

## New Zealand Data Sheet

# Kenacort-A 40

*Triamcinolone acetonide*

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## Presentation

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Kenacort-A 40 injection provides a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action. Each mL of the sterile, aqueous suspension provides 40mg of **triamcinalone acetonide**, with 6.6 mg sodium chloride for isotonicity, 15mg benzyl alcohol as a preservative, 6.4 mg carmellose sodium, and 0.4mg polysorbate 80 in water for injection qs to 1mL. At the time of manufacture, the air in the container is replaced by nitrogen. Kenacort A40 is suitable for intramuscular, intrarticular and intra-synovial injection. This formulation is not suitable for intravenous, intradermal or intraocular use.

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## Uses

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### *Actions*

Naturally occurring glucocorticoids (hydrocortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogues are primarily used for their potent anti-inflammatory effect in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

Kenacort-A 40 Injection has an extended duration of effect which may be permanent, or sustained over a period of several weeks. Studies indicate that following a single intramuscular dose of 60 to 100 mg of **triamcinolone acetonide**, adrenal suppression occurs within 24 to 48 hours and then gradually returns to normal, usually in 30 to 40 days. This finding correlates closely with the extended duration of therapeutic action achieved with the medication.

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## Indications

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### **Intramuscular**

The intramuscular administration of Kenacort-A 40 (Sterile Triamcinolone Acetonide Suspension USP) is indicated for systemic corticosteroid therapy in such conditions as allergic diseases, dermatoses, or generalised rheumatoid arthritis and other connective tissue disorders. Intramuscular administration is

particularly valuable in such conditions when oral corticosteroid therapy is not feasible.

### **Intra-Articular**

Kenacort-A 40 Injection (Sterile Triamcinolone Acetonide Suspension USP) is indicated for intra-articular or intrasynovial administration, and for injections into tendon sheaths, as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; acute gouty arthritis; epicondylitis; acute nonspecific tenosynovitis; post-traumatic osteoarthritis.

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## **Dosage And Administration**

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This preparation contains benzyl alcohol. Not for use in newborn or premature infants (see **Use in Children**)

### **General:**

The initial dose of Kenacort-A 40 Injection may vary from 5 to 60 mg per day depending on the specific disease entity being treated (see below under Dosage). In situations of less severity, lower doses will generally suffice while in selected patients higher initial doses may be required. Usually the parenteral dosage ranges are one-third to one-half the oral dose given every 12 hours. However, in certain overwhelming, acute, life-threatening situations, administration of dosages exceeding the usual doses may be justified and may be in multiples of the oral dosages.

The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, Kenacort-A 40 Injection should be discontinued and the patient transferred to other appropriate therapy.

*It should be emphasised that dosage requirements are variable and must be individualised on the basis of the disease under treatment and the response of the patient.*

After a favourable response is noted, the proper maintenance dosage should be determined by decreasing the initial dosage in small increments at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to medication dosage.

Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual medication responsiveness, and the effect of patient exposure to stressful situations not directly related to the

disease entity under treatment; in this latter situation it may be necessary to increase the dosage of Kenacort-A 40 Injection for a period of time consistent with the patient's condition.

If after long-term therapy the medication is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

### **Dosage**

*Systemic:* In maintenance therapy, the patient-to-patient response is not uniform and, therefore, the dose must be individualised for optimal control.

For adults and children over 12 years of age, the suggested initial dose is 60mg, injected deeply into the gluteal muscle. Subcutaneous fat atrophy may occur if care is not taken to inject the preparation intramuscularly. Dosage is usually adjusted within the range of 40 to 80 mg, depending upon patient response and duration of relief. However, some patients may be well controlled on dosage as low as 20 mg or less. Patients with hay fever or pollen asthma who are not responding to pollen administration and other conventional therapy may obtain a remission of symptoms lasting throughout the pollen season after one injection of 40 to 100 mg.

For children from 6 to 12 years of age, the suggested initial dose is 40 mg, although dosage depends on the severity of symptoms than on age or weight. There is insufficient clinical experience with Kenacort-A 40 Injection to recommend its use in children under six years of age.

