 months of age. The lotion vehicle allows for coverage of larger areas and hairy areas of affected skin. The lotion is available in 2-fluid ounce bottles. For more information, contact Triax Pharmaceuticals LLC by calling 908-372-0500.

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