Press Release

Hikma launches Bupivacaine HCl Injection, USP

London, 20 December 2021 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces it launched Bupivacaine HCl Injection, USP through its US affiliate, Hikma Pharmaceuticals USA Inc. The company has launched 0.25%, 0.5% and 0.75% in 10mL and 30mL doses.

Bupivacaine HCl Injection is indicated in adults for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.

According to IQVIA, US sales of Bupivacaine HCl Injection, USP, 0.25%, 0.5% and 0.75% in 10mL an 30mL were approximately $64 million in the 12 months ending October 2021.

Hikma is the second largest US supplier of generic injectable medicines by volume, with a growing portfolio of over 120 products. Today one in every six injectable generic medicines used in US hospitals is a Hikma product.

- ENDS -

Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050
uk-investors@hikma.uk.com

Steve Weiss
David Belian
US Communications and Public Affairs

+1 732 720 2830/ +1 732 788 8279
+1 732 720 2814/+1 848 254 4875
uscommunications@hikma.com

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

Hikma helps put better health within reach every day for millions of people around the world. For more than 40 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 the United States (US), 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 non-branded generic medicines. Together, our 8,600 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

hikma.

Important Safety Information for Bupivacaine HCl Injection, USP, 0.25%, 0.5% and 0.75%:

BOXED WARNING

WARNING: RISK OF CARDIAC ARREST WITH USE OF BUPIVACAINE HYDROCHLORIDE IN OBSTETRICAL ANESTHESIA
There have been reports of cardiac arrest with difficult resuscitation or death during use of Bupivacaine Hydrochloride for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of Bupivacaine Hydrochloride is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary *[see Warnings and Precautions (5.1)].*

CONTRAINDICATIONS

Bupivacaine Hydrochloride injection is contraindicated in:
- Obstetrical paracervical block anesthesia. Its use in this technique has resulted in fetal bradycardia and death.
- Intravenous regional anesthesia (Bier Block) *[see Warnings and Precautions (5.7)]*.
- Patients with a known hypersensitivity to bupivacaine or to any local anesthetic agent of the amide-type or to other components of Bupivacaine Hydrochloride injection.

WARNINGS & PRECAUTIONS

- **Risk of Cardiac Arrest with Use of Bupivacaine Hydrochloride injection in Obstetrical Anesthesia –** There have been reports of cardiac arrest with difficult resuscitation or death during use of Bupivacaine Hydrochloride injection for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. The 0.75% (7.5 mg/mL) concentration of Bupivacaine Hydrochloride injection is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.
- **Dose-Related Toxicity –** Delay in proper management of dose-related toxicity, underventilation from any cause, and/or altered sensitivity may lead to the development of acidosis, cardiac arrest, and, possibly, death. Use the lowest dosage of Bupivacaine Hydrochloride injection that results in effective anesthesia to avoid high plasma levels and serious adverse effects. Avoid rapid injection of a large volume of Bupivacaine Hydrochloride solution and administer fractional (incremental) doses when feasible.
- **Methemoglobinemia –** Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition.
- **Chondrolysis with Intra-Articular Infusion –** Intra-articular infusions of local anesthetics including Bupivacaine Hydrochloride injection following arthroscopic and other surgical procedures is an unapproved use, and there have been post-marketing reports of chondrolysis in patients receiving such infusions.
- **Risk of Cardiac Arrest with Intravenous Regional Anesthesia Use (Bier Block) –** There have been reports of cardiac arrest and death during the use of bupivacaine for intravenous regional anesthesia (Bier Block). Information on safe dosages and techniques of administration of Bupivacaine Hydrochloride injection in this procedure is lacking. Therefore, Bupivacaine Hydrochloride injection is contraindicated for use with this technique.
- **Risk of Systemic Toxicities with Unintended Intravascular or Intrathecal Injection –** Unintended intravascular or intrathecal injection of Bupivacaine Hydrochloride injection may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Unintentional intrathecal injection during the intended performance of caudal or lumbar epidural block or nerve blocks near the vertebral column has resulted in underventilation or apnea.
- **Risk of Toxicity in Patients with Hepatic Impairment –** Because amide local anesthetics such as bupivacaine are metabolized by the liver, consider reduced dosing and increased monitoring for bupivacaine systemic toxicity in patients with moderate to severe hepatic impairment who are treated with Bupivacaine Hydrochloride injection, especially with repeat doses.
- **Risk of Use in Patients with Impaired Cardiovascular Function –** Bupivacaine Hydrochloride injection should be given in reduced doses in patients with impaired cardiovascular function (e.g., hypotension, heartblock)