*Local:* For intra-articular or intrasynovial administration and for injection into tendon sheaths, the initial dose of Kenacort-A 40 Injection (Sterile Triamcinolone Acetonide Suspensions USP) may vary from 2.5 to 5 mg for smaller joints and from 5 to 15 mg for larger joints depending on the specific disease entity being treated. (A more dilute form of Sterile Triamcinolone Acetonide Suspension USP is available as Kenacort-A 10). For adults, doses up to 10 mg for smaller areas and up to 40 mg for larger areas have usually been sufficient to alleviate symptoms. Single injections into several joints for multiple locus involvement, up to a total of 80 mg have been given without undue reactions. A single local injection of triamcinolone acetonide is frequently sufficient, but several injections may be needed for adequate relief of symptoms. The lower dosages in the initial dosage range of triamcinolone acetonide may produce the desired effect when the corticosteroid is administered to provide a localised concentration. The site of the injection and the volume of the injection should be carefully considered when triamcinolone acetonide is administered for this purpose.

### **Administration - General:**

#### **STRICT ASEPTIC TECHNIQUE IS MANDATORY**

Shake the vial before use to ensure a uniform suspension. After withdrawal, inject without delay to prevent settling in the syringe. Careful technique should

be employed to avoid the possibility of entering a blood vessel or introducing infection.

Routine laboratory studies, such as urinalysis, two-hour post-prandial blood sugar, determination of blood pressure and body weight and a chest x-ray should be made at regular intervals during prolonged therapy. Upper GI x-rays are desirable in patients with an ulcer history or significant dyspepsia.

### **Systemic:**

For systemic therapy, injection should be made *deeply into the gluteal muscle* to ensure intramuscular delivery (see Warnings and Precautions). For adults, a minimum needle length of 38 mm is recommended. In obese patients, a longer needle may be required. Use alternate sites for subsequent injections.

### **Local:**

For treatment of joints, the usual intra-articular injection technique, as described in standard textbooks, should be followed. If an excessive amount of synovial fluid is present in the joint, some, but not all, should be aspirated to aid in the relief of pain and to prevent undue dilution of the corticosteroid.

With intra-articular or intrasynovial administration, and with injection of the medication into tendon sheaths, the use of a local anaesthetic may often be desirable. When a local anaesthetic is used its package insert should be read with care and all the precautions connected with its use should be observed. The local anaesthetic should be injected into the surrounding soft tissues prior to the injection of the corticosteroid. A small amount of the anaesthetic solution may be instilled into the joint. Care should be taken with intra-articular and intra-synovial injections (particularly in the deltoid region) and with injection into tendon sheaths to avoid injecting the solution into the tissues surrounding the site since this may lead to tissue atrophy.

In treating acute nonspecific tenosynovitis, care should be taken to ensure that the injection of the corticosteroid is made into the tendon sheath rather than the tendon substance. Epicondylitis (tennis elbow) may be treated by infiltrating the preparation into the area of the greatest tenderness.

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## **Contraindications**

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Corticosteroids are contraindicated in patients with systemic infections. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

Kenacort-A 40 is also contraindicated in patients with a sensitivity to the active or inactive ingredients.

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## **Warnings And Precautions**

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Because it is a suspension, the preparation should not be administered intravenously. Strict aseptic technique is mandatory. This preparation is not recommended for children under six years of age.

Unless a deep intramuscular injection is given, local atrophy is likely to occur. (For recommendations on injection techniques, see **Dosage and Administration**). Due to the significantly higher incidence of local atrophy when the material is injected into the deltoid area, this injection site should be avoided in favour of the gluteal area. Only very unusual circumstances would warrant injection into the deltoid area.

When patients who are receiving corticosteroid therapy are subjected to unusual stress, increased dosage of rapidly acting corticosteroids is indicated before, during, and after the stressful situation.

Corticosteroids may mask some signs of infection and new infections may appear during their use. There may be decreased resistance and inability to localise infection when corticosteroids are used. If an infection occurs during corticosteroid therapy it should be promptly controlled by suitable antimicrobial therapy (see Precautions). In addition, patients who are on immunosuppressant drugs including corticosteroids are more susceptible to infections than those not taking these drugs. Moreover, chickenpox and measles can have a more serious or even fatal course in patients on corticosteroids. In such children, or adults receiving corticosteroids who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox or herpes zoster develops, treatment with antiviral agents may be considered. Similarly, corticosteroids should be used with great caution in patients with *Strongyloides* (threadworm) infestation because corticosteroid-induced immunosuppression may lead to *Strongyloides* hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicaemia.

