

**ADVICE NOTE FOR INTRAMUSCULAR TRIAMCINOLONE ACETONIDE IN ADULT  
ASTHMA PATIENTS**

(For use in a fully assessed and monitored patient as part of a difficult asthma service)

**Background**

A small number of patients with severe asthma remain poorly controlled despite adhering to oral corticosteroid therapy. In addition, it is well recognised that there is poor adherence to prescribed medicines in adult asthma (1). There is evidence that intramuscular (IM) Triamcinolone Acetonide (TA) (Kenalog®) is more effective than low dose prednisolone in the treatment of severe, chronic, difficult to control asthma (2). The intramuscular injection provides an extended duration of therapeutic effect and fewer side effects of the kind associated with oral corticosteroid therapy, particularly gastro-intestinal reactions such as peptic ulceration.

Biologically active levels of TA are achieved systemically for prolonged periods (weeks to months). Studies indicate that, following a single IM dose of TA 80mgs, adrenal suppression occurs within 24-48 hours and then gradually returns to normal, usually in around three weeks (3). This finding correlates closely with the extended duration of therapeutic action of TA. The dose and duration of systemic steroid treatment that results in significant immunosuppression is considered to be prednisolone 2mgs/kg/day for more than one week or 1mg/kg/day for more than one month – or 20mg prednisolone a day (3). In terms of anti-inflammatory equivalence, 800mcgs of TA is equivalent to 1 mg of Prednisolone (4). However, it is not possible to calculate an equivalent daily dose when administered by IM injection. Immunosuppression is thought to occur with TA when doses exceed normal physiological production, i.e. at more than one 40mg IM injection in a three week period (3).

**Preliminary assessments**

**INDICATIONS FOR USE IN ASTHMA**

1. To improve asthma control and/or act as a steroid sparing agent in patients with severe, chronic, difficult to control asthma who are not responding to high dose inhaled steroids/oral steroids (step 5 level) characterised by:

- i. Continued repeat hospitalisations despite intensive treatment
  - ii. Objective evidence of poorly controlled asthma (E.g. FEV<sub>1</sub><75%, FeNO>50ppb, ACT <20)
  - iii. Excessive absence from work
2. In a confirmed poor or non compliance situation in a steroid-responsive patient

## PRE-TREATMENT SCREENING

All patients must have additional safety checks as below before commencing TA.

Item check	Action
Adrenal function status Patient must have had a low dose synacthen test within previous 12 months	If abnormal (peak cortisol <500nmol/l or incremental rise <200nmol/l) no need to repeat post treatment. If normal (peak cortisol >500nmol/l) repeat 2-3 months post treatment. If repeat Synacthen result equivocal (post-stimulation synacthen cortisol 200-500nmol/l) then repeat synacthen in 2 months.
Chickenpox status	Has patient had chickenpox?  If Yes, can this be confirmed by parent or carer ± evidence of scars? If yes, no further action is needed and the TA may be given.  If No, or there is any doubt, check IgG to Varicella Zoster Virus (VZV). If negative consider giving VZV vaccination but discuss with ID team if concerned that the patient may be immunocompromised from current oral steroids at an immunosuppressive dose.  <b>Live vaccines should NOT be given to immunocompromised patients.</b>

## PRECAUTIONS / CONTRAINDICATIONS

Suppression of the inflammatory response and immune function increases susceptibility to infections and their severity. The clinical presentation may be atypical and serious infections such as septicaemia might be masked.

Chickenpox and measles are of particular concern since these normally minor illnesses may be fatal in immunocompromised patients. Unless they have had chickenpox, patients receiving parenteral corticosteroids should be regarded as being at risk of severe chickenpox.

Patients should be advised to avoid exposure of patient to chickenpox and measles and to make immediate contact with the hospital if it occurs.

Passive protection against chickenpox with varicella zoster immunoglobulin (VZIG) is needed for exposed non-immune patients who are receiving systemic corticosteroids (including TA) or who have used them in the previous 3 months. VZIG must be given within 72 hours of exposure. If exposure occurred longer than the 72 hour period, contact and discuss with the Infectious Diseases (ID) team. VZIG does not prevent infection even if given within 72 hours of exposure, but may attenuate an attack if given within 10 days after exposure.

Confirmed chickenpox warrants specialist care and urgent treatment. Manifestations of fulminant illness include pneumonia, hepatitis and disseminated intravascular coagulation, rash is not necessarily a prominent feature. If the patient develops chickenpox or shingles, admit, treat with IV Aciclovir and discuss with ID team.

During corticosteroid therapy, antibody response will be reduced and therefore affect the patients response to vaccines. Live vaccines should **NOT** be administered.

