

Head Lice Treatment

New Options for an Ancient Adversary

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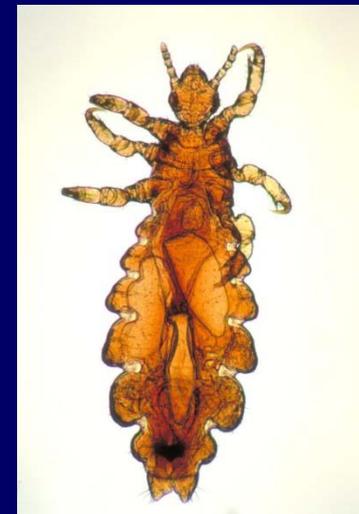
Presentation Outline

- I. Head Lice Are With Us
- II. Approaches to Head Lice Treatment
- III. The Role of Health-Care Providers (HCP)
in Head Lice Management
- IV. Sklice (Ivermectin) Lotion, 0.5%
- V. Educational Resources

Full Prescribing Information for Sklice Lotion will be provided.

Head Lice Are With Us

“Lice occur wherever there are humans.”¹



CDC/Dr. Dennis D. Juranek

Reference: 1. Lice (pediculosis). In: Paller AS, Mancini AJ, eds. *Hurwitz Clinical Pediatric Dermatology. A Textbook of Skin Disorders of Childhood and Adolescence*, 4th ed. New York, Elsevier Saunders, 2011:424-427.

Head Lice Infestation: A Common Pediatric Condition

- Pediculosis is the most prevalent parasitic infestation among humans¹
- Head lice infestations are pervasive among school-age children in the United States^{2,3}
- ~6-12 million infestations occur each year in children 3 to 11 years of age³
 - More common in females⁴
- All socioeconomic groups are affected²⁻⁴
 - Contrary to myth, “head lice prefer clean, healthy hosts”⁴



Photo Researchers



Getty Images/Peter Dazeley

References: 1. Hodgdon HE, et al. *Pest Manag Sci.* 2010;66(9):1031-1040. 2. Frankowski BL, et al. *Pediatrics.* 2010;126(2):392-403. 3. Centers for Disease Control and Prevention (CDC). Head lice. Epidemiology & risk factors. <http://www.cdc.gov/parasites/lice/head/epi.html>. Accessed July 16, 2012. 4. Meinking T, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology.* 4th ed. Mosby Elsevier; 2011:1525-1583.

Pediculus Humanus Capitis: A Closer Look at the Critter¹

- The adult louse is 2-3 mm long (size of a sesame seed)
 - Usually pale gray; color may vary (red when engorged with blood)
- The louse feeds by injecting small amounts of saliva and taking tiny amounts of blood from the scalp every few hours
- Lice usually survive less than 1 day away from the scalp at room temperature



Head louse family portrait, left to right: nymph stages 1, 2, and 3; adult male, adult female.²

CDC. J. Strycharz, PhD;
K.S. Yoon, F. Collins, PhD.



CDC.

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. Meinking TL, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology*. 4th ed. Mosby Elsevier; 2011:1525-1583.

