

**LYCELLE® HEAD LICE REMOVAL KIT**  
**Rx Only**

**CAUTION: Federal law restricts this device to sale by or on the order of a physician.**

**For topical dermatological use only. Not for oral or ophthalmic use.**

-----**DESCRIPTION**-----

LYCELLE® Head Lice Removal Kit helps to kill and remove lice and eggs from the hair and scalp. LYCELLE® does not contain any pesticides.

-----**INTENDED USE**-----

LYCELLE® kills and removes both head lice and their eggs from hair of adults and children two years of age and older. Additional kits may be needed for hair longer than shoulder length.

-----**MODE OF ACTION**-----

Testing performed in the laboratory with both laboratory lice and lice collected from humans have shown that LYCELLE® demonstrates both a pediculicidal and ovicidal activity. Highly magnified images obtained by scanning electron microscopy before and after application demonstrated LYCELLE® resulted in significant destruction of the lipid, waxy outer surface of both lice and their eggs. This outer surface is known to regulate moisture levels critical for survival. Destruction of these surfaces leads to paralysis and death at the time of exposure. LYCELLE® dissolves the outer lipid layer of lice and their eggs resulting in sudden dehydration. The effect is nearly immediate immobilization of live lice, followed by death, and termination of egg development. This aids the removal of lice and eggs from the hair with the included comb.

**In vitro pediculicidal and ovicidal assessments**

Various formulations of LYCELLE® have been tested extensively for pediculicidal and ovicidal activity utilizing standardized test methods in the laboratory setting. Initial assessments were performed using laboratory bred and grown lice. These formulations exhibited 100% lethal activity against live laboratory lice and their eggs.

**In vitro ovicidal assessment with human head lice and ova**

Additional laboratory studies, *in vitro* pediculicidal and ovicidal activity studies, were performed to assess the ability of LYCELLE® to kill lice and their eggs. These assessments included the ability to determine the time following exposure when LYCELLE® causes death. These assessments demonstrated that LYCELLE® works by a mechanism different from action on the central nervous system. Results are shown in Table 1:

	LYCELLE® Replicate				Water Control
	1	2	3	4	
% Pediculicidal Activity	100.0%	100.0%	100.0%	100.0%	12.0%
% Killed (not moribund)	100.0%	93.0%	100.0%	98.0%	12.0%
% Ovicidal Activity	100.0%	100.0%	100.0%	99.5%	10.2%
% Eggs Undeveloped	99.5%	99.8%	98.1%	98.0%	53.0%

*In vitro* pediculicidal assessment with human head lice system at The University of Massachusetts at Amherst, MA Human head lice (SF-HL) were collected from infested children and maintained on an *in vitro* rearing system at the University of Massachusetts at Amherst, MA. Mortality bioassays were performed to determine lethal time to 50% mortality (LT50) values for LYCELLE® as compared to another existing competitor product (positive control) and water (negative control). All lice used in experiments were newly hatched first instars, randomly collected from the *in vitro* rearing system. These lice were exposed to LYCELLE® for 10 minutes. Results are shown in Table 2:

**Table 2**

Exposure	Treatment	Avg LT50 (95% CL)	LT95	% Mortality
10 minutes	LYCELLE®	< 5 min	< 5 min	100 ± 0.0
	Competitor X	4.3 d	> 20 d	80.3 ± 3.5
	Water	14.9 d	> 20 d	63.3 ± 2.5

Because LYCELLE® does not contain any pesticides and works differently, no resistance has been observed with its use to date.

-----**WARNINGS**-----

- LYCELLE® should only be used on children two years of age or older and under the direct supervision of an adult.
- LYCELLE® can irritate the eyes. Caution should be exercised when applying the product to avoid exposure to the eyes. Protect eyes with a washcloth or towel and keep eyes tightly closed during administration. If the product comes into contact with the eyes, immediately flush thoroughly with water. Consult a physician if eye irritation persists.
- If skin irritation occurs, discontinue use of the product until the irritation resolves. Reapply LYCELLE® and if irritation reoccurs, consult a physician.
- Slight stinging sensations may occur with the use of LYCELLE®. This may be due to LYCELLE® coming into contact with broken skin that is already irritated due to the presence of existing lice bites.

General: Keep out of reach of children. Close eyes tightly during product application. As with any topical product, the person applying LYCELLE® should wash his or her hands immediately after application. LYCELLE® should only be used on children two years of age or older under the direct supervision of an adult. Safety of LYCELLE® has not been evaluated in patients over 60 years of age.

-----**PRECAUTIONS**-----

The gel included in LYCELLE® can be irritating to the skin, scalp, and eyes. If irritation occurs, immediately flush the affected area thoroughly with water. A stinging sensation may occur at the sites of existing lice bites. LYCELLE® may have the potential to cause contact allergic sensitization.

Discard any unused components of LYCELLE® after use. LYCELLE® should not be shared.

