Press Release

Hikma launches Triamcinolone Acetonide Injectable Suspension, USP, in the US

London, 5 June 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Triamcinolone Acetonide Injectable Suspension, USP, in a 40mg/mL dose in the US. The product is indicated for various inflammatory, autoimmune, hormonal, and other conditions where a corticosteroid may be used.

According to IQVIA, US sales of Triamcinolone Acetonide Injectable Suspension, USP, 40mg/mL, were approximately $39 million in the 12 months ending February 2025.

Commenting on this launch, Dr Bill Larkins, President of Injectables, said: "We are excited to launch Triamcinolone Acetonide Injection in the US, a complex injectable suspension and the first of its kind in our portfolio. This launch demonstrates our ability to develop and manufacture complex products, and we look forward to continuing to deliver solutions that help improve patient outcomes."

Hikma is a top three supplier of generic injectable medicines by volume in the US[1], with a growing portfolio of more than 170 products. We are continuously expanding our portfolio of essential medicines and introducing new dosage forms that enhance patient care.

- ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/positive Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and

[1] Source: IQVIA MAT February 2025, generic injectable volumes by eaches, excluding branded generics and Becton Dickinson

hikma.

non-branded generic medicines. Together, our 9,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Important Safety Information for Triamcinolone Acetonide Injectable Suspension, USP, 40mg/mL:

Please see package insert for referenced section/section numbering, where appropriate.

CONTRAINDICATIONS

Triamcinolone acetonide injectable suspension is contraindicated in patients who are hypersensitive to any components of this product (see **WARNINGS: General**).
Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

WARNINGS & PRECAUTIONS

- **Serious Neurologic Adverse Reactions with Epidural Administration –** Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.
- **Benzyl Alcohol –** 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.
- **Anaphylaxis –** Rare instances of anaphylaxis have occurred in patients receiving corticosteroid therapy. Cases of serious anaphylaxis, including death, have been reported in individuals receiving triamcinolone acetonide injection, regardless of the route of administration.
- **Local Atrophy –** Because triamcinolone acetonide injectable suspension is a suspension, it should not be administered intravenously. Unless a deep intramuscular injection is given, local atrophy is likely to occur. 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 favor of the gluteal area.
- **Acute Stress Situations –** Increased dosage of rapidly acting corticosteroids is indicated in patients on corticosteroid therapy subjected to any unusual stress before, during, and after the stressful situation. Triamcinolone acetonide injectable suspension is a long-acting preparation, and is not suitable for use in acute stress situations.
- **Traumatic Brain Injury –** Results from one multicenter, randomized, placebo-controlled study with methylprednisolone hemisuccinate, an intravenous corticosteroid, showed an increase in early (at 2 weeks) and late (at 6 months) mortality in patients with cranial trauma who were determined not to have other clear indications for corticosteroid treatment. High doses of systemic corticosteroids, including triamcinolone acetonide injectable suspension, should not be used for the treatment of traumatic brain injury.
- **Cardio-Renal –** Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.
- **Endocrine –** Corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment.
- **Immunosuppression and Increased Risk of Infection –** Corticosteroids, including triamcinolone acetonide, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroid-associated infections can be mild but can be severe and at times fatal.
    - *Tuberculosis:* If triamcinolone acetonide is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of the disease may occur.
    - *Varicella Zoster and Measles Viral Infections:* Varicella and measles can have a serious or even fatal course in non-immune patients receiving corticosteroids, including triamcinolone acetonide.
    - *Hepatitis B Virus Reactivation:* Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including triamcinolone acetonide.
    - *Fungal Infections:* Corticosteroids, including triamcinolone acetonide, may exacerbate systemic

