

INFORMATION & CONSENT FORM

We want you to have clear information about your choice to have a Kenalog injection to relieve the symptoms of hay fever.

It is really important you understand this information so please discuss any questions with the doctor. We also encourage you to seek further information online or elsewhere to make sure you are comfortable with the risks and benefits of this treatment.

Reasons for having a Kenalog injection:

Treatment of severe hay-fever, that is resistant to alternative treatments:

Hay fever is caused by your immune system reacting unnecessarily to pollens. Your immune system is such an important part of your body that it will preferentially use up a lot of your energy uselessly 'fighting off' pollens which it interprets as attacking you. The energy that would be much better utilized elsewhere in life.

Trees can begin to produce pollen in late January and some grasses continue producing pollen until September so depending on what you're allergic to, the season can be many months.

Between 10-15% of us suffer from hay fever symptoms. For many people it causes significant fatigue and problems with concentration and alertness. Research has shown that people can do 5-10% worse in their exams during hay fever season compared with other times of the year.

Of those 10-15% of people with hay fever, about 10% do not respond to conventional, easily available treatments like antihistamine tablets, nasal sprays and eye drops. Many of these people consider a Kenalog injection to help them get through the season.

Each Kenalog injection contains Triamcinolone acetonide 40mg/1ml as the active ingredient. Triamcinolone acetonide belongs to a group of medicines called corticosteroids (steroids). The principal effect of corticosteroids is to reduce the body's inflammatory &

allergic response and they are used very commonly for many serious medical conditions. Their use has saved countless lives since their discovery in the 1940's but they do have significant risks.

Kenalog injections were given routinely to severe hay fever sufferers via the NHS until about 5-10 years ago but have now fallen out of favour and the NHS no longer prescribes or administers Kenalog for hay fever as their guidelines have determined that the potential risks do not justify the benefits that people may gain from the treatment.

There are many people who have used this treatment to good effect and while we do not directly disagree with the assessment of the NHS, we do believe in patient choice and are happy to make this treatment available to people who have thoroughly considered the risks.

Kenalog is still officially licensed for the treatment of severe hay fever in the UK and continues to be routinely administered to patients in most other countries around the world.

A Kenalog injection does not cure hay fever. It just temporarily suppresses the immune system enough to take away the symptoms in most people who need it.

The potential problems from Kenalog last for about 3 weeks after the injection but many people find the relief from symptoms commonly lasts the entire season.

Procedure:

Kenalog is an injection that is injected into the buttock (gluteal) muscle. This is known as an IntraMuscular (IM) injection. The skin surface is thoroughly cleaned with an alcohol swab prior to the injection.

It takes a few seconds and is not a very painful injection as the substance itself is not irritating to the tissue.

Potential Benefits:

A Kenalog injection helps many people with their symptoms of severe hay fever. For many people it completely relieves the symptoms for the entire season and for others it reduces the severity of the symptoms to a point where adding other treatments can allow life as normal.

Occasionally a second dose of Kenalog may be needed. The doctor will discuss this with you. It is not recommended that anyone has more than 80mg (2 injections) per season except in exceptional circumstances.

Possible Side-effects:

Steroids are powerful medications designed to reduce the body's inflammatory and allergic responses. An injection of Kenalog 40mg is approximately equivalent to the effects you would get from taking a 5mg tablet of Prednisolone every day for about 3 weeks.

Kenalog injections like all steroids can cause unwanted side effects, although these are rare at the dose levels that you get from a Kenalog injection. The unique issue with a Kenalog injection that differentiates it from oral steroids is that once the injection is administered the effects last for at least 3 weeks. With tablets, the effects are gone within about 24 hours or less. This is the main reason NHS guidelines have identified this method of administering steroids as a problem. There are occasions when the body needs its immune system at top strength and there are theoretical concerns that having it partially suppressed like this for up to 3 weeks could cause significant problems.