because they may be less able to compensate for functional changes associated with the prolongation of AV conduction produced by Bupivacaine Hydrochloride injection.

- **Risk of Adverse Reactions with Use in Head and Neck Area –** Small doses of local anesthetics (e.g., Bupivacaine Hydrochloride injection) injected into the head and neck area, including retrobulbar, dental, and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. The injection procedures require the utmost care.
- **Risk of Respiratory Arrest with Use in Ophthalmic Surgery –** Clinicians who perform retrobulbar blocks should be aware that there have been reports of respiratory arrest following local anesthetic injection. A concentration of 0.75% bupivacaine is indicated for retrobulbar block; however, this concentration is not indicated for any other peripheral nerve block, including the facial nerve, and not indicated for local infiltration, including the conjunctiva.
- **Risk of Inadvertent Trauma to Tongue, Lips, and Buccal Mucosa in Dental Applications –** Because of the long duration of anesthesia, when Bupivacaine Hydrochloride injection with epinephrine [0.5% (5 mg/mL) of bupivacaine] is used for dental injections, warn patients about the possibility of inadvertent trauma to tongue, lips, and buccal mucosa and advise them not to chew solid foods until sensation returns.

ADVERSE REACTIONS

The following clinically significant adverse reactions have been reported and described in the Warnings and Precautions section of the labeling:

- Cardiac Arrest in Obstetrical Anesthesia *[see Warnings and Precautions (5.1)]*
- Dose-Related Toxicity *[see Warnings and Precautions (5.2)]*
- Methemoglobinemia *[see Warnings and Precautions (5.3)]*
- Chondrolysis with Intra-Articular Infusion *[see Warnings and Precautions (5.5)]*
- Cardiac Arrest with Intravenous Regional Anesthesia Use *[see Contraindications (4), Warnings and Precautions (5.7)]*
- Systemic Toxicities with Unintended Intravascular or Intrathecal Injection *[see Warnings and Precautions (5.9)]*
- Respiratory Arrest Following Retrobulbar Block *[see Warnings and Precautions (5.15)]*

Adverse reactions to Bupivacaine Hydrochloride injection are characteristic of those associated with other amide-type local anesthetics. A major cause of adverse reactions to this group of drugs is excessive plasma levels, which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation.

The most commonly encountered acute adverse reactions that demand immediate counter-measures were related to the CNS and the cardiovascular system. These adverse reactions were generally dose-related and due to high plasma levels which may have resulted from overdosage, rapid absorption from the injection site, diminished tolerance, or from unintentional intravascular injection of the local anesthetic solution. In addition to systemic dose-related toxicity, unintentional intrathecal injection of drug during the intended performance of caudal or lumbar epidural block or nerve blocks near the vertebral column (especially in the head and neck region) has resulted in underventilation or apnea (“Total or High Spinal”). Also, hypotension due to loss of sympathetic tone and respiratory paralysis or underventilation due to cephalad extension of the motor level of anesthesia have occurred. This has led to secondary cardiac arrest when untreated.

Nervous System Disorders

Adverse reactions were characterized by excitation and/or depression of the central nervous system and included restlessness, anxiety, dizziness, tinnitus, blurred vision, tremors, convulsions, drowsiness, unconsciousness, respiratory arrest, nausea, vomiting, chills, pupillary constriction.

In the practice of caudal or lumbar epidural block, unintentional penetration of the subarachnoid space by the catheter or needle has occurred. Subsequent adverse effects may have depended partially on the amount of drug administered intrathecally and the physiological and physical effects of a dural puncture. A high spinal has been characterized by paralysis of the legs, loss of consciousness, respiratory paralysis, and bradycardia.

