

Plain English Summary

This small clinical trial looked at how safe and effective Aurase Wound Gel (AWG) is for cleaning and healing chronic skin wounds compared to a standard wound treatment (ActivHeal). The study lasted 26 days, and patients received up to 11 applications of the treatment (roughly once every 2–3 days).

A total of 14 patients completed the trial: 11 used the Aurase Wound Gel and 3 used the standard ActivHeal treatment.

1. Safety and Side Effects

Overall, Aurase Wound Gel was found to be safe, well-tolerated, and did not cause any major safety concerns.

- *Side Effects:* There were 13 total side effects reported during the study (10 in the AWG group and 3 in the standard treatment group). However, 5 of the side effects in the AWG group happened to just one single patient.
- *Relation to Treatment:* Over 92% of the side effects had nothing to do with the wound gel (for example, things like minor injuries, anemia, or nosebleeds). Only one side effect - temporary pain where the gel was applied - was thought to be possibly linked to the gel.
- *Severity:* Every side effect reported was mild or moderate and went away during the study. No severe side effects were caused by the treatment. One patient did catch viral meningitis and had to go to the hospital, but doctors confirmed this was completely unrelated to the wound gel.

2. Pain and Comfort at the Wound Site

Doctors tracked wound pain, redness, swelling, fluid leakage, skin hardening, and bleeding at every visit.

- *Pain:* Patients using AWG did not experience an increase in pain. In fact, pain scores slightly decreased over time as the wounds began to heal. There was no meaningful difference in pain between the two treatment groups, and patients didn't need extra painkillers during application.
- *Other Symptoms:* The gel did not cause skin redness or swelling. No patients experienced any skin hardening or bleeding during the trial.

3. Cleaning the Wound (Debridement)

Before a wound can heal, dead tissue (called slough and eschar) needs to be cleared away. AWG performed significantly better at clearing out this dead tissue than the standard treatment.

- *Clearing Efficiency:* Over the 26 days, the wound gel removed a median of 65% of the dead tissue, compared to just 9% removed by the standard treatment.
- *Speed:* The wound gel cleared dead tissue much faster, at a rate of 0.17 cm² per day compared to practically zero (0.01 cm² per day) for the standard treatment.
- *Complete Clearing:* About 18% of patients (2 out of 11) using the gel had their wounds completely cleared of dead tissue (defined as over 90% cleared). Nearly half (45.5%) had their wounds more than 80% cleared. Nobody in the standard treatment group achieved these results.
- *Thicker Wounds:* The gel worked exceptionally well on wounds that had medium-to-thick layers of dead tissue at the start of the study.

4. Wound Healing

AWG actively promoted faster and more effective wound healing across multiple measurements.

- *Shrinking the Wound:* By day 26, wounds treated with the gel shrank by a median of 58%, compared to only a 15% reduction in the standard treatment group.
- *Success Rate:* Nearly two-thirds of the patients (63%) treated with the gel saw their wound size cut at least in half by week 4.
- *New Tissue Growth:* Patients using the gel saw a continuous, steady growth of healthy new tissue and skin over the course of the trial, while the standard treatment group saw no real change.
- *Healing Speed:* At the 4-week mark, wounds using the gel were healing at a median rate of 0.14 cm² per day, compared to just 0.02 cm² per day for standard care.
- *The Connection:* The data proved a direct link: the better the gel was at clearing away dead tissue, the faster the wound healed. However, once the 26-day treatment stopped, healing paused, meaning longer treatment might be needed for full closure.

5. Quality of Life

Patients who used the Aurse Wound Gel reported better everyday well-being. They showed consistent improvements in physical comfort, psychological state, and daily living. They also scored higher on a "Forgotten Wound" scale, meaning they were mentally able to focus less on their wound as it improved.

Main Conclusion

Aurse Wound Gel is safe to use and does not cause unexpected pain or skin irritation. It is significantly faster and more effective at clearing out dead tissue and shrinking wounds than standard medical care, directly leading to a better quality of life for patients.