The Life Cycle of the Head Louse^{1,2}

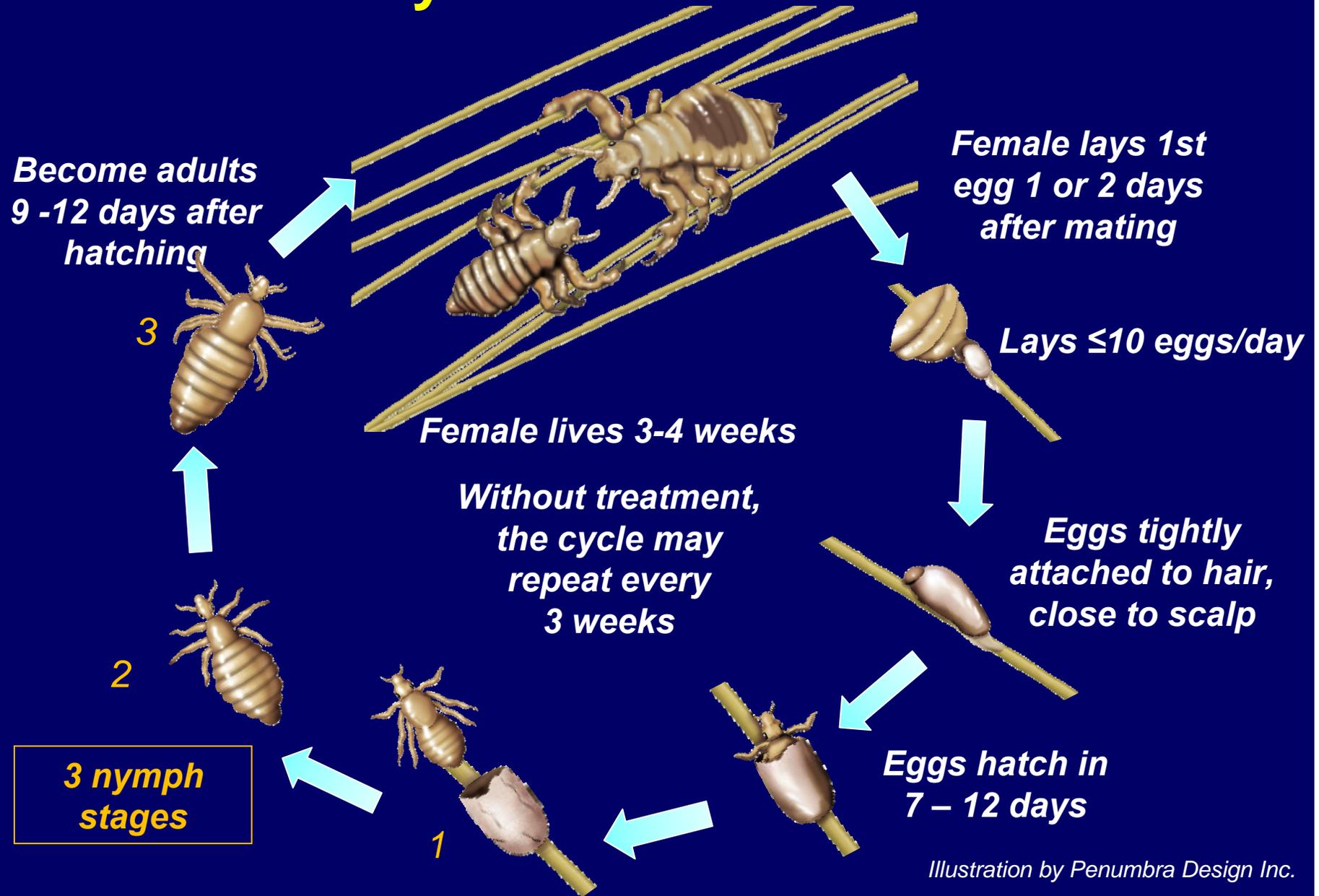


Illustration by Penumbra Design Inc.

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. Meinking TL, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology*. 4th ed. Mosby Elsevier; 2011:1525-1583.

Transmission: Think Head-to-Head^{1,2}

- Transmission of lice typically occurs by direct head-to-head contact with an infested individual^{1,2}
- Indirect spread via contact with personal items (combs, brushes, hats) is less likely but can occur^{1,2}
- Itching is the most common symptom
 - It may take 4-6 weeks for itching to develop in someone infested for the first time¹
 - In someone with previous episodes, itching may develop within 48 hours³
 - Excoriation, crusting, secondary bacterial infection may result from scratching¹⁻³



Getty Images/Westend61



© Getty Images
Getty Images/Photodisc

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. CDC. Head lice. Epidemiology & risk factors. <http://www.cdc.gov/parasites/lice/head/epi.html>. Accessed July 16, 2012. 3. Meinking TL, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology*. 4th ed. Mosby Elsevier; 2011:1525-1583.

Careful Inspection Needed for Proper Diagnosis

CDC/Dr. Dennis D. Juranek.



Unhatched nit of a head louse, firmly cemented to hair shaft.



A 10-year-old girl complained of scalp pruritus for several weeks. Nits (within white circle) were visible on hairs above the ear. Note the brown scaly fecal material below the hair line (black circle).

Infection: An Uncommon Consequence



Reproduced with permission from Meinking TL, et al.¹ © Elsevier 2011.

Although uncommon in the US, secondary bacterial infection may result from pruritus and excoriations associated with head lice infestation. The photo here shows a case of streptococcal-staphylococcal pyoderma.

It is important to note that decreases in the prevalence and severity of scalp pyoderma have been noted following treatment for head lice, even without the use of antibiotics.

Reference: 1. Meinking TL, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology*. 4th ed. Mosby Elsevier; 2011:1525-1583.