Neurologic effects following epidural or caudal anesthesia have included spinal block of varying magnitude (including high or total spinal block); hypotension secondary to spinal block; urinary retention; fecal and urinary incontinence; loss of perineal sensation and sexual function; persistent anesthesia, paresthesia, weakness, paralysis of the lower extremities and loss of sphincter control, all of which had slow, incomplete, or no recovery; headache; backache; septic meningitis; meningismus; slowing of labor; increased incidence of forceps delivery; and cranial nerve palsies due to traction on nerves from loss of cerebrospinal fluid.

Neurologic effects following other procedures or routes of administration have included persistent anesthesia, paresthesia, weakness, paralysis, all with slow, incomplete, or no recovery.

Convulsions: Incidence varied with the procedure used and the total dose administered. In a survey of studies of epidural anesthesia, overt toxicity progressing to convulsions occurred in approximately 0.1% of local anesthetic administrations. The incidences of adverse neurologic reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration, and the physical status of the patient.

Cardiac Disorders
High doses or unintentional intravascular injection have led to high plasma levels and related depression of the myocardium, decreased cardiac output, heartblock, hypotension, bradycardia, ventricular arrhythmias, including ventricular tachycardia and ventricular fibrillation, and cardiac arrest.

Immune System Disorders
Allergic-type reactions have occurred as a result of sensitivity to bupivacaine or to other formulation ingredients, such as the antimicrobial preservative methylparaben contained in multiple-dose vials or sulfites in epinephrine-containing solutions. These reactions were characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and severe hypotension. Cross sensitivity among members of the amide-type local anesthetic group has been reported.

DRUG INTERACTIONS

Refer to package insert for full drug interaction information.

Local Anesthetics
The toxic effects of local anesthetics are additive. If coadministration of other local anesthetics with Bupivacaine Hydrochloride injection cannot be avoided, monitor patients for neurologic and cardiovascular effects related to local anesthetic systemic toxicity.

Drugs Associated with Methemoglobinemia
Patients who are administered Bupivacaine Hydrochloride injection are at increased risk of developing methemoglobinemia when concurrently exposed to following drugs, which could include other local anesthetics. Refer to the table in the package insert for examples of drugs associated with methemoglobinemia.

Potent Inhalation Anesthetics
Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are used in patients during or following the administration of potent inhalation anesthetics.

USE IN SPECIFIC POPULATIONS

Pregnancy
Risk Summary
Bupivacaine Hydrochloride injection is contraindicated for obstetrical paracervical block anesthesia. Its use in this technique has resulted in fetal bradycardia and death.

There are no available data on use of Bupivacaine Hydrochloride injection in pregnant women to inform a drug-associated risk of adverse developmental outcomes.

Local anesthetics rapidly cross the placenta, and when used for epidural, caudal, or pudendal block anesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, inform the patient of the potential hazard to the fetus.

Clinical Considerations
Maternal Adverse Reactions

Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves.

Labor or Delivery
Epidural, caudal, or pudendal anesthesia may alter the forces of parturition through changes in uterine contractility or maternal expulsive efforts. Epidural anesthesia has been reported to prolong the second stage of labor by removing the parturient's reflex urge to bear down or by interfering with motor function. The use of obstetrical anesthesia may increase the need for forceps assistance.

Lactation
Lactation studies have not been conducted with bupivacaine. Bupivacaine has been reported to be excreted in human milk suggesting that the nursing infant could be theoretically exposed to a dose of the drug.

Bupivacaine Hydrochloride injection should be administered to lactating women only if clearly indicated. Studies assessing the effects of Bupivacaine Hydrochloride injection in breastfed children have not been performed. Studies to assess the effect of Bupivacaine Hydrochloride injection on milk production or excretion have not been performed.

Pediatric Use
Bupivacaine Hydrochloride injection is approved for use in adults. Administration of Bupivacaine Hydrochloride injection in pediatric patients younger than 12 years is not recommended.

