

PI Impact!

PI Fundamentals and **PI Annotation** provide a comprehensive, integrated training platform for all of your PI training needs.

days/week; or Cohort 3, 300 mg twice daily for 14 days followed by a 7-day rest (induction). In Cohort 1, at least a partial response was not observed then patients were dosed with a maintenance regimen of 200 mg twice daily. The primary efficacy endpoint, objective response, was measured by the Physician's Global Assessment (PGA) scale. The investigators assessed improvement of overall disease compared to baseline based on the investigator's overall impression. Index lesions included cutaneous lesions as well as cutaneous tumors, lymphadenopathy, and all other disease manifestations also assessed and included in the overall clinical response. Patients were required 100% clearing of and PR required at least 50% improvement in disease.

The median age was 67.0 years (range 26.0 to 88.0). The majority of patients (75%) were female. Fifteen percent of patients had Stage IIB, III, IVA, or IVB CTCL. All patients had prior systemic therapy.

In all patients treated, the objective response was 36.4% in the overall population. The response rates were 30.8%, 9.1% and 33.3% in Cohort 1, Cohort 2, and Cohort 3, respectively. The 300 mg twice daily regimen had higher toxicity with no additional benefit over the 200 mg twice daily regimen. No CCR was observed.

Among the 8 patients who responded to study treatment, the median time to response was 66 to 110 days (range 25 to 153 days). The median response duration was 211.5 days (range 94 to 255 days). The median time to progression was 211.5 days (range 94 to 255 days).

15 REFERENCES

1. NIOSH Alert: Preventing occupational asthma. U.S. Department of Health and Human Services, 2004. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH Publication No. 2004-109.



Developed specifically for the
Pharmaceutical & Biotech Professional

PI Fundamentals

An interactive guide to the contents and organization of the package insert.

PI Fundamentals enables

New Hires to master key concepts quickly and effectively and provides a refresher course for experienced sales representatives.

FEATURES

- Dynamic, instructional presentations summarize the contents and organization of each section of the PI.
- Real-world **Examples** contain annotated excerpts from actual PIs to reinforce key concepts.
- Practical **Field Applications** explain how to translate an understanding of the PI to selling your products more effectively.
- Screen-specific **Glossary Guide** and an overall **Program Glossary** provide easy access to key term definitions.
- **Progress-Check Questions** for each section and a **Program Assessment** evaluate and reinforce content comprehension and mastery.

EXAMPLE

LESSONS

Lessons reflect PI sections.

PI Fundamentals

teratogenic nonteratogenic fetus

Pregnancy Categories

	Animal Studies	Clinical Studies	Population Investigations	Risk/Benefit
A				
B	increased risk to fetus	no studies conducted		benefits may outweigh risks
C	no studies conducted	no studies conducted		benefits may outweigh risks
D				
X				

LOW RISK (A, B, C) | HIGH RISK (D, X)

Click on each pregnancy category, then click Next to continue. Examples Field Application Challenge

GLOSSARY GUIDE

chronic idiopathic urticaria
recurrent episodes (for at least six weeks with no known cause) of pruritic skin eruptions characterized by transient wheals with well-defined erythematous margins and pale centers

perennial allergic rhinitis
inflammation of the nasal passages caused by a localized sensitivity reaction to dust or animal dander; symptoms include a watery nasal discharge, itching of the nose and eyes, sneezing, and congestion

seasonal allergic rhinitis
inflammation of the nasal passages caused by a localized sensitivity reaction to pollen; symptoms include a watery nasal discharge, itching of the nose and eyes, sneezing, and congestion; also called hay fever

1 Pregnancy category B

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Teratogenic Effects
Pregnancy Category B. There are no adequate and well-controlled studies with [redacted] in pregnant women. There were no adverse fetal effects in animal reproduction studies of [redacted] in rabbits. Because animal reproduction studies are not always predictive of human response, [redacted] should be used during pregnancy only if clearly needed. A reproduction study conducted in rabbits at oral [redacted] doses approximately 9-fold the maximum recommended human [redacted] dose (60 mg) revealed no evidence of harm to the fetus due to [redacted]. In addition, reproduction studies performed in pregnant rats with oral [redacted] at doses up to 40 times the recommended human dose and in pregnant rabbits at oral [redacted] doses up to 16 times the recommended human dose revealed no evidence of impaired fertility or [redacted].

Pregnancy category B: Animal reproduction studies failed to demonstrate fetal harm, but no adequate, well-controlled clinical studies in pregnant women were conducted.

Because animal reproduction studies are not always predictive of human response, pregnancy category B drugs should be used during pregnancy only if clearly needed.

The Pregnancy subsection includes the species of animals involved in the studies and the degree to which the [redacted] the recommended [redacted].

PI Annotation

An annotated program for teaching key concepts and field applications for your product PIs.

FIELD APPLICATIONS

ANNOTATIONS PROGRESS CHECK



PI Annotation integrates comprehensive, customized training for your entire sales force on any of your product PIs.

FEATURES

- Interactive verbatim package insert can be viewed in **Full View Mode** or **Magnification Mode**.
- **Annotations** link important and/or difficult topics in the PI with easily accessible explanations or reinforcement.
- **Field Applications** link selected PI topics to tips for selling products more effectively and addressing physician questions and concerns.
- **Look Back/Look Ahead** feature connects key concepts to related topics covered in previous and subsequent sections.
- Hyperlinked **PI Glossary Guide** provides easy access to key term definitions.
- **Progress-Check Questions** and an overall **PI Assessment** evaluate and reinforce content mastery.

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PI Annotation

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ANNOTATION

The recommended dosage for the treatment of uncomplicated skin manifestations of chronic urticaria in children and adolescents of 6 months to 17 years of age is based on the extrapolation of efficacy data from clinical trials in adults.

The recommended dosages for the treatment of the symptoms of perennial allergic rhinitis and chronic idiopathic urticaria in patients 6 months to 11 years of age and the symptoms of seasonal allergic rhinitis in patients 2 to 11 years of age are based on cross-study comparisons of the systemic exposure (area under the curve) in adult and pediatric patients and the safety profile in adult and pediatric patients at doses equal to or higher than recommended doses.

A LOOK BACK - Dosage and Administration
The recommended dosages are 5 mg once daily in the evening for adults and children 12 years of age and older, 2.5 mg once daily in the evening for children 6 to 11 years of age, and 1.25 mg once daily in the evening for children 6 months to 5 years of age.

A LOOK AHEAD - Clinical Pharmacology
Administration of a 2.5 mg dose in children 6 months to 11 years of age and a 1.25 mg dose once daily in children 6 months to 5 years of age results in an area under the curve (AUC) comparable to that of a 5 mg dose once daily in adults and adolescents 12 years of age and older.

GLOSSARY GUIDE

GLOSSARY GUIDE

The package insert is viewed by physicians and other healthcare practitioners as a comprehensive and unbiased guide to the safe and effective use of a drug or biological product. **PI Impact!** ensures that your sales professionals thoroughly understand their product PIs and can communicate this information effectively and confidently with customers.

Dynamic learning for an effective salesforce.

PI Impact! is a comprehensive, fully integrated sales training platform that:

- provides critical PI training for New Hires.
- offers refresher PI training for experienced representatives.
- seamlessly integrates comprehensive PI training for all of your product PIs.
- supplies a platform "architecture" that provides future expansion to house an unlimited number of PI annotations, dramatically increasing your training ROI.
- provides a web-based technical platform that can be readily integrated into your internal Learning Management System (LMS).