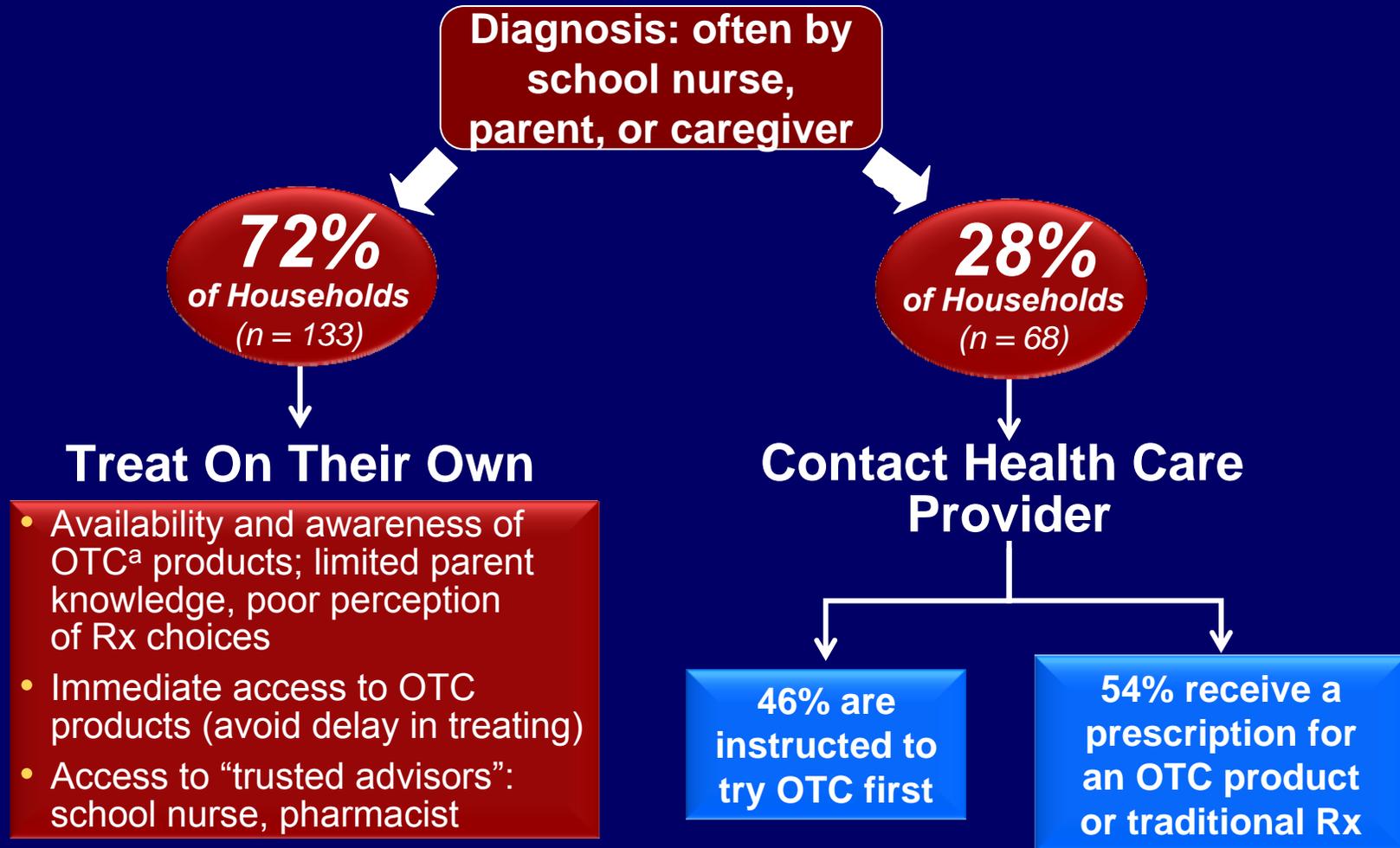
Nymphs, Nits, and Knowing What to Do

- Definitive diagnosis is made by finding a live louse or nymph on the scalp or head^{1,2}
- Nits attached >1 cm from the scalp are usually non-viable¹
 - In some warmer climates, viable nits may be found several inches from the scalp³
 - Close inspection is needed
- Nits may be confused with dandruff, fibers, scabs, hair casts, droplets of hair spray, plugs of desquamated cells, or particles of dirt^{1,3,4}

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. CDC. Head lice. Diagnosis. <http://www.cdc.gov/parasites/lice/head/diagnosis.html>. Accessed July 16, 2012. 3. Lice (pediculosis). In: Paller AS, Mancini AJ, eds. *Hurwitz Clinical Pediatric Dermatology. A Textbook of Skin Disorders of Childhood and Adolescence*, 4th ed. New York, Elsevier Saunders, 2011:424-427. 4. American Academy of Pediatrics. Pediculosis capitis (head lice). In: *Red Book. 2012 Report of the Committee on Infectious Diseases*. Pickering LK, ed. 29th ed. Elk Grove Village, IL, American Academy of Pediatrics, 2012, 543-546.

Approaches to Head Lice Treatment

Current Treatment Paradigm for Head Lice¹



^a OTC = Over-the-counter.

Treating Head Lice: Many Choices

OTC	Prescription
Nix [®] , ^a (permethrin, 1%)	Lindane ^c 1% shampoo
RID [®] , ^b et al (pyrethrins with piperonyl butoxide)	Ovide [®] , ^d (malathion, 0.5% lotion)
	Ulesfia [®] , ^e (benzyl alcohol, 5% lotion)
	Natroba [®] , ^f (spinosad, 0.9% suspension)
	Sklice [®] , ^g (ivermectin, 0.5% lotion)

Important Safety Information for Sklice Lotion

The most common adverse reactions for Sklice (<1%) are conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Full Prescribing Information for Sklice Lotion will be provided.

^a Nix[®] is a registered trademark of Insight Pharmaceuticals, LLC. ^b RID[®] is a registered trademark of Bayer HealthCare, LLC. ^c Lindane is manufactured by Morton Grove Pharmaceuticals. ^d Ovide[®] is a registered trademark of Taro Pharmaceuticals, U.S.A., Inc. ^e Ulesfia[®] is a registered trademark of Shionogi Pharma, Inc. ^f Natroba[®] is a registered trademark of ParaPRO LLC. ^g Sklice is a registered trademark of Sanofi Pasteur Inc.

Other Approaches

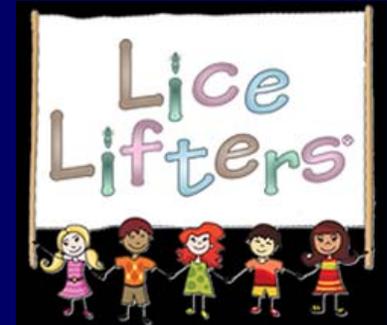
- Home remedies and "natural" products¹
 - Essential oils, plant extracts
 - Occlusive agents: Mayonnaise, petroleum jelly, tub margarine, Cetaphil cleanser
 - Vinegar and vinegar-based products
- Removal of nits and lice
 - Products such as dimethicone gel (LiceMD[®],^a) and gel containing citric acid, isopropanol, other ingredients (Lycelle[®],^b)
- Nitpicking salons

^a LiceMD[®] is a registered trademark of Quantum Pharmaceuticals.

^b Lycelle[®] is a registered trademark of Mission Pharmacal Company.