Kenacort-A 10 is a long-acting preparation and is not suitable for use in acute situations. Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when they are used in large doses: dietary salt restriction and potassium supplementation may be necessary (see **Precautions**). All corticosteroids increase calcium excretion.

Patients should not be vaccinated against smallpox while on corticosteroid therapy. Other immunisation procedures should not be undertaken in patients who are on corticosteroids, especially on high dose because of possible hazards of neurological complications and a lack of antibody response. The

use of **triamcinolone acetonide** in patients with active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary since reactivation of the disease may occur. During prolonged corticosteroid therapy these patients should receive chemoprophylaxis.

Because rare instances of anaphylactoid reactions have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any medication.

Adequate studies to demonstrate the safe use of Kenacort-A 40 Injection by intratubinal, subconjunctival, subtenons, retrobulbar and intraocular (intravitreal) injection have not been performed. Endophthalmitis, eye inflammation, increased intraocular pressure and visual disturbances including vision loss have been reported with intravitreal administration. Several instances of blindness have been reported following injection of corticosteroid suspensions into the nasal turbinates and intralesional injection about the head. Administration of Kenacort-A 10 by any of these routes is not recommended.

This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with serious adverse events and death, particularly in pediatric patients. The "gaspings syndrome" has been associated with benzyl alcohol. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gaspings syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity.

### ***Use in Pregnancy:***

Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been done with corticosteroids, the use of these medications in pregnancy, nursing mothers, or women of child-bearing potential requires that the possible benefits of the medication be weighed against the potential hazards to the mother and the embryo, foetus, or nursing infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

### ***Use in Children:***

Because corticosteroids can suppress growth, the development of infants and children on prolonged corticosteroid therapy should be carefully observed. Caution should be used in the event of exposure to chicken pox, measles or other communicable diseases. Children should not be vaccinated or

immunised while on corticosteroid therapy (See WARNINGS). Corticosteroids may also affect endogenous steroid production.

Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol (see WARNINGS).

### **Precautions:**

Medication-induced secondary adrenocortical insufficiency may be minimised by a gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy: therefore, in any situation of stress (such as trauma, surgery or severe illness) occurring during that period, hormone therapy should be reinstated. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced corticosteroid effect in patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition being treated. A gradual reduction in dosage should be made when possible.

Psychic derangements may appear when corticosteroids are used. These may range from euphoria, insomnia, mood swings, personality changes and severe depression to frank psychotic manifestations. Existing emotional instability of psychotic tendencies may also be aggravated by corticosteroids. The use of antidepressant medications does not relieve and may exacerbate adrenocorticoid-induced mental disturbances.

Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinaemia.

Corticosteroids should be used with caution in patients with nonspecific ulcerative colitis if there is a probability of impending perforation, abscess, or other pyogenic infection. Corticosteroids should also be used cautiously in patients with diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, acute glomerulonephritis, vaccinia, varicella, exanthema, Cushing's syndrome, antibiotic-resistant infections, diabetes mellitus, congestive heart failure, chronic nephritis, thromboembolic tendencies, thrombophlebitis, convulsive disorders, metastatic carcinoma and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Although therapy with Kenacort-A 40 may ameliorate symptoms, it is in no sense a cure and the hormone has no effect on the cause of the inflammation. Therefore, this method of treatment does not obviate the need for the conventional measures usually employed.

Intra-articular injection of the suspension into the soft tissues surrounding a joint is not harmful but may lead to the occurrence of systemic effects, and is the most common cause of failure to achieve the desired local results.

Following intra-articular steroid therapy, patients should be specifically warned to avoid overuse of joints in which symptomatic benefit has been obtained. Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid. To detect deterioration, follow up x-ray examination is suggested in selected cases.

