# ADCON® GEL 3g

## Product Ordering Information

<table>
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<tr>
<th>Cat No</th>
<th>Description</th>
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<tbody>
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<td>93AG-CE30</td>
<td>ADCON® Gel 3g</td>
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ADCON®GEL 3g
Review of key clinical studies


Abstract: A prospective, multicenter, randomised, double-blind, controlled study of Adcon-L Anti-Adhesion Barrier Gel was conducted in 298 patients undergoing first-time lumbar discectomy to evaluate the safety and effectiveness of Adcon-L in preventing post-operative peridural fibrosis and in improving patient clinical outcome. After lumbar discectomy, patients were randomised to receive either Adcon-L gel or nothing (control group) at the conclusion of the surgical procedure. Six months after surgery, peridural scar was evaluated by MRI, and post-operative pain and straight-leg-raise angle were assessed.

No statistically significant differences between the Adcon-L and control groups were observed in terms of adverse events or wound healing characteristics. Adcon-L gel was shown to be safe and to significantly inhibit peridural scar compared with the control group (p = 0.002). That peridural scarring was reduced with Adcon-L gel was further supported by direct visualization of scar tissue at re-operation in both groups. Adcon L treated patients had better clinical outcomes than did control patients. The incidence of activity-related pain was significantly reduced (p = 0.013), straight-leg-raise examination scores were significantly improved (p = 0.024 on the operative side), and Adcon-L reduced low back pain when it was most severe (p = 0.047) and at the end of the day (p = 0.044).


Abstract: This paper is to report the results from a retrospective clinical study of Adcon-L for inhibition of post-operative peridural fibrosis following spinal root decompression. The purpose of the study was to collect surgeon experience data related to the use of Adcon-L following primary lumbar nerve root decompression in adult patients. Ten US investigators (spinal surgeons) have independently collected and reviewed information retrospectively from the post-operative medical records from consecutive series of patients who had undergone a single level, lumbar nerve root decompression with Adcon-L application. Patient records were retrieved for evaluations on demographics, surgical use, and complications, re-operations, medical events and adverse events. There was a total of 847 Adcon-L treated patients of which 819 eligible patients were included in the evaluable analysis. In the evaluable patient population, 64.3% of the patients were male and the mean age was 43 years.

An overall medical event incidence rate of 12.7% was seen. Common medical events included pain in limb (1.3%), back pain (0.9%), intervertebral disc herniation (0.9%), headache (0.6%) and insomnia (0.4%). Common adverse events included pain in limb (8.5%), back pain (8.3%), intervertebral disc herniation (3.9%), radiculitis (3.2%), muscle spasms (2.1%), radiculopathy (0.9%) and hypoaesthesia (0.9%). The surgeons review of the medical and adverse events indicated 83.8% were unrelated to Adcon-L and only 16.2% were considered possibly related. No event was considered probably or definitely related to Adcon-L. Re-operations were performed in 4.3% of eligible patients. Of the 35 patients who underwent re-operation, there was no significant peridural fibrosis in 26 (74.3%) patients. A total of five eligible patients were seen with cerebrospinal fluid leakage or pseudomeningocele, comprising 0.6% of the total eligible population. There were no anaphylactic/anaphylactoid reactions or patient deaths reported among the 847 patients followed in the study.