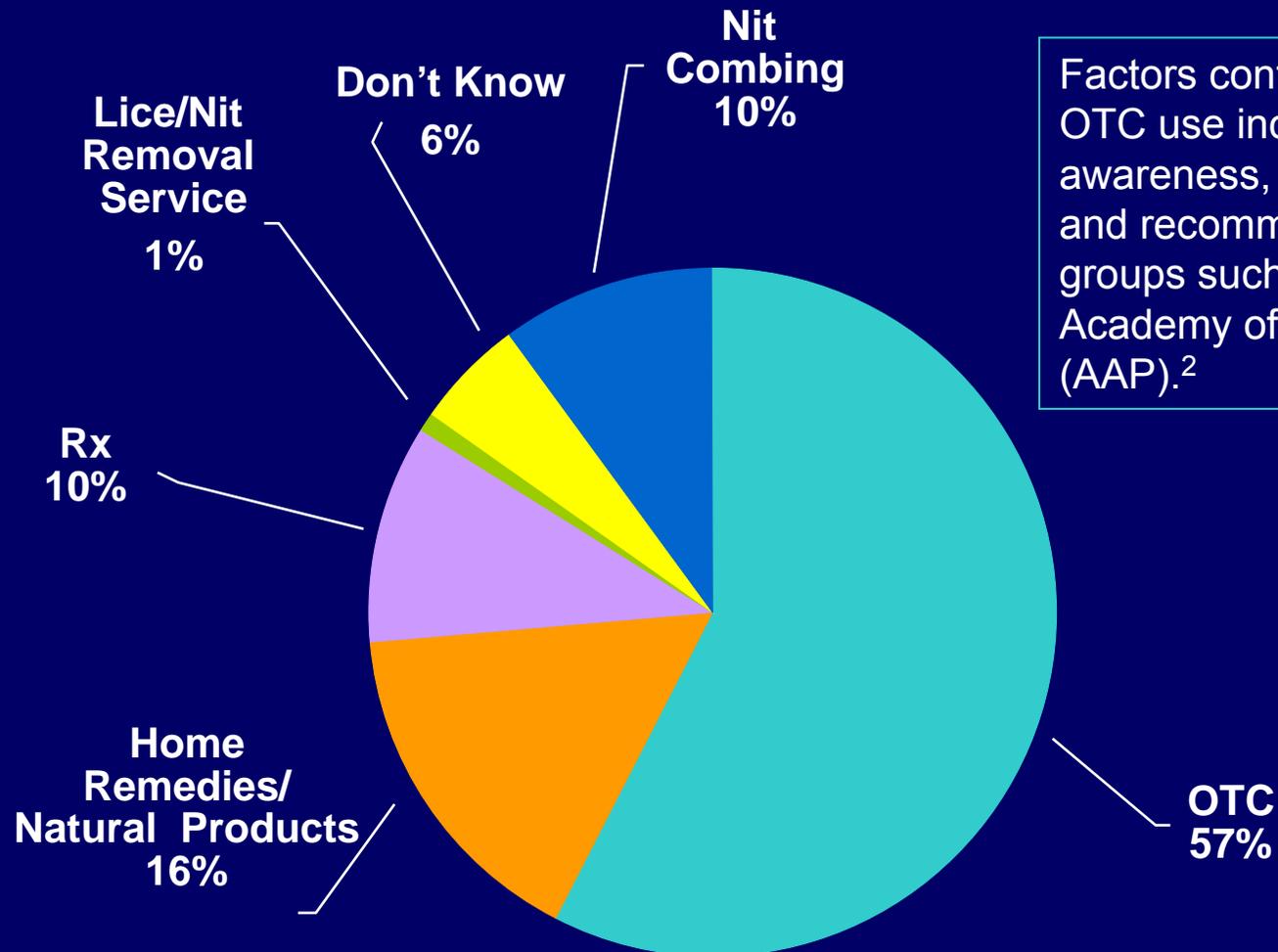
Nitpicking Salons: An Emerging Phenomenon

- Nitpicking salons have gained favor in certain parts of the US (California, Florida, Texas, Northeastern states) with some franchises^{1,2}
 - Advertise a “natural” or “chemical-free” approach to lice and nit removal
 - \$100 per hour for a “comb-out” is a common fee^{1,2}
- Treatments may also include various applications of controlled hot air^{1,3}



References: 1. LiceLifters. <http://www.licelifters.com>. Accessed July 16, 2012. 2. Texas Lice Squad. <http://www.texaslicesquad.com>. Accessed July 16, 2012. 3. Goates B, et al. *Pediatrics*. 2006;118(5):1962-1967.

How Head Lice Cases Are Treated Today¹



Factors contributing to OTC use include consumer awareness, ease of access, and recommendations by groups such as the American Academy of Pediatrics (AAP).²

References: 1. Sanofi Pasteur Inc., Data on file. Excel Omnibus Studies. 2. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403.

Prescription Lice Products

	Benzy alcohol, 5% (Ulesfia)¹	Malathion, 0.5% (Ovide)²	Spinosad, 0.9% (Natroba)³	Ivermectin, 0.5% (Sklice Lotion)⁴	Lindane, 1%⁵
Age indication	≥6 mo	Safety not shown <6 y	≥4 y	≥6 mo	Use w/caution in those <110 lb
Dosage	4-48 oz (varies with hair length)	2-oz bottles; apply enough to wet hair and scalp	Up to 120 mL (1 bottle) depending on hair length	Up to 120 mL (4-oz tube)	1-2 oz depending on hair length and density
Time of application	10 min; repeat treatment after 7 d	8–12 hrs; repeat treatment in 7-9 d if lice present	10 minutes; repeat treatment in 7 d if lice present	10 minutes; tube is intended for single use only; consult HCP prior to re-treatment	4 min; do not re-treat

The clinical significance of this information has not been established.

References: 1. Ulesfia Prescribing Information. Atlanta, GA: Shionogi Pharma, 2010. 2. Ovide Prescribing Information. Hawthorne, NY: Taro Pharmaceuticals, 2011. 3. Natroba Prescribing Information. Carmel, IN, ParaPRO, 2011. 4. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012. 5. Lindane Prescribing Information. Morton Grove, IL: Morton Grove Pharmaceuticals, 2005.

Full Prescribing Information for Sklice Lotion will be provided.