Patients should carry steroid treatment cards which give clear guidance of the precautions to be taken to minimise risk and which provide details of prescribes, drug, dosage and the duration of treatment.

## **UNDESIRABLE EFFECTS**

Where adverse reactions occur they are usually reversible on cessation of therapy. The incidence of predictable side-effects, including hypothalamic-pituitary-adrenal suppression, correlate with the relative potency of the drug, dosage, timing of administration and duration of treatment.

Severe pain has been reported following intramuscular injection. Sterile abscesses, subcutaneous atrophy, hyper-pigmentation, hypo-pigmentation and Charcot like arthropathy have also occurred.

## **INTERACTIONS WITH OTHER MEDICINES**

If patient is prescribed any of the following discuss with Respiratory Consultant as TA treatment may be contraindicated:

- TA (Kenalog) may antagonise (decrease) the action of the following drugs: Anti-cholinesterases, Anti-diabetics, Anti-hypertensives, Isoniazid, Human Growth Hormone and Aspirin.

- TA may potentiate (increase) the action of the following drugs: Cyclosporin, Digitalis Glycosides, Oestrogens.
- TA may antagonise or potentiate the action of the following drugs: Anticoagulants, Non-depolarising Muscle Relaxants.
- Hepatic Enzyme Inducers (e.g. barbiturates, phenytoin, carbamazepine, rifampicin) may increase the clearance of Kenalog, reducing the effect of the steroid.
- Ketaconazole may reduce the clearance of Kenalog, resulting in increased effects.
- Clearance of steroids is decreased in hypothyroid patients and increased in hyperthyroid patients.
- Corticosteroids may increase the incidence and/or severity of GI bleeding associated with NSAIDS.
- Amphotericin B and potassium depleting agents e.g., diuretics, increase risk of hypokalaemia.

## Treatment Phase

### REGIME

Discontinue oral steroids at time of first injection and issue/or update steroid card.

Duration: One IM injection every four to six weeks, depending on response, with a maximum of three injections. Duration of effect is variable, hence subsequent doses should be given when symptoms recur and not at set intervals.

Dosage: 12 years+ - start at 40mgs. Subsequent dosage depends on the patient's response and period of relief. Consider increasing to 60mgs if poor clinical response (3-5). Maximum recommended single dose is 100 mg (5).

### ADMINISTRATION/PROCEDURE

- Strict aseptic precautions should be observed
- To avoid the danger of subcutaneous fat atrophy at injection site ensure that **deep intramuscular injection** is given into the outer quadrant of the gluteal muscle by a nurse experienced in giving deep IM injections
- Alternate sites should be used for subsequent injections
- It is important to photograph injection sites at each visit

## **TREATING ACUTE EXACERBATIONS**

Exacerbations occurring during TA treatment should be dealt with promptly. In the event patients will be told to commence high dose bronchodilators and oral steroids, and present to hospital for further assessment. Patients prescribed TA will by definition be people with very difficult to control asthma ± a history of severe acute episodes. At least at the start of TA treatment we would recommend admission for 24-48 hours during exacerbation as decline may have been triggered by recent stoppage of oral steroids. Discuss with Respiratory Consultant for asthma.

Two further interventions will be activated at the start of TA treatment. Firstly, the patients will be provided with a letter to present on arrival to hospital. The letter will stress the recommendation to treat the acute asthma with further oral steroids and admit to the respiratory ward for further observation. The acute receiving staff may not be familiar with TA and may delay further steroid loading.

Secondly, the clinical nurse specialist for asthma will alert all Respiratory Consultants by email 7-10 days in advance of a patient commencing TA in case the patient is admitted during treatment. The email will specify the intended start and expected end date of the treatment. Copies of the TA protocol will be available on the ward.

### **Objective Assessments**

#### **MONITORING**

For the duration of the IM TA treatment the patient will be seen every 4-6 weeks by a Respiratory Consultant and/or the Clinical Nurse Specialist for asthma at a nurse run asthma clinic or the severe asthma clinic. A structured assessment (See Visit Checklist) will be conducted at every visit. One would consider that TA has shown benefit if there is a reduction in exacerbations, FeNO, reversibility to nebulised salbutamol and asthma control questionnaire score; along with an increase in FEV1 and asthma control test score.

In patients who have received more than one injection during a three week period, or those receiving daily oral prednisolone prior to commencing IM TA, withdrawal should not be abrupt and additional corticosteroid cover may be required. Discuss with Respiratory Consultant in Asthma.

