

Gel-One[®] Cross-Linked Hyaluronate



The only single injection 3 mL Gel

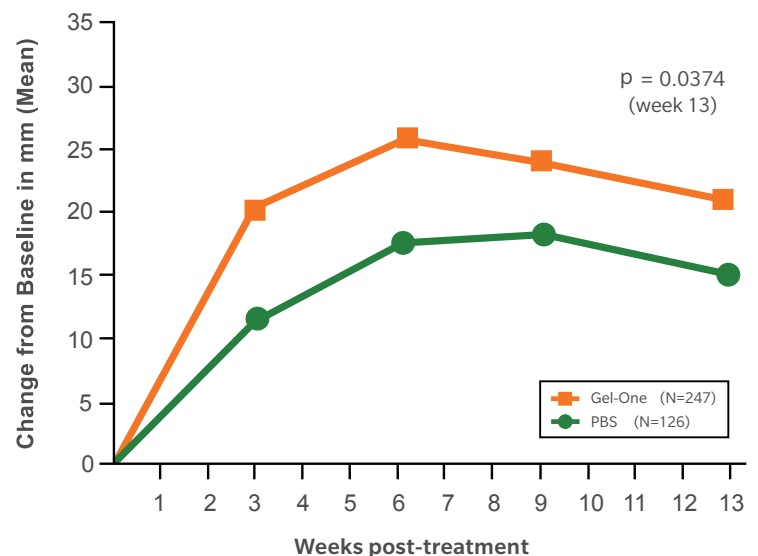
Gel-One[®] Hyaluronate is a sterile, transparent, viscoelastic hydrogel approved for the treatment of pain in osteoarthritis (OA) of the knee. The unique cross-linking process enables increased viscoelasticity, which serves to provide pain relief and improved knee function.

Safety and Efficacy

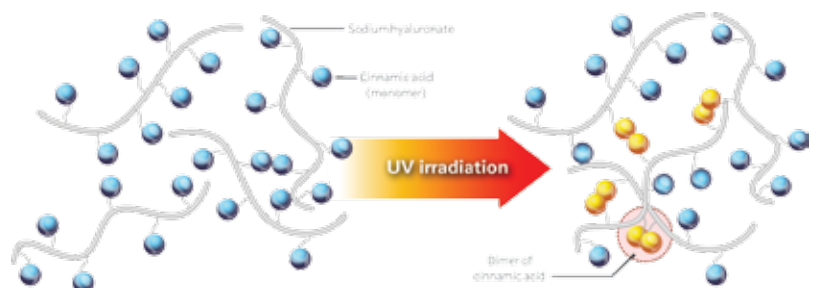
In the *Gel-One* Hyaluronate clinical study, pain relief was measured at 1, 3, 6, 9, and 13 weeks demonstrating statistically significant improvement over the Phosphate Buffered Saline control (PBS).* Patients receiving *Gel-One* Hyaluronate experienced, on average, a nearly 40% reduction in pain from baseline (28 mm reduction in WOMAC pain on a 100 mm VAS, Visual Analog Scale)

*Incidence of adverse effects did not differ significantly between *Gel-One* Cross-linked Hyaluronate and PBS. There were no serious adverse effects or pseudoseptic reactions related to *Gel-One* Cross-linked Hyaluronate injection.

WOMC VAS pain subscore



Structural Formula of *Gel-One* Hyaluronate

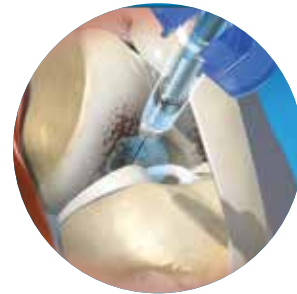


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Gel-One Cross-Linked Hyaluronate Injection Technique

- 1** Using strict aseptic technique apply antiseptic and, if desired, local anesthetic. The knee joint space is accessed through the soft palpable anterolateral port that can be felt just lateral to the inferior pole of the patella and the proximal portion of the patella tendon.
- 2** If present, remove joint effusion through an 18-20 gauge needle before injecting Gel-One Hyaluronate. Maintain needle placement in the joint while disconnecting the syringe used to remove joint effusion. Discard the syringe containing the removed joint effusion.
- 3** Peel off the lid from the Gel-One Hyaluronate blister package and remove the syringe.
- 4** Carefully remove the tip cap of the Gel-One Hyaluronate syringe, and aseptically attach the syringe to an 18-20 gauge needle (if aspiration of joint effusion occurred, the same needle may be used). To ensure a tight seal and to prevent leakage during administration, secure the needle tightly while firmly holding the Luer-Lok. Twist the tip cap before pulling it off to minimize leakage.
- 5** Inject the full 3 mL of Gel-One Hyaluronate into the knee joint through the needle using aseptic injection technique. If treatment is being administered to both knees, use a separate syringe of Gel-One Hyaluronate for each knee.

Note: Injection techniques will vary by physician and may include different approaches in patient positioning.



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Important Safety Information

Before using Gel-One Hyaluronate, tell your doctor if you are allergic to hyaluronan products, cinnamon, or products from birds such as feathers, eggs, and poultry. Gel-One Hyaluronate is only for injection into the knee, performed by a doctor or other qualified health care professional. You should not receive a Gel-One Hyaluronate injection if you have a skin disease or infection around the area where the injection will be given. Gel-One Hyaluronate has not been tested to show pain relief in joints other than the knee and for conditions other than OA. Gel-One Hyaluronate has not been tested in patients who are pregnant, mothers who are nursing, or anyone under the age of 21. You should tell your doctor if you think you are pregnant or if you are nursing a child. Talk to your doctor before resuming strenuous or pro-longed weight-bearing activities after treatment. The safety and effectiveness of repeat treatment cycles of Gel-One Hyaluronate have not been established. The side effects most commonly seen after injection of Gel-One Hyaluronate in the clinical trial were knee pain, swelling, and/or fluid build-up around the knee. These reactions are generally mild and do not last long. Other conditions, including but not limited to skin redness and rash, knee stiffness, knee muscular weakness and dizziness, were also reported rarely. If any of these symptoms or signs appear after you are given Gel-One Hyaluronate or if you have any other problems, you should call your doctor.

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