Why Some Cases May Persist After Treatment

1. Misdiagnosis (no active infestation or misidentification)¹⁻³
 - Non-lice, not-nit debris may be mistaken for infestation²
 - Other conditions may be mistaken for head lice³
 - Contact or seborrheic dermatitis, eczema, psoriasis, insect bites, piedra
2. Lack of adherence to the treatment regimen (such as not using enough product to saturate the hair)
3. Reinfestation¹
4. Lack of ovicidal or residual killing properties of the product¹
5. Resistance of lice to the pediculicide¹

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. CDC. Parasites-lice. <http://www.cdc.gov/parasites/lice/head/diagnosis.html>. Accessed July 16, 2012. 3. Meinking TL, et al. Infestations. In: Schachner LA, Hansen RC, eds. *Pediatric Dermatology*. 4th ed. Mosby Elsevier; 2011:1525-1583.

The Role of HCP in Head Lice Management

AAP Issues a Call— Get More Involved in Head Lice Treatment¹

- Historically, *diagnosis of infestations by parents* and other non-health care personnel, combined with easy availability of OTC pediculicides, essentially removed the HCP from the treatment process
- *Emergence of resistance* to available products and development of new products call for increased provider involvement in diagnosing and treating head lice
- Health-care providers should be *knowledgeable about head lice infestations* and treatments
 - They should take an *active role as information resources* for families, schools, other community agencies
 - *Instructions on the proper use of products* should be carefully communicated

Guidance on Managing Infestations

- Never initiate treatment without a clear diagnosis of head lice^{1,2}
 - Check all household members, other close contacts, and treat if active infestation is found²
- In recommending treatment products, consider:¹
 - Effectiveness
 - Safety
 - Ease of use
 - Cost
 - Local patterns of resistance (if known)
- 1% permethrin or pyrethrins can be used to treat active infestations unless resistance has been noted in the community¹
- If treatment does not seem to be working, it may be caused by incorrect use or by resistance²

References: 1. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403. 2. CDC. Head lice. Treatment. <http://www.cdc.gov/parasites/lice/head/treatment.html>. Accessed June 28, 2012.

Keeping Kids in School

- The AAP and National Association of School Nurses state: No healthy child should be allowed to miss school time because of head lice^{1,2}
- “No-nit” policies for return to school should be abandoned^{1,2}
- School-based head lice screening programs have not had a significant effect on incidence of head lice in schools and are not cost-effective²
- School nurses in concert with other health-care providers should become involved in helping school districts develop evidence-based policies¹

References: 1. Pontius D, Teskey C. Pediculosis management in the school setting, position statement, National Association of School Nurses, 2011. <http://www.nasn.org/PolicyAdvocacy/PositionPapersandReports/NASNPositionStatementsFullView/tabid/462/ArticleId/40/Pediculosis-Management-in-the-School-Setting-Revised-2011>. Accessed July 16, 2012. 2. Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403.

Sklice[®] (Ivermectin) Lotion, 0.5%

Full Prescribing Information for Sklice Lotion will be provided.

Sklice Lotion Indication¹

Sklice Lotion was approved by the US Food and Drug Administration in February 2012

Indication

Sklice Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older

Adjunctive Measures

Sklice Lotion should be used in the context of an overall lice management program:

- Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels
- Wash personal care items such as combs, brushes, and hair clips in hot water
- A fine tooth comb or special nit comb may be used to remove dead lice and nits



Please see next slide for Full Important Safety Information.

Full Prescribing Information for Sklice Lotion will be provided.

Important Safety Information for Sklice Lotion

No contraindications.

In order to prevent accidental ingestion, Sklice Lotion should only be administered to pediatric patients under the direct supervision of an adult.

The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Sklice Lotion Formulation¹

Formulation

Each gram of Sklice Lotion contains 5 mg of ivermectin

Inactive ingredients include water, olive oil, oleyl alcohol, Crodalan AWS, lanolin alcohol, cyclomethicone, shea butter, sodium citrate, sorbitan tristearate, methylparaben, propylparaben, and citric acid

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

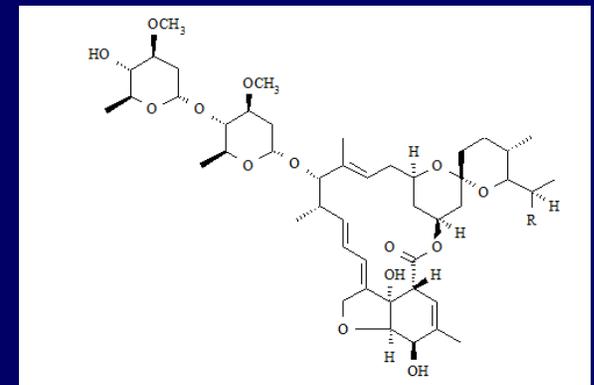
Ivermectin and Its Mechanism of Action

- Ivermectin – from fermentation of a natural, soil-dwelling actinomycete, *Streptomyces avermitilis*¹
 - An avermectin: anthelmintic and insecticide
- Proven antiparasitic effects
 - Binds selectively, primarily to glutamate-gated chloride channels in invertebrate cells¹⁻³
 - Increased permeability of cell membrane to chloride ions leads to:
 - Hyperpolarization of nerve or muscle cell
 - Paralysis and death of the parasite¹



Streptomyces avermitilis

Courtesy of BACMAP Genome Atlas, <http://bacmap.wishartlab.com>



Chemical structure of ivermectin¹

Full Prescribing Information for Sklice Lotion will be provided.

References: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012. 2. Cully DF, et al. *J Biol Chem.* 1996;271(33):20187-20191. 3. Kane NS, et al. *Proc Natl Acad Sci.* 2000;97(25):13949-13954.