## References

- (1) Gamble J, Stevenson M, McLean E, Heaney LG: The prevalence of nonadherence in difficult asthma. *Am J Resp Crit Care Med* 2009; 180: 817- 822
- (2) Ogirala RJ *et al.* High-dose intramuscular triamcinolone in severe, chronic life threatening asthma. *N Engl J Med* 1991;324:584-9.
- (3) Electronic Medicines Compendium. Electronic Citation (2008) Available from: URL:<http://emc.medicines.org.uk>
- (4) Kroger AT, Atkinson, WL, Marcuse, EK, et al. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.*2006;55(RR-15):1–48.
- (5) Vaccination in the Immunocompromised Person Grabosky, Hadler, Chen & Edwards, *Bulletin of Rheumatic Disease* 1995 44(8) 36
- (6) BNF version 60, 2010. Ref Type: Generic

This protocol should be used in conjunction with the package insert and Summary of Product Characteristics. The list of cautions, contraindication and adverse effects is not necessarily complete. For further advice contact Respiratory Consultant for Asthma and/or the Clinical Nurse Specialist for Asthma.

### **Modification of SOP for paediatric protocol which was written by:**

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## **Appendix A: Visit Checklist**

<b>BASELINE</b>	<b>Visit 1</b>
Discontinue any concurrent oral steroids	
Provide steroid card	
Short Synacthen Test result	
Ask about concurrent medication – Do not proceed if YES for any on the list in SOP	
Ask about concurrent illness – Do not proceed if acutely unwell	
Chickenpox status & need to check VZV titre	
Explain ' <b>No vaccines</b> ' during treatment trial	
Give product patient information leaflet	
Provide information on acute adrenal suppression illness cover	
Ask if any other treatment is planned over next 3 months e.g. dental work?	
Photograph injection sites	
Prescribe bisphosphonate & calcium/Vitamin D	

<b>DATE</b>					
<b>ASSESSMENT</b>	<b>Visit 1</b>	<b>Visit 2</b>	<b>Visit 3</b>	<b>Visit 4</b>	<b>Visit 5</b>
	<i>1<sup>st</sup> TA</i>	<i>1<sup>st</sup> TA + 2 weeks</i>	<i>2<sup>nd</sup> TA</i>	<i>3<sup>rd</sup> TA</i>	<i>3<sup>rd</sup> TA + 2/4 weeks</i>
Any URTI or viral exacerbation?					
Have any new medicines been prescribed?					
Height					
Weight					
FeNO					
FEV <sub>1</sub>					
Reversibility					
Asthma Control Test (Short) (25=full control)					
Asthma Control Questionnaire (6=poor control)					
HADS (11-14 mod, 15-21 severe)					
<b>SIDE-EFFECT SCREENING</b>					
Record BP					
Standard urinalysis					
Injection site (record site used and condition)					
Any facial hair growth?					
Any acne developing?					
Any muscle weakness or fatigue?					
Any other issues raised by the patient?					
Does Short Synacthen test need to be booked?					

## Appendix B: Patient Information Leaflet

### PATIENT INFORMATION LEAFLET

# KENALOG

INTRA-ARTICULAR/  
INTRAMUSCULAR INJECTION

40 mg/ml

Triamcinolone Acetonide

**Kenalog IA/IM Injection is a steroid**

**medicine**, prescribed for many different conditions, including serious illnesses.

- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Kenalog IA/IM Injection can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, **but see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take it for more than 3 weeks, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, see your doctor straight away.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

Your doctor has prescribed Kenalog injection for you. This leaflet gives a summary of information about your medicine. If you want to know more, or are not sure about anything, ask your doctor or pharmacist.

**REMEMBER:** This medicine is for YOU. Only a doctor can prescribe it. Never give it to anyone else. It may harm them even if they have the same symptoms as you.

### **Q.WHAT IS IN KENALOG INTRAARTICULAR/ INTRA-MUSCULAR INJECTION?**

A. Kenalog IA/IM Injection belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Kenalog IA/IM Injection) is an effective way to treat various illnesses involving inflammation in the body. Kenalog IA/IM Injection reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it. The injection contains triamcinolone acetonide 40mg/ml and is supplied in 1.0ml glass vials.

The 1.0 ml vial contains 40mg of triamcinolone acetonide . The injection can be given as an intra-articular or intramuscular injection but the needle provided with the ready-filled syringes is only for deep intramuscular injection into the large muscle of the buttock.

The other ingredients are benzyl alcohol, polysorbate 80, carmellose sodium, sodium chloride and water.