Overdistention of the joint capsule and deposition of steroid along the needle track should be avoided in intra-articular injection since this may lead to subcutaneous atrophy.

Corticosteroids should not be injected into unstable joints. Repeated intra-articular injection may in some cases result in instability of the joint. In selected cases, particularly when repeated injections are given, x-ray follow up is suggested.

An increase in joint discomfort has seldom occurred. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of a septic arthritis. If these complications should appear, and the diagnosis of septic arthritis is confirmed, administration of **triamcinolone acetonide** should be stopped and antimicrobial therapy should be instituted immediately and continued for 7 to 10 days after all evidence of infection has disappeared. Appropriate examination of any joint fluid present is necessary to exclude a septic process.

Local injection of a steroid into a previously infected joint is to be avoided. Repeated injection into inflamed tendons has been followed by tendon rupture. Therefore it should also be avoided.

Kenacort-A 40 should be administered only with full knowledge of characteristic activity of, and varied responses to, adrenocortical hormones. Like other potent corticosteroids, **triamcinolone acetonide** should be used under close clinical supervision. **Triamcinolone acetonide** can cause elevation of blood pressure, salt and water retention, and increased potassium and calcium excretion necessitating dietary salt restriction and potassium supplementation. Oedema may occur in the presence of renal disease with a fixed or decreased glomerular filtration rate.

During prolonged therapy *a liberal protein intake is essential* for counteracting the tendency to gradual weight loss sometimes associated with negative nitrogen balance, wasting and weakness of skeletal muscles.

When local or systemic microbial infections are present, therapy with **triamcinolone acetonide** is not recommended, but may be employed with caution and only in conjunction with appropriate antibiotic or chemotherapeutic medication. **Triamcinolone acetonide** may mask signs of infection and enhance dissemination of the infecting organism. Hence, all patients receiving **triamcinolone acetonide** should be watched for evidence of inter-current infection. Should infection occur, vigorous appropriate anti-infective therapy should be initiated. If possible, abrupt cessation of steroids should be avoided because of the danger of superimposing adrenocortical insufficiency on the infectious process.

*Menstrual irregularities* may occur, and this possibility should be mentioned to female patients past menarche.

In peptic ulcer, recurrence may be asymptomatic until perforation or haemorrhage occurs. Long-term adrenocorticoid therapy may evoke hyperacidity or peptic ulcer: therefore, as a prophylactic measure, an ulcer regimen and the administration of an antacid are highly recommended. X-rays should be taken in peptic ulcer patients complaining of gastric distress or when therapy is prolonged. Whether or not changes are observed, an ulcer regimen is recommended.

As with other corticosteroids the possibility of other severe reactions should be considered. If such reactions should occur appropriate corrective measures should be instituted and use of the medication discontinued.

Continued supervision of the patient after termination of **triamcinolone acetonide** therapy is essential since there may be a sudden reappearance of severe manifestations of the disease for which the patient was treated.

**USE IN THE ELDERLY:** The common adverse effects of systemic corticosteroids such as osteoporosis or hypertension may be associated with more serious consequences in old age. Close clinical supervision is recommended.

## **DRUG INTERACTIONS**

*Amphotericin B injection and potassium-depleting agents:* Patients should be observed for hypokalemia

*Anticholinesterases:* Effects of the anticholinesterase agent may be antagonised.

*Anticoagulants, oral:* Corticosteroids may potentiate or decrease anticoagulant action. Patients receiving oral anticoagulants and corticosteroids should be closely monitored.

*Antidiabetics:* Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued, or changed in dosage.

*Antitubercular drugs:* Isoniazid serum concentrations may be decreased.

*Cyclosporine*: Monitor for evidence of increased toxicity of cyclosporine when the two are used concurrently.

*Digitalis glycosides*: Co-administration may enhance the possibility of digitalis toxicity.

*Estrogens, including oral contraceptives*: Corticosteroid half-life and concentration may be increased and clearance decreased.

*Hepatic Enzyme Inducers (eg. Barbiturates, phenytoin, carbamazepine, rifampin)*: There may be increased metabolic clearance of Triamcinolone Acetonide. Patients should be carefully observed for possible diminished effect of steroid, and the dosage of Kenacort A should be adjusted accordingly.