Sklice (Ivermectin) Lotion: Results of Phase 1 and 2 Studies

- Phase 1 *in vitro* studies to demonstrate efficacy^{1,2}
- Phase 2 **dose ranging** study³
 - Based on these 2 studies, a lotion concentration of 0.5% was selected as optimal for safety, efficacy
- Repeat contact dermatology study in adults
 - No cumulative dermal irritation, no contact sensitization; less irritating than normal saline

Important Safety Information for Sklice Lotion

The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Full Prescribing Information for Sklice Lotion will be provided.

References: 1. Strycharz JP, et al. *J Med Entomol.* 2008;45(1):75-81. 2. Meinking TL, Villar ME. *Turkiye Parazitol Derg.* 2010;34(suppl1):118. 3. Meinking TL, et al. *Pediatr Dermatol.* 2010;27(5):573.

Sklice (Ivermectin) Lotion: Results of Phase 1 and 2 Studies (*cont*)

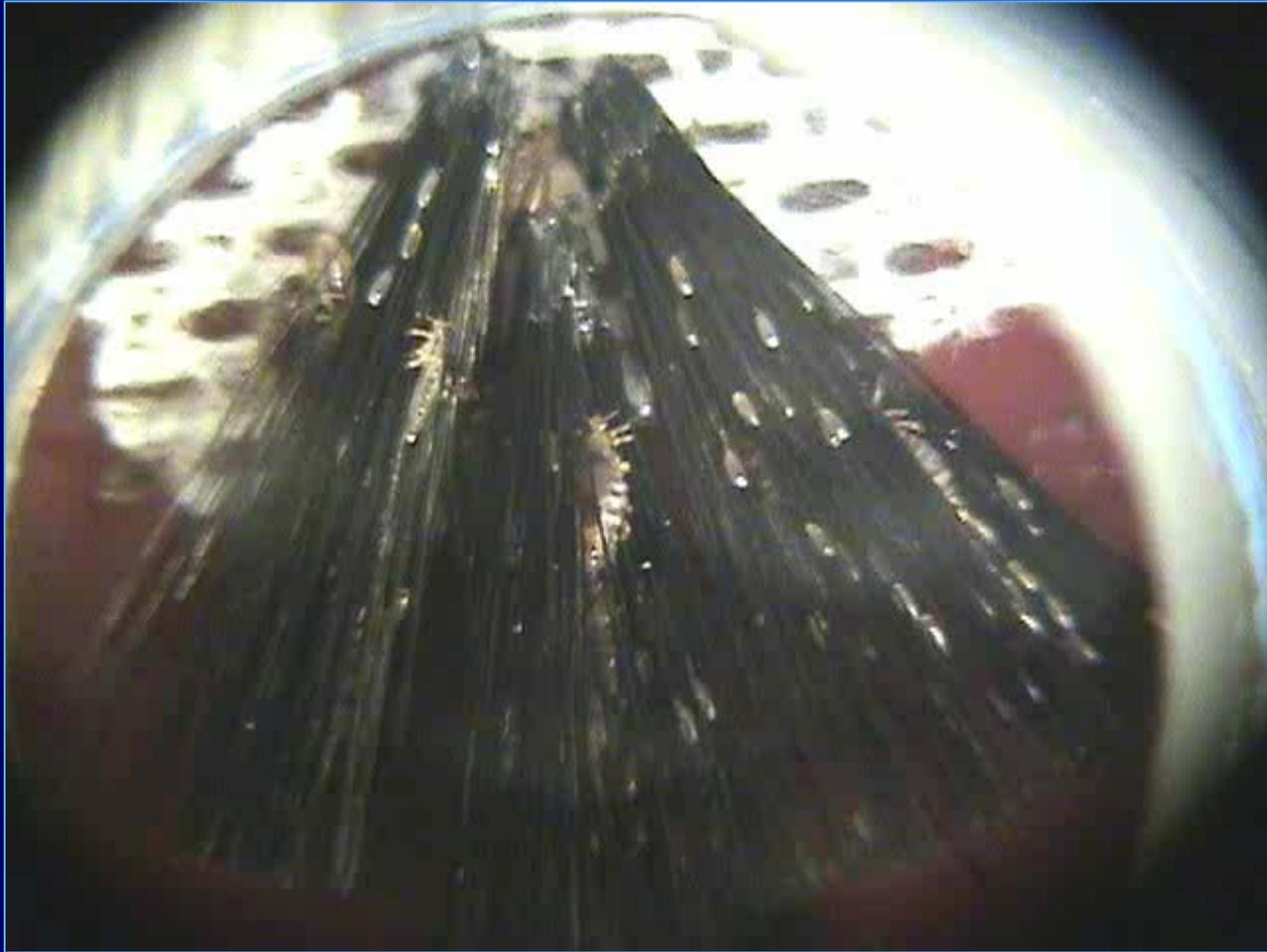
- Pediatric pharmacokinetics study^{1,2}
 - Minimal systemic absorption in children 6 months-3 years of age

Important Safety Information for Sklice Lotion

- The safety and effectiveness of Sklice Lotion has not been established in pediatric patients below the age of 6 months. Sklice Lotion is not recommended in pediatric patients under 6 months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.