### **UK PRODUCT LICENCE**

Held by: E.R. Squibb & Sons Limited  
Uxbridge Middlesex UB8 1DH  
United Kingdom

Tel. No.: 0800 7311736

**MANUFACTURER**

Bristol-Myers Squibb Srl,  
Contrada Fontana del Ceraso,  
03012 Anagni (FR), Italy

**Q.WHAT IS THIS MEDICINE FOR?**

A. Kenalog injection is for the treatment of various inflammatory and/or allergic disorders. These include asthma, seasonal allergies, arthritis, blood disorders, hormone problems, rheumatic fever, problems with kidneys, lungs or skin.

**BEFORE RECEIVING YOUR MEDICINE**

**Q. Should I be receiving Kenalog Injection?**

A. You should **not** receive this medicine if you have ever had an allergic reaction to similar medicines or to any of the medicines or to any of the ingredients in Kenalog injection. You should **not** receive this medicine if you are suffering from an infection unless your doctor has also prescribed a treatment for the infection.

**Q. Is there anything else I should discuss with my doctor before receiving Kenalog injection?**

A. Check with your doctor before receiving Kenalog injection if you have had any recent infection, tuberculosis (TB), bowel disorders, an ulcer, blood clots, cancer, thin (brittle) bones, high blood pressure or heart failure, mental disorders, epilepsy, myasthenia gravis or glaucoma (increased pressure in your eyes).

**Check with your doctor first:**

- **If you have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Kenalog IA/IM Injection.
- If any of your close family has had these illnesses.

If either of these applies to you, **talk to a doctor before taking Kenalog IA/IM Injection**. If you are receiving long-term intramuscular treatment with Kenalog injection your doctor may advise you to eat more protein. This should help to reduce the gradual loss of weight that can sometimes occur with longterm treatment.

**Q. What if I am in contact with someone who has an infectious disease such as Chickenpox, Shingles or Measles?**

A. Steroid medicines suppress your body's natural immune response. Therefore, if you come into contact with anyone who has an infectious disease such as chickenpox, shingles or measles, consult your doctor promptly.

**Q. Can I be immunised (vaccinated)?**

A. While you are being treated with this medicine (or you have recently stopped a course of treatment) do not have any immunisation without consulting your doctor.

**Q. What if I am pregnant or think I may be pregnant?**

**What if I am planning to become pregnant?**

**What if I am breast-feeding?**

A. You should make sure you discuss this with your doctor as soon as possible before receiving Kenalog injection.

**Q. What if I have had problems with my kidneys, liver or thyroid?**

A. Remind your doctor as the dose of Kenalog may need to be adjusted.

**Q. Can I take other medicines?**

A. Corticosteroids can increase the chance of bleeding from the gut caused by aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs

(NSAIDs). If you have hypothrombinaemia (a tendency to bleed), your doctor will be more careful about giving you Kenalog if you are taking ibuprofen or another NSAID. Always tell your doctor about all other medicines you are taking, even those you have bought at a pharmacy or other places, e.g. supermarket. Some medicines used to treat epilepsy, tuberculosis or breast cancer can reduce the effectiveness of Kenalog. On the other hand, Kenalog can affect the action of some medicines used to treat diabetes, high blood pressure, to slow the heart or to thin the blood. Always tell your doctor if you are taking oral contraceptives, hormone replacement therapy (HRT), growth hormone, thyroid drugs, cyclosporin, medicines for treating fungal infections or if you are to be vaccinated or to be given an anaesthetic.

**Q. Is it alright to take exercise?**

A. You must take care not to over-use a joint which feels better after you receive Kenalog injection as the joint will still need to recover from the inflammation which caused your symptoms.

**Q. Is it alright to drive?**

A. This medicine does not usually affect your ability to drive but it can affect your eyesight. Tell your doctor immediately if you have any pain in the eyes or visual disturbances.

**Q. Is it alright to drink alcohol?**

A. There is no known interaction between Kenalog and alcohol.

**Q. What if I am diabetic?**

A. Remind your doctor as your insulin dose may need to be changed.

**Q. Who should I tell that I have received this injection?**

A. Your doctor or pharmacist will have given you a Steroid Treatment Card with your prescription or medicine. YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it must be shown to any of the following persons:  
Doctor or Nurse - before having any surgery or emergency treatment or if any new treatment is prescribed.

Dentist - before having any dental surgery

Pharmacist - before buying any medicines

Optician - it is advisable to have regular eye tests.

**Q. Is there any important information about the ingredients of Kenalog that I need to know?**

A. Kenalog injection contains 15mg/ml benzyl alcohol which may cause harmful or allergic reactions in infants and children. Kenalog injection must not be given to premature or newly born babies.

