

BioClarity™ for Treatment of Acne in Teens and Young Adults

The BioClarity System

BioClarity is a new acne treatment regimen especially formulated for the skin of teenagers and young adults. It combines a well known over-the-counter acne medication with a unique naturally-derived ingredient and natural extracts to clear up acne blemishes and reduce the appearance of redness and pore size. It is directly available on-line, without a prescription.

BioClarity is a twice daily, 3-step system that combines an effective over-the-counter acne medication, at the highest allowable concentration, with natural extracts to cleanse and soothe the skin.

BioClarity consists of 3 steps:

- Step 1: Cleanser
- Step 2: Treatment
- Step 3: Restore Gel

Independent Clinical Study

An 8-week independent clinical study of BioClarity was conducted in young adults with mild to moderate acne.

Study Participants

Thirty individuals participated in the clinical study of BioClarity to test the activity and safety of the regimen. Participants included males and females of various ethnicities, with mild to moderate acne.

The characteristics of the 30 clinical trial participants were:

- Sex:
 - Male = 13 (43%)
 - Female = 17 (57%)
- Age:
 - Average = 17 years
 - Range = 13 – 24 years
- Ethnicity:
 - Caucasian = 10 (33%)
 - Asian = 10 (33%)
 - African American = 6 (20%)
 - Hispanic = 4 (13%)

Study Procedures

Potential participants were evaluated in the clinic to confirm their eligibility for the study and provided written informed consent and a photographic release form. Eligible subjects were enrolled in the study and underwent baseline (pre-treatment) evaluations of their acne and had photographs taken.

Subjects were instructed to use the BioClarity system in the morning and evening daily for 8 weeks. The first application was performed in the clinic.

The procedures for using BioClarity were:

1. Wash face with Step 1: Facial Cleanser
2. Apply a pea size amount of Step 2: Treatment Gel to the fingertips and gently spread over the face. Allow gel to dry.
3. Apply 2 pumps of Step 3: Restore Gel to the fingertips and gently spread over the face.

Subjects were further instructed to avoid extended periods of sun exposure, the use of tanning beds, and sunless tanning products. Sun exposure was to be avoided between 10 am and 4 pm. The use of any other anti-acne products during the study period was not allowed.

Study Evaluations

Subjects returned to the clinic at Week 2, Week 4 and Week 8 for evaluations by the investigator.

The following evaluations were performed at each visit and the results were compared with measurements taken before starting the treatment:

- Overall acne assessment
- Counts of various types of acne lesions on face
- Assessment of redness and size of inflamed acne lesions
- Investigator assessments of redness, dryness/scaling, and swelling of the face
- Subject self-assessments of burning, stinging, itching, dryness/tightness of the face
- Measurements of the amount of oil on the face
- Photographs of the face

In addition, the study participants also completed a self-assessment questionnaire regarding their opinions of the effectiveness and tolerability of BioClarity.

Study Results

Results of Investigator Evaluations

The following tables show the average results of the investigator's assessment of improvement after 2, 4, and 8 weeks of use of BioClarity among the 30 subjects in the clinical study. All of the measures examined showed improvement at 2 weeks, and continued showing additional improvement at 4 weeks and at 8 weeks.

Investigator Evaluation	% Improvement at 2 Weeks	% Improvement at 4 Weeks	% Improvement at 8 Weeks
Count of inflamed pimples (without pus) on face	14%	21%	33%
Count of inflamed pimples (containing pus) on face	40%	41%	55%
Count of blackheads on face	25%	37%	47%
Count of whiteheads on face	9%	18%	33%
Count of all acne lesions on face	16%	24%	37%

There was also improvement in the investigator's overall assessment of acne including redness, lesion size, and oiliness.

Investigator Evaluation	Average % Improvement at 8 Weeks
Overall acne assessment	19%
Overall redness of inflamed lesions	13%
Overall size of inflamed lesions	12%
Oil on face	16%

Subject Self-Assessment Results

The following table shows the percentage of study participants that agreed with each questionnaire statement after 2, 4, and 8 weeks of use of BioClarity. Improvements were seen at 2 weeks, with progressive improvements from Week 2 to Week 4 to Week 8.

After 8 weeks of treatment, 90% of subjects agreed that BioClarity reduced the number of blemishes on their skin and would recommend the products to others.

Statement	% that agree at 2 Weeks	% that agree at 4 Weeks	% that agree at 8 Weeks
Reduces the number of blemishes on my skin	80%	90%	90%
My facial blemishes are less noticeable	77%	80%	77%
Reduces the size of my facial pores	57%	60%	70%
Reduces the oiliness and shininess of my facial skin	57%	70%	77%
Improves the overall appearance of my facial skin	80%	83%	87%
Products are easy to use	90%	93%	97%
I am satisfied with the results from using these products	80%	80%	83%
I would recommend these products to others	--	--	90%

Evaluation of Side Effects

Both the investigator and subject evaluations of safety of BioClarity showed that it was very well tolerated with only very occasional mild redness, dryness, stinging or itching.

Conclusions

The results of this clinical study of BioClarity for treatment of acne showed that in an ethnically diverse group of teen and young adult study subjects, both the investigator and the subject self-assessments showed strong positive results for BioClarity after 2, 4, and 8 weeks of use.

BioClarity was very well tolerated without the typical bothersome side effects of redness, dryness, stinging, itching, and burning often seen with other acne products.