NEUTROGENA
Light Therapy
Acne Mask

Instructions for Use
Neutrogena Light Therapy Acne Mask

Experience a revolutionary device inspired by dermatologist treatments that brings acne light therapy into your home. Therapeutic blue and red lights treat acne by targeting the bacteria that cause acne.

Use Light Therapy Acne Mask once a day.

Light Therapy Acne Mask will turn off automatically at the end of each 10 minute treatment and will last for 30 treatment-sessions.

Continue to use Light Therapy Acne Mask after your 30 treatment-sessions end to see further improvement in your skin.

Welcome to a new you.

www.neutrogena.com
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Getting to know the Light Therapy Acne Mask
How Light Therapy Acne Mask works
Acne starts with the buildup of oil under the skin which causes a type of bacteria called *P. acnes* to multiply. Pores get blocked with this bacteria, excess oil, and dead skin cells. The result is an acne breakout.

Blue and red light therapy treats acne by targeting the bacteria in the skin that causes acne breakouts. The light gently penetrates the skin to reduce the bacteria. When you reduce bacteria, you reduce the appearance of acne breakouts\(^1\)\(^,\)\(^2\)\(^,\)\(^3\). Light Therapy Acne Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

Footnotes:

1. Goldberg, D. and Russell, B. Combination Blue (415 nm) and Red (633 nm) LED Phototherapy in the Treatment of Mild to Severe Acne Vulgaris. *Journal of Cosmetic and Laser Therapy*. 2006; 8: 71-75
Who should use Light Therapy Acne Mask

Use this chart to help determine if Light Therapy Acne Mask is right for you.

Indications for Use: Light Therapy Acne Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

<table>
<thead>
<tr>
<th>Acne Type</th>
<th>Should You Use Light Therapy Acne Mask</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear Skin</td>
<td>No</td>
<td>No Acne</td>
<td></td>
</tr>
<tr>
<td>Mild Acne</td>
<td>Yes</td>
<td>Up to some blackheads and whiteheads, a few pimples and pustule, no nodules</td>
<td></td>
</tr>
<tr>
<td>Acne Type</td>
<td>Should You Use Light Therapy Acne Mask</td>
<td>Description</td>
<td>Example</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Moderate Acne</td>
<td>Yes</td>
<td>Up to many blackheads and whiteheads, some pimplies and pustules, only a few small nodules.</td>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td>Severe Acne</td>
<td>No. This product is not recommended for severe acne as the benefits have not been established.</td>
<td>Up to many blackheads, whiteheads, pimplies and pustules, some nodules.</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
</tbody>
</table>

See glossary for definitions.

Footnotes:

4. Acne assessment criteria are based off of the FDA Proposed Acne Scale for Baseline Assessment.
Warnings

**DO NOT USE** Light Therapy Acne Mask if you are pregnant, may be pregnant, or nursing as the risks are unknown and have not been established.
Precautions

Do not get water or liquid inside any part of the device as it may cause the device to not turn on.

Do not store near heat or hot surfaces.

Do not use while walking or driving.

Do not connect your device or Activator to any other item.

This device is limited to single patient use. Do not share the device with other persons.

Discontinue use if you experience any discomfort or if skin reddening or discoloration lasts more than 24 hours.

Do not use device if your skin is light sensitive or you are currently using medication that may cause sensitivity of skin to light.

DO NOT USE Light Therapy Acne Mask if the device is visibly damaged, and never attempt to open or repair the device.

Keep the device out of reach of children.

See Instructions for Use

Type B Applied Part

Use By YYYY-MM-DD

Enclosure protection rating against the ingress of solids and water
How to use Light Therapy Acne Mask

1. Connect the Light Therapy Acne Mask to the Activator. Make sure the plug is fully inserted into the Activator, with no silver metal visible. Your Mask will last for 30 treatment-sessions. Each treatment-session lasts for 10 minutes. Use the Mask once daily.

2. Wash and dry your face prior to each treatment-session to remove oil and makeup.

3. Open the over-ear arms and put on Light Therapy Acne Mask like you would a pair of glasses.
4. Press and hold the power button for 1-3 seconds to begin your treatment until your mask powers on. Relax with the Light Therapy Acne Mask for 10 minutes.

5. Light Therapy Acne Mask will turn off automatically after 10 minutes. If you need to turn Light Therapy Acne Mask off during the treatment, press and hold the power button for 1 second. Note that doing so will decrease the remaining number of sessions by one.

6. After each treatment-session, the counter will show how many treatment-sessions remain. Once the counter reaches 0, disconnect and discard the Activator. Keep the Mask and purchase a new Activator for more treatment-sessions.
Risks

Event: Correct Use: 35 of 35 subjects made no error using the device.

