**Risk Alert**

**Physician Beware: Even a Time-Tested Favorite Drug Can Pose Significant Risk**

**Description**

To many physicians and patients, Kenalog is a medication with a long history of relatively problem-free administration (as long as the prescribing physician and patients observe routine precautions for steroid use). Injectable Kenalog, however, poses risks of which physicians, staff, and patients must be aware. One side effect of injectable Kenalog that has recently led to claims is tissue atrophy.

Internet blog entries written by patients about their Kenalog side effects describe dents in the upper arms or buttocks that are ‘huge’, ‘the size of a baseball’, or ‘the size of an orange’. They describe spending significant time and money on trips to other physicians to find out what caused the dent, and what might be done to remove it.

Though these ‘dents’ caused by tissue atrophy are usually the primary allegation in a Kenalog claim, other complaints are also voiced. Side effects such as cardiovascular problems, severe pain, menometrorrhagia, skin discoloration, headache, and a variety of other complaints have been reported.

In some cases, physicians who use Kenalog injections for their patients were not aware of the possibility of tissue atrophy or some of these other side effects. Since they were unaware, they could not advise their staff or patients of the risks associated with the injections. Tissue atrophy then came as a surprise to all involved, and the patient expressed even more anger because they felt that the doctor should have known about the side effect they experienced. This is, unfortunately, an ideal situation for a claim to arise.

There is a great deal of information on Kenalog and its side effects on package inserts and on internet information sites. Unfortunately, there is limited reference to tissue atrophy in connection with intramuscular injection of Kenalog on Kenalog-specific sites. Only Drugs.com makes specific reference to the need for a deep, intramuscular injection to avoid ‘local atrophy’. Drug package inserts from the manufacturer do not mention tissue atrophy for the 10 mg intramuscular dose, however, the 40 mg package insert states: “The suggested initial dose is 60 mg, injected deeply into the gluteal muscle. Atrophy of subcutaneous fat may occur if the injection is not properly given.” These package inserts were updated in November, 2007. If a medical practice is not in the habit of checking for changes, or if their pharmaceutical representative did not inform them of a change, then this update may have gone unnoticed.

It is important that physicians who give their patients intramuscular injections of Kenalog take steps to protect their patients and reduce potential liability. Following are a list of the specific risks encountered in this situation and recommendations for reducing those risks.

**Risks**

- Potential for patient and physician complacency with a medication which has been on the market for many years.
- Practitioners who are unaware of potential side effects of the injected medication because they are uninformed of updated package inserts.
- Real or perceived inadequate communication between practitioner and patient, such as complaints of:
  - Little or no information given on potential side effects.
  - Little or no support given in response to side effects.
  - Patients not told the name of the specific medication they are receiving.
- Patients who are actively communicating their experiences with each other through blogs, but may not be communicating their unhappiness as clearly to their physicians.

**Recommendations**

For practices that give Kenalog injections, the following steps can help reduce liability.

- All Kenalog injections should be given according to manufacturer’s directions, that is, deep into the muscle; they should never be given in the deltoid, only in the buttocks.
- Before giving a Kenalog injection to a patient, a physician must discuss the medication with the patient, including its risks, benefits, side effects, and complications.
- It is beneficial to have a written sheet which also describes the
medication, its risks, benefits, side effects, and complications.

- The written description sheet can also include a signature line for patient and a witness. In this way the sheet is used as an informed consent. Therefore, the original signed copy should be placed in the patient’s chart and a photocopy should be given to the patient.

**Comment**

In some Princeton claims which involved Kenalog injections, the staff member who injected the patient was a Certified Medical Assistant (CMA). All physicians must be aware of the New Jersey Board of Medical Examiner (BME) regulations regarding CMAs performing injections.

Though CMAs are allowed to give these injections under BME regulations, they must be conscious of the risks involved, and of the proper method of administration. Before giving the injection, they should make sure that the physician has educated the patient about the risks and given the patient a written description of those risks, as noted above.

Working as a team, physician, staff, and patient can still successfully use a medication which has proven itself to be effective for many years. Success requires communication, knowledge of the issues, and a focus on patient safety from all involved.

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**Resources:**

1. [http://www.medications.com/se/kenalog](http://www.medications.com/se/kenalog)