*Human growth hormone (eg. Somatrem)*: The growth-promoting effect of somatrem may be inhibited.

*Ketoconazole*: Corticosteroid clearance may be decreased, resulting in increased effects.

*Nondepolarising muscle relaxants*: Corticosteroids may decrease or enhance the neuromuscular blocking action.

*Nonsteroidal anti-inflammatory agents (NSAIDs)*: Corticosteroids may increase the incidence and/or severity of GI bleeding and ulceration associated with NSAIDs. Also, corticosteroids can reduce serum salicylate levels and therefore decrease their effectiveness. Conversely, discontinuing corticosteroids during high-dose salicylate therapy may result in salicylate toxicity. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinemia.

*Thyroid drugs*: metabolic clearance of adrenocorticoids is increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in adrenocorticoid drugs.

*Vaccines*: Neurological complications and lack of antibody response may occur when patients taking corticosteroids are vaccinated (see WARNINGS).

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## **Adverse Effects**

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### **Following Administration by Any Route:**

Patients should be watched closely for the following adverse reactions which may be associated with any corticosteroid therapy.

### **Fluid and electrolyte disturbances:**

Sodium retention, fluid retention, associated with hypertension or congestive heart failure in susceptible patients, potassium loss, cardiac arrhythmias or ECG changes due to potassium deficiency, hypokalemic alkalosis.

***Musculoskeletal:***

Muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, delayed healing of fractures, aseptic necrosis of femoral and humeral heads, pathologic fractures of long bones and spontaneous fractures.

***Gastrointestinal:***

Peptic ulcer with possible subsequent perforation and haemorrhage, pancreatitis, abdominal distension and ulcerative oesophagitis.

***Dermatological:***

Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lupus erythematosus-like lesions, hives, rash and suppressed reactions to skin tests.

***Neurological:***

Convulsions, increased intracranial pressure with papilloedema (pseudo-tumour cerebri) usually after treatment, vertigo, headache, neuritis or paraesthesias, aggravation of pre-existing psychiatric conditions depression (sometimes severe), euphoria, mood swings, psychotic symptoms and personality changes.

***Endocrine:***

Menstrual irregularities, development of the cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g. trauma, surgery or illness) decreased carbohydrate tolerance, manifestations of latent diabetes mellitus and increased requirements for insulin or oral hypoglycaemic agents in diabetics.

***Ophthalmic:***

Posterior subcapsular cataracts, increased intraocular pressure, glaucoma and exophthalmos.

***Metabolic:***

Hyperglycaemia, glycosuria and negative nitrogen balance due to protein catabolism.

***Others:***

Necrotising angitis, thrombophlebitis, thromboembolism, aggravation or masking of infections, insomnia, syncopal episodes and anaphylactoid reactions.

#### **Following Intra-articular Administration:**

Undesirable reactions have included post injection flare, transient pain, occasional irritation at the injection site, sterile abscess formation, hyperpigmentation and hypopigmentation, charcot-like arthropathy and occasional brief increase in joint discomfort.

#### **Following Intramuscular Administration:**

Severe pain has been reported in a few cases. Sterile abscess formation, subcutaneous and cutaneous atrophy, hyperpigmentation and hypopigmentation and charcot-like arthropathy have also occurred.

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## **Overdose**

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### ***Chronic***

The symptoms of glucocorticoid overdose may include confusion, anxiety, depression, gastrointestinal cramping or bleeding, ecchymosis, moon face and hypertension. After long-term use, rapid withdrawal can result in acute adrenal insufficiency (which also may occur in times of stress). Cushingoid changes can result from continued use of large doses.

### ***Acute***

There is no specific treatment for overdose, but supportive therapy should be instituted and, if gastrointestinal bleeding occurs, it should be managed.

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## **Pharmaceutical Precautions**

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Store below 30°C; avoid freezing. Store upright. Protect from light.

Shelf life: 36 months

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## **Medicine Classification**

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Prescription Medicine.

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## **Package Quantities**

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40 mg/mL 5x1 mL ampoules.

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## **Name and Address**

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Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics  
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NEW ZEALAND

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## **Date of Preparation**

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14 July 2010