



STEPS



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Acne Study : Comedone Count and Classification

Supportable Claims

- Reduction in Severity
- Acne Treatment
- Non-comedogenic Claim

Subjects

Panels of subjects, male and female, professionally assessed as exhibiting acne conditions.

Parental consent of minors is obtained.

Prior to initiation of a test, each subject will complete a medical history form.

number of test subjects. The initial index in all cases will be 3.

Comedogenicity Test

Thrice weekly, 0.2 to 0.5mL of the test material is delivered to the test site via syringe. The test sites, each measuring 4x4cm are covered with a piece of non-absorbing cotton cloth. The patches are closely secured to the skin by occlusive or semi-occlusive, hypoallergenic tape using an over-layer of adhesive taping if necessary. The procedure is repeated every other day until three applications per week is accomplished for a total of four weeks for occlusive and 6 weeks for semi-occlusive conditions. Patches are removed after 48 hour exposure and once weekly after 72 hour exposure. On removal all sites are cleaned and evaluated for any overt signs of irritation prior to re-patching. sum of all patients' degree of reaction .

Subjects are asked to apply the product on affected area as per sponsor supplied directions. Visual counts and classifications of lesions will be done, typically at day 0 (pre-treatment), 2 & 4 weeks.

Percent difference (reduction) in separate types (comedones, papules & pustules) and total count of lesions are calculated. The skin condition is evaluated in terms of adverse reactions, such as erythema, itching, burning, scaling, and irritation. The overall improvement in skin condition is graded using evaluation indices. The grading of efficacy is expressed as 0 = excellent, >66% improvement; 1 = very good, 33% to 66% improvement; 2 = good, <33% improvement; and 3 = no change. The weighted mean will be calculated by dividing the sum of all individual patient indices by the total

References

1. Burke BM, Cunliffe WJ. The assessment of acne vulgaris - the Leeds technique. Br J Dermatol 1984; 111: 83-92
2. Ayres, JD., Mills, OH., Lyssikatos, J., Kligman., AM, Groh., DG: Assessment of a new method for determining the acnegenic potential of topically applied materials on human subjects. IFSCC International Congress, Yokohama, Japan, October 13-16, 1992.

Acne Gradings

0 = Normal, clear skin with no evidence of acne vulgaris

1 = Skin is almost clear: rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink red)

2 = Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodulo-cystic lesions)

3 = Non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, and there may or may not be one small nodulo-cystic lesion

4 = Inflammatory lesions are more apparent: many comedones and papules/pustules, there may or may not be a few nodulo-cystic lesions

5 = Highly inflammatory lesions predominate: variable number of comedones, many papules/pustules nodulo-cystic lesions

Combined acne severity classification

Severity	Definition
Mild acne	Fewer than 20 comedones, or Fewer than 15 inflammatory lesions, or Total lesion count fewer than 30
Moderate acne	20–100 comedones, or 15–50 inflammatory lesions, or total lesion count 30–125
Severe acne	More than 5 nodules, or Total inflammatory count greater than 50, or Total lesion count greater than 125

Papules / Pustules - inflamed

Nodulocystic Lesions

Non-inflammatory lesions:

- * Open comedones (blackheads)
- * Closed comedones (whiteheads)
- * Uninflamed nodules (sometimes called cysts)

Inflammatory lesions:

- * Papules (small red bumps)
- * Pustules (white or yellow 'squeezable' spots)
- * Inflamed nodules (large red lumps)

Secondary lesions:

- * Excoriations (picked or scratched spots)
- * Erythematous macules (red marks from recently healed spots, mostly in fair skin)
- * Pigmented macules (dark marks from old spots, mostly in dark skin)
- * Scars

Proposed areas for measurement and photography.

Cheek Neck Forehead