**ADMINISTRATION OF YOUR MEDICINE**

**Q. How will Kenalog injection be given and how often?**

A. The effect of the injection will vary from patient to patient and further injections may be given when symptoms return and not at regular intervals.

**Use in inflammatory joint disorders:**

The dose of injection into a joint or into a tendon sheath depends upon the size of the joint and the condition which is being treated. Doses of 5-10mg (0.125-0.25ml) for smaller joints and up to 40mg (1.0ml) for larger joints may be given. This medicine should not be used for injection into the Achilles tendon.

**Use in allergic disorders:**

**Deep intramuscular injection must be given into the large muscles of the buttock and not into the upper arm or the thigh. This medicine should not be given into a vein.**

The usual starting dose is 40mg (1.0ml) injected deeply into the upper outer area of the buttock. If you require a further injection, this should

be made into the same area on the other buttock. Some patients with hay fever or pollen asthma find that one injection of 40-100mg lasts throughout the pollen season.

**Children:** Kenalog is not recommended for children under 6 years of age. It may be given to older children but the dose is adjusted according to their size and weight and is always kept as low as possible for the shortest possible time. During times of illness or stress, patients on longterm treatment may require the addition of oral steroid tablets, or, if they have recently finished a course of Kenalog injections, may need to start taking oral steroid tablets for a while.

**Q. How long should I continue receiving Kenalog injection?**

A. Your doctor will advise you whether it is wise for you to have further injections. Treatment with steroids is usually kept as short as possible and must not be stopped abruptly. Joints may become permanently damaged by repeated injections over a long period of time. When the treatment is stopped you may notice flu-like symptoms, runny nose or itchy eyes or skin.

**Mental problems while taking Adcortyl IA/ID injection**

Mental health problems can happen while taking steroids like Kenalog IA/IM Injection (see also section 4 Possible Side Effects).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment. Talk to a doctor if you (or someone taking this medicine), shows any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

**UNDESIRABLE EFFECTS**

**Q. Are there any unwanted effects of Kenalog injection?**

A. All medicines may cause some unwanted or "side" effects. Some which can occur with steroid treatment are as follows. Tell your doctor immediately if you get ulcer pains in your stomach, severe pain in your abdomen or tarry black stools, facial swelling or an unexpected rash. Steroid treatment may cause: Increased appetite, weight gain, indigestion, bloating feeling tired or weak. Increased risk of infection; Thinning of bones or tendons causing fractures or torn muscles and muscle wasting; Wounds or broken bones may be slow to heal; Water retention, changes in potassium, sodium and calcium levels, heart problems, irregular heart beat, high blood pressure or blood clots, increase in white blood cells; Skin disorders, including bruising, rashes, redness, itching, itchy raised lumps (hives) and other serious skin conditions. Acne, increased hair growth, increased sweating, flushing and thinning of the skin, and eye problems, including glaucoma and cataracts, may occur. Treatment with steroids can stop the body from producing some hormones and may slow or stop children's growth rate. If you are female, your periods may stop or become irregular. Elevation or depression of mood, feelings of dependence on the medicine, worsening of psychiatric conditions, sleeplessness, dizziness, fainting, convulsions, tingling, numbness, wheezing, breathing problems and severe headaches have been reported. When Kenalog is injected into a joint you may notice some indentation or skin discolouration appearing after a while in the surrounding area. There may also be some temporary worsening of the pain, irritation and discomfort after the injection. These changes should disappear in time. Occasionally, Kenalog given by deep intramuscular injection produces dimpling of the buttock,

caused by loss of fat under the skin. Severe pain and changes in skin colour around the injection site can also occur.

Tell your doctor or pharmacist if you notice any other troublesome side effects.

**Serious effects: tell a doctor straight away**

Steroids including Kenalog IA/IM injection can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Kenalog IA/IM injection.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away.**

**LOOKING AFTER YOUR MEDICINE**

Kenalog injection will be kept in the pharmacy until it is given to you by your doctor or nurse. It should not be stored above 25°C nor should it be allowed to freeze. The container should be kept in the outer carton and this should be kept out of the reach and sight of children. It should not be used after the expiry date shown on the outer packaging.

**DATE OF LAST REVISION**

**November 2009**

**Appendix C: Letter for patient to give to assessing medical team in event of acute illness**

To whom it may concern,

This patient is receiving intramuscular triamcinolone for his/her severe asthma. If the patient has an acute exacerbation of asthma or any acute illness, it is important that further oral/intravenous steroids are administered and if possible please admit to the respiratory ward for further observation.

It is important that there is not a delay in further steroid loading in the event of an acute illness. Triamcinolone therapy is associated with a risk of adrenal suppression.

Yours faithfully,

Respiratory Consultant