----- **DOSAGE AND ADMINISTRATION** -----

1. Apply LYCELLE® directly to DRY hair in an amount sufficient to thoroughly wet hair and scalp. Pay particular attention to the back of the head and neck when applying LYCELLE®, as this is where the lice and their ova are more likely to be located. Wash hands immediately after the application process is complete.
2. After allowing product to remain on the hair and scalp for 10 minutes, rinse hair thoroughly, shampoo and condition the hair, again paying attention to the back of the head and neck while shampooing. (LYCELLE® has been shown to be safe if left on the hair for up to 30 minutes).
3. Use the included fine-toothed comb to remove dead lice and eggs.
4. Further treatment is generally not necessary. However, if lice are still present after 7 - 9 days, repeat with a second application of LYCELLE®.
5. All family members should be examined for infestation, and if infestation is present, should be immediately treated with new, individual LYCELLE® kits.

----- **SAFETY ASSESSMENTS** -----

Study BCG20-0582:

The study objective was to assess the safety and tolerability of LYCELLE® after 30 minutes of exposure as compared to placebo in head lice-infested subjects treated once or twice by healthcare professionals in a controlled environment. This was a 4-arm, randomized, double-blinded, placebo-controlled study in subjects with head lice infestation. The study consisted of the following 6 visits: Visit 1 (Day 1), Visit 2 (Day 2), Visit 3 (Day 8 ±1 day), Visit 4 (Day 9 ±1 day; only for subjects who required a second treatment), and either Visit 5 or Visit 6 (Day 15 or Day 22 ±2 days). Each qualified subject was treated with the assigned study product on Day 1, and treatment with the same study product was repeated on Day 8 for any subjects found to have live lice at that visit. All subjects receiving a second treatment on Day 8 returned for an evaluation on Day 9. For all other subjects, a follow-up visit and assessment was done 14 days after the last treatment day. Safety assessments were made by monitoring of adverse events throughout the study. Results are summarized below and shown in Table 3:

LYCELLE® was well tolerated in all dose groups during this study.

- There were no deaths or serious adverse events (SAEs) reported during this study.
- During the study, two subjects experienced adverse events (AEs) of severe intensity: severe application site pruritus and severe application site irritation.
- One subject experienced an AE classified as severe: application site irritation.
- Several subjects experienced AEs of continuous character; most were AEs of dandruff and application site irritation.
- Most AEs were considered to be possibly related to study medication. Application site irritation and dandruff were the most frequently reported AEs with a possible or probable relationship to the treatment in all treatment groups.
- With respect to skin and scalp evaluations, there were no notable differences among the treatment groups. No relationship between the doses and the change in severity of skin and scalp conditions were observed. Some overall improvement in pruritus was noted immediately post-treatment, and further, the day after treatment. Overall, fewer and milder skin and scalp-related findings were observed 14 days after the last treatment compared with pre-treatment.

**To report** a serious adverse event call Mission Pharmacal at 210-696-8400 or call the Food and Drug Administration (FDA) at 1-800-FDA-1088.

----- **HOW SUPPLIED** -----

LYCELLE® Head Lice Removal Kit (NDC 0178 0732 01) is supplied as one - 100 ml bottle of gel and comb.

LYCELLE® Gel contains: citric acid, Cytanyl 5™, hydroxypropyl methylcellulose, isopropanol, methylparaben, methyl salicylate, and sodium laureth sulfate. The kit also includes a comb to remove lice, eggs, and nits.

Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

**Table 3 - Most Frequent (Reported by at Least Two Subjects Overall) Treatment-Emergent Adverse Events (Safety Population)**

MedDRA Term	Placebo (N=59)		LYCELLE® 1 (N=59)		LYCELLE® 2 (N=56)		LYCELLE® 3 (N=56)	
	Subjects* n (%)	Events n	Subjects* n (%)	Events n	Subjects* n (%)	Events n	Subjects* n (%)	Events n
<b>Any Adverse Events</b>								
At least one AE	11 (18.6)	17	13 (22.0)	24	10 (17.9)	16	16 (28.6)	29
Application site irritation	3 (5.1)	4	8 (13.6)	9	5 (8.9)	5	8 (14.3)	9
Application site pain	0 (0.0)	0	3 (5.1)	3	0 (0.0)	0	4 (7.1)	4
Application site pruritus	5 (8.5)	5	4 (6.8)	5	2 (3.6)	2	2 (3.6)	2
Dandruff	5 (8.5)	5	3 (5.1)	3	5 (8.9)	5	8 (14.3)	8

\*: Subjects experiencing multiple episodes of a given AE are counted once within each MedDRA term and each System Organ Class.  
AE=adverse event, MedDRA=Medical Dictionary for Regulatory Activities

Manufactured for:



Mission Pharmacal Company  
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Under license from Efficon® Laboratories, Inc. U.S. Patent Nos. 5,902,595, 7,282,211 and 7,902,256.

LYCELLE® is a medical device registered with the United States Food and Drug Administration.

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LYC-01 C03 Rev 011110