fungal infections; therefore, avoid triamcinolone acetonide use in the presence of such infections unless triamcinolone acetonide is needed to control drug reactions.
    - *Amebiasis:* Corticosteroids, including triamcinolone acetonide, may activate latent amebiasis.
    - *Strongyloides Infestation:* Corticosteroids, including triamcinolone acetonide, should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation.
    - *Cerebral Malaria:* Avoid corticosteroids, including triamcinolone acetonide, in patients with cerebral malaria.
- **Vaccination – Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids.**
- **Neurologic –** Epidural and intrathecal administration of this product is not recommended. Reports of serious medical events, including death, have been associated with epidural and intrathecal routes of corticosteroid administration.
- **Ophthalmic –** 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 bacteria, fungi, or viruses. The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should not be used in active ocular herpes simplex. Intraocular pressure may become elevated in some individuals.
- **Kaposi's Sarcoma –** Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions.
- **General –** This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial. The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual. Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.
- **Cardio-Renal –** As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.
- **Endocrine –** Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage.
- **Gastrointestinal –** Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation. There is an enhanced effect of corticosteroids in patients with cirrhosis.
- **Intra-Articular and Soft Tissue Administration –** Intra-articularly injected corticosteroids may be systemically absorbed. Injection of a steroid into an infected site is to be avoided. Local injection of a steroid into a previously infected joint is not usually recommended. Corticosteroid injection into unstable joints is generally not recommended. Intra-articular injection may result in damage to joint tissues.
- **Musculoskeletal –** Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation and inhibition of osteoblast function. Special consideration should be given to patients at increased risk of osteoporosis (i.e., postmenopausal women) before initiating corticosteroid therapy.
- **Neuro-Psychiatric –** Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that they affect the ultimate outcome or natural history of the disease. An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission, or in patients receiving concomitant therapy with neuromuscular blocking drugs. Psychiatric derangements may appear when corticosteroids are used. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

ADVERSE REACTIONS

The following adverse reactions may be associated with corticosteroid therapy:
Allergic reactions: Anaphylaxis including death, and angioedema.
Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction (see **WARNINGS**), pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.
Dermatologic: Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypo-pigmentation, impaired wound healing, increased sweating, lupus erythematosus-like lesions, purpura, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine: Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, postmenopausal vaginal hemorrhage, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.
Fluid and electrolyte disturbances: Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.
Gastrointestinal: Abdominal distention, bowel/bladder dysfunction (after intrathecal administration [see **WARNINGS: Neurologic**]), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.
Metabolic: Negative nitrogen balance due to protein catabolism.
Musculoskeletal: Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, post injection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.
Neurologic/Psychiatric: Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychiatric disorders, vertigo. Arachnoiditis, meningitis, paraparesis/paraplegia, and sensory disturbances have occurred after intrathecal administration. Spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke (including brainstem) have been reported after epidural administration of corticosteroids (see **WARNINGS: Serious Neurologic Adverse Reactions with Epidural Administration** and **WARNINGS: Neurologic**).
Ophthalmic: Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections.
Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

DRUG INTERACTIONS

Aminoglutethimide: Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression.
Amphotericin B injection and potassium-depleting agents: When corticosteroids are administered concomitantly with potassium-depleting agents (*i.e.,* amphotericin B, diuretics), patients should be observed closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.
Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.
Anticholinesterases: Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy.
Anticoagulants, oral: Coadministration of corticosteroids and warfarin usually results in inhibition of response to warfarin, although there have been some conflicting reports. Therefore, coagulation indices should be monitored frequently to maintain the desired anticoagulant effect.
Antidiabetics: Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.
Antitubercular drugs: Serum concentrations of isoniazid may be decreased.
Cholestyramine: Cholestyramine may increase the clearance of corticosteroids.
Cyclosporine: Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.
CYP3A4 inhibitors: Triamcinolone acetonide is a substrate of CYP3A4. Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects. Co-administration of other strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin, cobicistat-containing products) with triamcinolone acetonide injectable suspension may cause increased plasma concentration of triamcinolone leading to adverse reactions. During postmarketing use, there have been reports of clinically significant drug interactions in patients receiving triamcinolone acetonide and strong CYP3A4 inhibitors (e.g., ritonavir). Consider the benefit-risk of concomitant use and monitor for systemic corticosteroid side effects.
Digitalis glycosides: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.
Estrogens, including oral contraceptives: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.
Hepatic enzyme inducers (e.g., barbiturates, phenytoin, carbamazepine, rifampin): Drugs which induce hepatic

microsomal drug metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.
Nonsteroidal anti-inflammatory drugs (NSAIDs): Concomitant use of aspirin (or other nonsteroidal anti-inflammatory drugs) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.
Skin tests: Corticosteroids may suppress reactions to skin tests.
Vaccines: Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Routine administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible.

USE IN SPECIFIC POPULATIONS

Carcinogenesis, Mutagenesis, Impairment of Fertility
No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis. Steroids may increase or decrease motility and number of spermatozoa in some patients.

Pregnancy
Teratogenic Effects
Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

Pediatric Use
This product contains benzyl alcohol as a preservative. Benzyl alcohol, a component of this product, has been associated with serious adverse events and death, particularly in pediatric patients.

The efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids which is similar in pediatric and adult populations. The adverse effects of corticosteroids in pediatric patients are similar to those in adults.

Geriatric Use
No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

DOSAGE AND ADMINISTRATION

General
The initial dose of triamcinolone acetonide injectable suspension may vary from 2.5 mg to 100 mg per day depending on the specific disease entity being treated. However, in certain overwhelming, acute, life-threatening situations, administration in dosages exceeding the usual dosages may be justified and may be in multiples of the oral dosages.

Dosage
Systemic
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. Dosage is usually adjusted within the range of 40 mg to 80 mg, depending upon patient response and duration of relief. However, some patients may be well controlled on doses as low as 20 mg or less.

Hay fever or pollen asthma: 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 a single injection of 40 mg to 100 mg.

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 160 mg of triamcinolone for a week followed by 64 mg every other day for one month are recommended.

In pediatric patients, the initial dose of triamcinolone may vary depending on the specific disease entity being treated. The range of initial doses is 0.11 mg/kg/day to 1.6 mg/kg/day in 3 or 4 divided doses (3.2 mg/m^{2}bsa/day to 48 mg/m^{2}bsa/day).

Local
Intra-articular administration: A single local injection of triamcinolone acetonide is frequently sufficient, but several injections may be needed for adequate relief of symptoms.

Initial dose: 2.5 mg to 5 mg for smaller joints and from 5 mg to 15 mg for larger joints, depending on the specific disease entity being treated. For adults, doses up to 10 mg for smaller areas and up to 40 mg for larger areas have usually been sufficient. Single injections into several joints, up to a total of 80 mg, have been given.

Administration
General
STRICT ASEPTIC TECHNIQUE IS MANDATORY. The vial should be shaken before use to ensure a uniform suspension. Prior to withdrawal, the suspension should be inspected for clumping or granular appearance (agglomeration). Agglomeration occurs when the drug substance separates from the solution and appears as a white precipitate in the vial. An agglomerated product should be discarded and should not be used. After withdrawal, triamcinolone acetonide injectable suspension should be injected 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.

Systemic
For systemic therapy, injection should be made **deeply into the gluteal muscle**. For adults, a minimum needle length of 1½ inches is recommended. In obese patients, a longer needle may be required. Use alternative sites for subsequent injections.

Local
For treatment of joints, the usual intra-articular injection technique 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 steroid.

With intra-articular administration, prior use of a local anesthetic may often be desirable. Care should be taken with this kind of injection, particularly in the deltoid region, to avoid injecting the suspension 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 may be treated by infiltrating the preparation into the area of greatest tenderness.

OVERDOSAGE

Treatment of acute overdosage is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

INDICATIONS AND USAGE

Intramuscular
Where oral therapy is not feasible, injectable corticosteroid therapy, including triamcinolone acetonide injectable suspension is indicated **for intramuscular use** as follows:
Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions.
Dermatologic diseases: Bullous dermatitis herpetiformis, exfoliative erythroderma,mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).

Endocrine disorders: Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance), congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.
Gastrointestinal diseases: To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis.
Hematologic disorders: Acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, pure red cell aplasia, selected cases of secondary thrombocytopenia.
Miscellaneous: Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy.
Neoplastic diseases: For the palliative management of leukemias and lymphomas.
Nervous system: Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor or craniotomy.
Ophthalmic diseases: Sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.
Renal diseases: To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.
Respiratory diseases: Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.
Rheumatic disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.

Intra-Articular
The intra-articular or soft tissue administration of triamcinolone acetonide injectable suspension is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied
Triamcinolone Acetonide Injectable Suspension, USP is supplied in vials providing 40 mg triamcinolone acetonide per mL and packaged in a carton containing 25 vials.
NDC 0143-9387-01: 40 mg/mL, 1 mL single-dose vial
NDC 0143-9387-25: 40 mg/mL, 25 single-dose vials in 1 carton

Storage
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]; protect from temperatures below 20°C (68°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Store vial in carton to protect from light. Do not refrigerate. Store vial upright.
Once in use: Chemical and physical in-use stability has been demonstrated for 28 days below 25°C (77°F).
From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at 15°C to 25°C (59°F to 77°F). Other in-use storage times and conditions are the responsibility of the user.

ENDING INFORMATION

Patient Information should be shared with the patient prior to administration. For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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