<table>
<thead>
<tr>
<th>Hazard</th>
<th>How Often Subjects Had the Hazard</th>
<th>Harm</th>
<th>How Often This Hazard Harmed Them</th>
</tr>
</thead>
<tbody>
<tr>
<td>No known hazard from correct use of the Light Therapy Acne Mask.</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Event: Correct Use: 0 of 35 subjects made at least one error using device**

<table>
<thead>
<tr>
<th>Hazard</th>
<th>How Often Subjects Had the Hazard</th>
<th>Harm</th>
<th>How Often This Hazard Harmed Them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device was shared with another person.</td>
<td>0 of 35 subjects</td>
<td>Possible cross contamination.</td>
<td>0 of 35 subjects</td>
</tr>
<tr>
<td>Did not remember or comprehend instructions and warnings about use while pregnant or nursing.</td>
<td>0 of 35 subjects</td>
<td>Unknown, unreported, unobserved.</td>
<td>0 of 35 subjects</td>
</tr>
</tbody>
</table>
## Risks

<table>
<thead>
<tr>
<th>Hazard</th>
<th>How Often Subjects Had the Hazard</th>
<th>Harm</th>
<th>How Often This Hazard Harmed Them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not remember or understand instructions and warnings</td>
<td>0 of 35 subjects</td>
<td>Unknown, unreported, unobserved.</td>
<td>0 of 35 subjects</td>
</tr>
<tr>
<td>Water or liquid got inside the device</td>
<td>0 of 35 subjects</td>
<td>Device may not turn on.</td>
<td>0 of 35 subjects</td>
</tr>
</tbody>
</table>

*Correct use: Doing all things and steps exactly like the user manual directs.

**Incorrect use: Failing to follow the instructions for use given in the manual provided with Light Therapy Acne Mask device. Reasons for incorrect use include, but are not limited to, not understanding information and /or choosing to not follow instructions one does understand.

Note: The data provided in the above Risk charts was obtained from the Usability Study conducted in May 2013.

This data is representative of the potential risks that occur. Only the known risks are listed. However, the device is a minimal risk device when used in accordance with the Instructions for Use provided in the manual accompanying the device. Although the use of light therapy, such as used with the Light Therapy Acne Mask acne device has been shown to be safe, there may be unforeseeable risks that have not been identified at this time. The possibility of risks that may occur with the use of light therapy include:

1. Mild reddening of the skin
2. Mild tingling sensations
Storage & Care

Cleaning
Clean the eye shield frame or outside of Light Therapy Acne Mask whenever it appears dirty. Moisten a soft cloth with water or isopropyl alcohol and lightly wipe down the device. Do not get water or liquid inside any part of the device.

Maintenance
Light Therapy Acne Mask does not need regular or special maintenance. No modification of this equipment is allowed.

Operating Conditions
5 °C to 35 °C; 15%-75% Relative Humidity, non-condensing; Atmospheric Pressure: 700-1060 hPa

Transport and Storage Between Uses Conditions
-25 °C to 45 °C; up to 75% Relative Humidity, non-condensing

For best performance of the device, store in a cool dry place, but do not refrigerate. Do not store near heat or hot surfaces. For long-term storage, unplug the Mask from the Activator.

Travel
If traveling with Light Therapy Acne Mask, pack the device in its original packaging to prevent damage.

Life of the Activator
Activator is designed to work for 30 treatment-sessions. Dispose of properly after session counter reaches 0 and replace with a new Activator refill to re-activate the Mask.

Shelf Life
For the Activator, refer to the expiration date on the back panel of the Activator.
For the Mask, refer to the expiration date on the eyeglass arm.

Disposal
(4 AA batteries included)
When you have finished your last treatment session, please remove the batteries in the Activator. Please follow your local regulations for proper disposal of battery operated devices. Dispose of batteries by removing the back panel of the Activator.
## Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit will not function</td>
<td>Mask cord is not fully connected to Activator and silver plug is showing</td>
<td>Make sure Mask is fully plugged in to Activator, with no metal visible</td>
</tr>
<tr>
<td></td>
<td>‘On’ power button was not pressed and held for 1-3 seconds until mask powers on</td>
<td>‘On’ button should be pressed and held for 1-3 seconds until the Mask powers on and is located on the Activator</td>
</tr>
<tr>
<td></td>
<td>All 30 treatment-sessions have been used</td>
<td>See counter for remaining sessions and dispose of the device accordingly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dispose and purchase a new refill Activator</td>
</tr>
<tr>
<td></td>
<td>Mask or Activator are used past the Expiration Date</td>
<td>Dispose and purchase a new Activator</td>
</tr>
<tr>
<td>Mask does not fit</td>
<td>Over-ear arms have not been extended properly</td>
<td>Use over-ear arms and nosepiece to position the Mask for a comfortable fit</td>
</tr>
<tr>
<td>Light flickers during session</td>
<td>Battery power intermittent or power jack of the Mask is not fully plugged into the Activator port.</td>
<td>Check that the power cord is in good condition and that the Mask is fully plugged in to the Activator, with no metal visible. If the problem persists, contact 800-582-4048. Outside US, dial collect 215-273-8755</td>
</tr>
</tbody>
</table>

If you have any unresolved problems, 800-582-4048; Outside US, dial collect 215-273-8755. www.neutrogena.com
Glossary

Bacteria
*Propionibacterium acnes*  
(*P. acnes*) that causes acne breakouts. It lives on oil secreted by the skin.

Blackhead
A small bump on the skin with a black center, not inflamed.

Inflamed
Red and sensitive to the touch.

Nodule
An inflamed mass, like a knot, either raised or felt under the skin.

Pimple
A red and sensitive (inflamed) bump on the skin.

Pustule
A red and sensitive (inflamed) bump on the skin with a white or yellow center.

Whitehead
A small bump on the skin with a white center, not inflamed.
Uses
Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

Directions
See Insert-Instructions for Use

Warnings
See Pregnancy Warning on Page 10

Operating Conditions
5 °C to 35 °C; 15%-75% Relative Humidity, non-condensing;
Atmospheric Pressure: 700-1060 hPa

Transport and Storage Between Uses Conditions
-25 °C to 45 °C; up to 75% Relative Humidity, non-condensing

Questions? 800-582-4048;
www.neutrogena.com

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