Serious possible adverse Effects:

Anaphylactic allergic reactions have been very rarely reported.

You must contact a doctor IMMEDIATELY (by going to an Accident & Emergency department) if you notice any of the following symptoms of an anaphylactic reaction:

- Swelling of the face, lips or throat
- Breathing difficulties
- Skin itching, redness or a rash
- Sticky black stools
- Severe abdominal pain
- Vomiting blood

Possible psychological effects of all steroids:

All steroids, including Kenalog, can occasionally cause mental health problems although this is usually associated with much higher doses of steroid than what is given in a Kenalog injection.

If you experience any of the symptoms listed below, please contact your doctor straight away.

- Feeling depressed, including thinking about suicide
- Feeling high (mania), or moods that go up and down
- Feeling anxious or having problems sleeping, difficulty in thinking or being confused and losing your memory
- Feeling, seeing or hearing things that do not exist

Other possible side effects specific to Kenalog injection:

- Increased risk of infections
- It is theoretically possible that if you were to get an infection such as measles or chicken pox within 3 weeks of having a Kenalog injection it would be a worse episode than would otherwise be the case
- Pain and skin colour changes at site of injection
- Sterile abscess at site of injection. **This can cause an unsightly dimple and scar on the skin of your buttock**
- Dimpling of skin caused by loss of fat under the skin at injection site

Other possible side effects general to Steroids:

- Mood changes
- Indigestion, stomach pain, stomach ulcers, bloating, weight gain, pancreatitis
- Eye problems including glaucoma and cataracts
- Fungal infections e.g. thrush
- Osteoporosis (thinner bones)
- Reduction in the body's overall ability to respond to major stress resulting from serious injuries

Alternative treatments for Hay fever & Seasonal allergies:

It is always more effective to commence treatment for hay fever about 3 weeks prior to the season starting. Many people have had their lives transformed by starting treatment early and continuing treatment regularly throughout the season. This is often difficult to commit to however and many of us only remember we need treatment after the season is well underway.

Non-medical treatments:

- Stay indoors on high pollen count days
- Reduce bare skin as much as possible - the allergy can be made worse by pollen on the skin –not just the nose, eyes & mouth
- Have frequent showers to wash any pollen off the skin
- Vaseline on nostrils

Non-prescription medications which you should always try first:

There are several effective over-the-counter medications that should be explored before considering a Kenalog injection.

- Antihistamines tablets such as Loratadine, Cetirizine and Acravastine
- Eye Drops such as Sodium Cromoglycate
- Nasal Sprays such as Beclometasone & Fluticasone

Prescription Medications:

There are effective prescription only medications such as:

- Prednisolone oral tablets
- Antihistamine nasal sprays (Rhinolast) or combination antihistamine with steroids (Dymista)
- Fexofenadine antihistamine tablets
- Montelukast tablets
- Ranitidine tablets

In severe cases, oral steroid tablets (Prednisolone) are prescribed for short periods for special events like an outdoor wedding or for exams.

Prednisolone can also be very effective for severe sufferers who are organised enough to start treatment a few weeks prior to the season starting. The prednisolone is commenced at the same time as antihistamines. The prednisolone course is just for a few weeks to suppress the body's immune system and the antihistamines continued every day throughout the season to keep the allergy under control.

Immunotherapy (Desensitisation) Treatments:

Giving injections or tablets of what you are allergic to in slowly increasing doses can reduce your immune reactions and cure your hay fever permanently. Every dose must be monitored closely in case of an anaphylactic reaction and requires dedication and commitment as you need a dose every few weeks for at least 2 years if it is going to work at all. It is highly recommended in children with severe disabling allergies. Kenalog cannot be given at the same time as desensitisation treatments as it counteracts the effectiveness of the treatment regime.

If you have any questions regarding the procedure, risks, benefits, or alternative treatment, please ask your doctor. You will be asked to sign a consent form prior to receiving the injection confirming you have read this document, are aware of the risks and are happy to proceed.