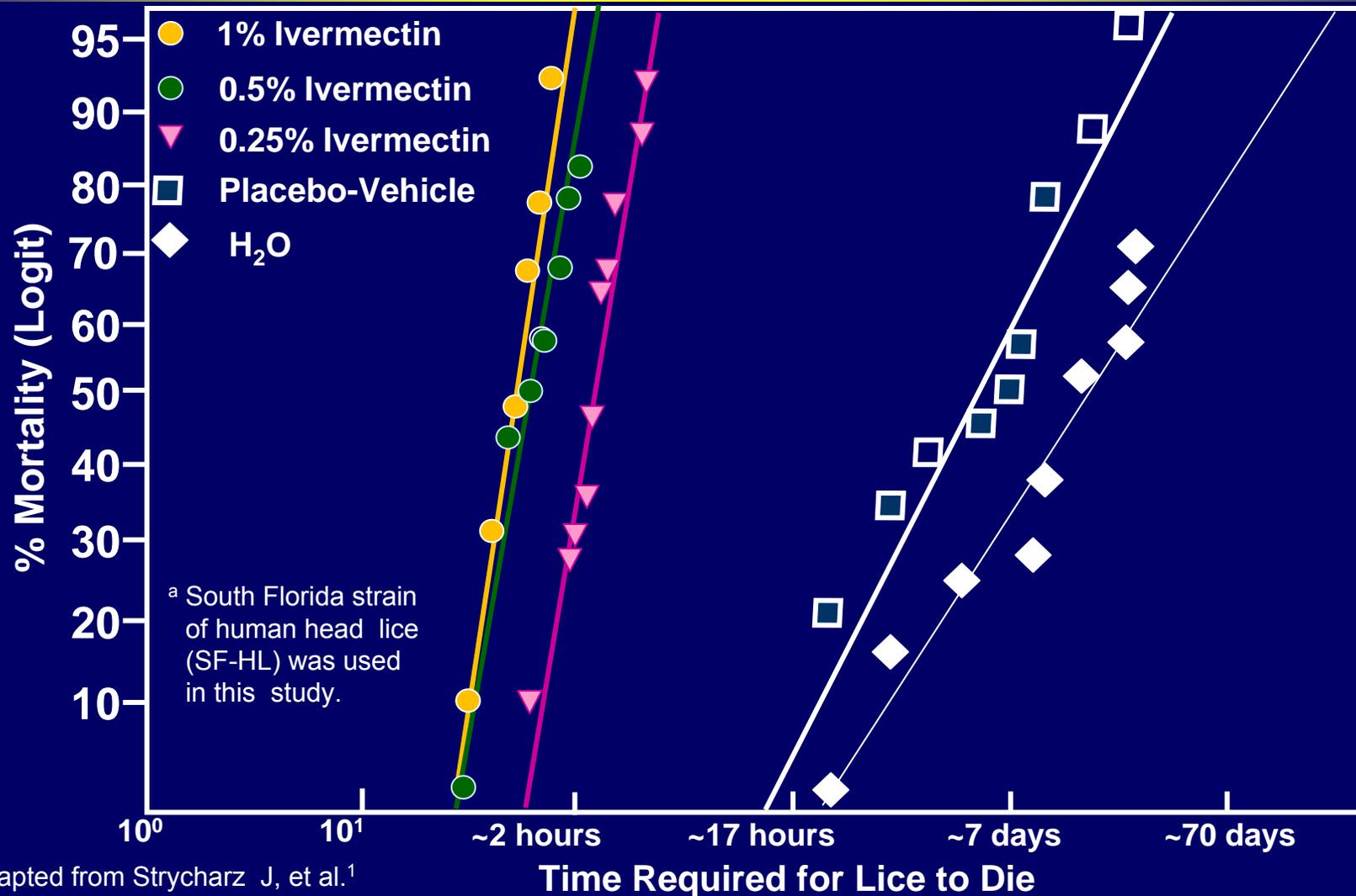
Full Prescribing Information for Sklice Lotion will be provided.

Video: Head Lice in the Laboratory



Video of crawling nits and lice, no audio

In vitro Dose Selection: 10-Minute Exposure Effectiveness Plateaus at 0.5%^{1,a}



Adapted from Strycharz J, et al.¹

Reference: 1. Strycharz J, et al. *J Med Entomol.* 2008;45(1):75-81.

Pivotal Phase 3 Studies¹

- 2 identical multi-center, randomized, double-blind, vehicle-controlled studies
 - All subjects were ≥ 6 months of age with active head lice infestation
 - Single application of Sklice Lotion or vehicle control at home
 - Instructions *not* to use a nit comb
 - Important to completely cover the entire head so that all lice and eggs are exposed to the lotion
- For efficacy evaluation, the youngest in each household was the index subject (N = 289)
 - Index patient had to have 3 or more live lice
- Other household members with live lice on Day 1 were enrolled, treated, and evaluated for all safety parameters

Full Prescribing Information for Sklice Lotion will be provided.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc. , 2012.

Phase 3 Studies: Assessment of Efficacy¹

- Primary efficacy
 - Defined as proportion of index subjects free of live lice at days 2, 8, and 14 (+2) days following a single application
 - Subjects with live lice at the time of these assessments were regarded as treatment failures

Full Prescribing Information for Sklice Lotion will be provided.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

Proportion of Index Subjects Free of Lice 14 Days After Treatment¹

Study	Vehicle % (n/N)	Sklice Lotion % (n/N)
Study 1 (TOP011)	16.2% (12/74)	76.1% (54/71)
Study 2 (TOP012)	18.9% (14/74)	71.4% (50/70)

Important Safety Information for Sklice Lotion

The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Full Prescribing Information for Sklice Lotion will be provided.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

Adverse Events Observed in Clinical Trials¹

- Safety data are based on exposure to a single 10-minute treatment of Sklice Lotion in 379 patients, 6 months of age and older, in placebo-controlled trials
- No adverse reactions were reported in >1% of subjects
- Adverse reactions reported in <1% of subjects included conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation
- No systemic adverse events were reported
- No serious adverse events were reported

Full Prescribing Information for Sklice Lotion will be provided.

