Loria Pharmaceutical, LLC

PROTOCOL

Protocol No.	500
Subject	Kenalog/ I&D Protocol
Effective Date	07-12-2021

Kenalog-40 (triamcinolone acetonide)

Kenalog is a potent glucocorticoid with anti-inflammatory effect and minimal mineralocorticoid activity.

The direct administration (or the chronic systemic use) of glucocorticoid steroids causes a reduction in the connective tissue in general, collagen and bone alike. Although the complete mechanism how these drugs work in reducing the collagen production is not yet completely understood, it is well known that it produces inhibition of the collagen synthesis.

This change is suspected to occur well within the molecular structure of the collagen fibers causing a disorganization of the intermolecular bonds as well, in addition to the fibroblast synthesis inhibition previously mentioned.

When tightly dense packed collagen fibers are produced due to the induction effect caused by the dermal filler formula, we could witness the appearance of granuloma type structures that although not harmful, could cause some discomfort or undesired appearance. It is then when we could perform a Kenalog injection procedure to target the focal delivery with pinpoint accuracy to address such granulomas or imbalances.

Kenalog injections must be performed at the office, to assure the correct delivery with the correct dilution. When administered carelessly, you could cause undesired effects. It could take up to 6 weeks to see results, and results could differ from patient to patient, therefore several appointments might be needed to achieve desired balance

STEP BY STEP KENALOG INJECTION TREATMENT

1- Gather all the material that you will need including the Kenalog medication vial, the Sodium Chloride and the syringes and needles and alcohol spray bottle.
2- Apply the EMLA cream over the shaft and cover it with saran wrap for 45 – 60 minutes. As an alternative and depending on the extension of the area to be treated, you could perform a local infiltration with your preferred anesthetic mix as well. Keep in mind

however, that you need to evaluate the discomfort benefit of this step though, if you plan on delivering the Kenalog treatment to a small area, you may want to limit the number of injections in favor of the patient's comfort.

3- Once the time with the topical numbing cream has expired, and you have removed it and cleaned the area with aseptic technique, we recommend start diluting the Kenalog.
4- Liberally spray the vials (Kenalog and sodium chloride) with the alcohol before removing the flip cap, and then liberally spray the top of the vial once you have exposed the rubber surface.
5- Connect a 18G needle to a 5cc syringe and draw 2cc of sodium chloride from the sodium chloride vial.
6- Then carefully inject the 2cc that you drew into the Kenalog vial and shake well.
7- Connect another 18G needle to the 1cc syringe and draw 1cc of the sodium chloride and Kenalog mix.
8- Disconnect the 18G needle from the 1cc syringe with the mix (Kenalog and sodium chloride) and connect a 25G needle.
9- Wipe down the area to be injected with an alcohol wipe before injecting.
10- Hold and isolate the area to be injected, with your non-dominant hand, and carefully introduce the needle in a swift continuous motion with your dominant hand to reduce the discomfort.
11- Once the needle is in, into the center of the bulging area itself, depending on the depth of the dense bundle of collagen area this could be about 1/8 or ¼ of an inch, you can inject the Kenalog and sodium chloride mix distributing the content accordingly to all the areas to be covered (usually ¼ - ½ cc (0.25cc – 0.5cc) for a ½" – ½" nodule).
12- Repeat steps 7 – 11 as needed to cover all the areas of concern.
13- After you have finished the injection process and you have covered all the areas of concern, safely discard the sharp elements in accordance with your state laws.
    a. Generally recommended is the use of an appropriate sharp's container.
14- Place a simple wrap with white gauze and stretch gauze on very light tension to collect any spot bleeding, which is normal the first couple of hours.
15- It is recommended to refrain from sexual intercourse, physical manipulation, or pressure on that area, for at least 1 week.
16- Remind patients to send photos every 2 weeks to monitor your progress.
17- Results are typically seen after 5-6 weeks; you may not see any changes during the first couple of weeks.

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A Kenalog treatment injection should always be a conservative procedure aimed to solve minor imbalances of the presence of granulomas that are hard in nature. No more than 80 mg administration is recommended per session.

Treatment sessions could be repeated every 6 weeks if needed or desired until the effect has been achieved. Local side effects could include but are not limited to:

- Bruising
- Dry skin
- Hyperpigmented skin patches
- Hypopigmented skin patches
- Depression of the skin at the injection site
- Redness, swelling, tenderness, or pain at the injection site
- Thin, fragile, or shiny skin

The remodeling caused by this treatment, could produce the formation of pockets of unconverted filler, that could later be drained and flattened with a simple needle poke. The patient must be informed of all these risks and potential developments.

ITEMS NEEDED FOR A KENALOG TREATMENT:

- Lidocaine-Prilocaine 2.5-2.5 % External Cream
- Kenalog 40 MG/ML Injection Suspension
- Sodium Chloride 0.9 % Intravenous Solution
- Hypodermic Needle 18G X 1"
- Hypodermic Needle 25G X 1"
- Easy Touch Syringe Barrel 1ml
- Easy Touch Syringe Barrel 5ml
- Alcohol wipes
- Isopropyl Alcohol sprayer
- White gauze