Dosage and Administration¹

- For topical use only. Not for oral, ophthalmic, or intravaginal use
- In order to prevent ingestion, Sklice Lotion should only be administered to pediatric patients under the direct supervision of an adult
- Apply Sklice Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp
- After 10 minutes, rinse off with water
- Tube is intended for single use. Discard any unused portion
- Avoid contact with eyes

Full Prescribing Information for Sklice Lotion will be provided.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

Use in Specific Populations

Pediatric Use

The safety and effectiveness of Sklice Lotion has not been established in pediatric patients below the age of 6 months. Sklice lotion is not recommended in pediatric patients under 6 months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.

Nursing Mothers

Following oral administration, ivermectin is excreted in human milk in low concentrations. This has not been evaluated following topical administration. Caution should be exercised when Sklice Lotion is administered to a nursing woman.

Pregnant Women

Sklice Lotion is a Pregnancy Category C product. There are no adequate and well controlled studies with Sklice Lotion in pregnant women. Sklice Lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Projected Out-of-Pocket Costs of Head Lice Treatments¹

Product	Unit Costs (2012) based on WAC ^a	Cost to Patients
OTC (RID/Nix)	\$24	~\$50 (avg 2x treatments)
Sklice Lotion	\$257.88	\$40-\$50/treatment
Natroba	\$219	\$40-\$50/treatment
Ulesfia	\$157 (\$52-\$135 depending on hair length)	\$40-\$50/treatment
Ovide	\$152	\$15/treatment
Permethrin 5%	\$34	\$15/treatment

^a WAC = Wholesale acquisition cost.

Reference: 1. Sanofi Pasteur Inc., Data on file. Medispan, September 14, 2011.

Summary

- Product can be used in children as young as 6 months of age
- Single 10-minute application (single 4-oz tube)
- Consistent 1-treatment efficacy results in clinical trials
 - 76% and 71% of subjects were lice-free 14 days post-treatment in the 2 pivotal phase 3 studies
- No nit combing requirement
 - A fine-tooth comb or special nit comb may be used to remove dead lice and nits as an adjunctive measure

Important Safety Information for Sklice Lotion

The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Full Prescribing Information for Sklice Lotion will be provided.

For the HCP

- *Encourage parents to consult a health-care provider* when seeking treatment of head lice infestation
- *Take an active role in diagnosis and management* of pediculosis and helping families sort through the treatment choices
- *Develop collaborative relationships* with school nurses, school administrators, pharmacists, public health officials, and their professional associations
- *Educate families and the community* to promote knowledgeable care and to dispel myths and misunderstandings about head lice

Educational Resources

Sklice Lotion: Instructions for Use¹

- 1** Apply Sklice Lotion directly to dry hair and scalp. Completely cover scalp and hair closest to the scalp first, then apply outwards toward the ends of hair. Avoid contact with eyes.
- 2** Rub Sklice Lotion throughout the hair. It is important to completely cover the entire head so that all lice and eggs are exposed to the lotion.
- 3** Be sure that each hair is coated from the scalp to the tip; use up to 1 entire tube (4 oz) to completely cover hair and scalp.

Important Safety Information for Sklice Lotion

In order to prevent accidental ingestion, Sklice Lotion should only be administered to pediatric patients under the direct supervision of an adult.

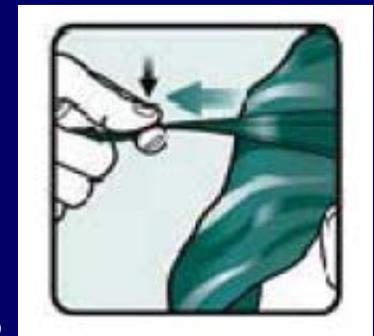
Full Prescribing Information for Sklice Lotion will be provided.



1



2



3

Sklice Lotion: Instructions for Use (cont)¹

- 4 Allow Sklice Lotion to stay on the hair and scalp for 10 minutes after it has been applied. Use a timer or clock. Start timing after you have completely covered the hair and scalp.
- 5 After 10 minutes, rinse lotion from hair and scalp using only water.
- 6 You or anyone who helps you apply Sklice Lotion should wash their hands after application.
- 7 Do not use Sklice Lotion again without talking to your health-care provider first.

4



5



For single use only; do not re-treat. Discard tube after use.

Full Prescribing Information for Sklice Lotion will be provided.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

Adjunctive Measures¹

- Sklice Lotion should be used in the context of an overall lice management program:
 - Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels
 - Wash personal care items such as combs, brushes, and hair clips in hot water.
 - A fine tooth comb or special nit comb may be used to remove dead lice and nits.

Reference: 1. Sklice Lotion Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc., 2012.

Helpful Resources for Parents and Practitioners on Head Lice

- Centers for Disease Control and Prevention
 - <http://www.cdc.gov/parasites/>
- National Association of School Nurses, 2011 policy statement
 - <http://www.nasn.org/PolicyAdvocacy/PositionPapersandReports/NASNPositionStatementsFullView/tabid/462/ArticleId/40/Pediculosis-Management-in-the-School-Setting-Revised-2011>
- American Academy of Pediatrics, 2010 policy statement
 - Frankowski BL, et al. *Pediatrics*. 2010;126(2):392-403.
- American School Health Association, 2005 policy statement
 - <http://www.ashaweb.org/files/public/Resolutions/Pediculosis.pdf>
- American Academy of Dermatology, parent resources
 - <http://www.kidsskinhealth.org/grownups/lice.html>
- Web MD, Head lice slideshow: What parents should know
 - <http://children.webmd.com/ss/slideshow-lice-overview>