Continuous infusions of bupivacaine in pediatric patients have been reported to result in high systemic levels of bupivacaine and seizures; high plasma levels may also be associated with cardiovascular abnormalities.

Geriatric Use
Patients 65 years and over, particularly those with hypertension, may be at increased risk for developing hypotension while undergoing anesthesia with Bupivacaine Hydrochloride injection.

In clinical studies of bupivacaine, elderly patients reached the maximal spread of analgesia and maximal motor blockade more rapidly than younger adult patients.

This product is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. Elderly patients may require lower doses of Bupivacaine Hydrochloride injection.

Hepatic Impairment
Amide-type local anesthetics, such as bupivacaine, are metabolized by the liver. Patients with severe hepatic impairment, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations, and potentially local anesthetic systemic toxicity. Therefore, consider reduced dosing and increased monitoring for local anesthetic systemic toxicity in patients with moderate to severe hepatic impairment treated with Bupivacaine Hydrochloride injection, especially with repeat doses.

Renal Impairment
Bupivacaine is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with renal impairment. This should be considered when selecting the Bupivacaine Hydrochloride injection dosage.

DOSAGE AND ADMINISTRATION

Refer to package insert for full dosing and administration information.

Important Dosage and Administration Information
- Bupivacaine Hydrochloride injection is not for intrathecal use.
- Discard unused portions of solution not containing preservatives, i.e., those supplied in single-dose vials, following initial use.
- Visually inspect this product for particulate matter and discoloration prior to administration whenever solution and container permit. Bupivacaine Hydrochloride injection is a clear, colorless solution. Do not administer solutions which are discolored or contain particulate matter.

- Mixing or the prior or intercurrent use of any other local anesthetic with Bupivacaine Hydrochloride is not recommended because of insufficient data on the clinical use of such mixtures.

Administration Precautions

- Bupivacaine Hydrochloride injection is to be administered in carefully adjusted dosages by or under the supervision of experienced clinicians who are well versed in the diagnosis and management of dose-related toxicity and other acute emergencies which might arise from the block to be employed.
- Use Bupivacaine Hydrochloride injection only if the following are immediately available: oxygen, cardiopulmonary resuscitative equipment and drugs, and the personnel resources needed for proper management of toxic reactions and related emergencies.
- The toxic effects of local anesthetics are additive. Monitor for neurologic and cardiovascular effects related to local anesthetic systemic toxicity when additional local anesthetics are administered with Bupivacaine Hydrochloride injection.
- Aspirate for blood or cerebrospinal fluid (where applicable) prior to injecting Bupivacaine Hydrochloride injection, both the initial dose and all subsequent doses, to avoid intravascular or intrathecal injection. However, a negative aspiration for blood or cerebrospinal fluid does not ensure against an intravascular or intrathecal injection.
- Avoid rapid injection of a large volume of Bupivacaine Hydrochloride injection and use fractional (incremental) doses when feasible.
- During major regional nerve blocks, such as those of the brachial plexus or lower extremity, the patient should have an indwelling intravenous catheter to assure adequate intravenous access. The lowest dosage of Bupivacaine Hydrochloride injection that results in effective anesthesia should be used to avoid high plasma levels and serious adverse reactions.
- Perform careful and constant monitoring of cardiovascular and respiratory (adequacy of oxygenation and ventilation) vital signs and the patient's level of consciousness after each local anesthetic injection.

Recommended Concentrations and Dosages of Bupivacaine Hydrochloride injection
The dosage of Bupivacaine Hydrochloride injection administered varies with the anesthetic procedure, the area to be anesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, the depth of anesthesia and degree of muscle relaxation required, the duration of anesthesia desired, individual tolerance, and the physical condition of the patient. Administer the smallest dosage and concentration required to produce the desired result.

The types of block and recommended Bupivacaine Hydrochloride injection concentrations are shown in Table 1 in the package insert.

At recommended dosages, Bupivacaine Hydrochloride injection produces complete sensory block, but the effect on motor function differs among the three concentrations. Table 2 in the package insert provides information on the expected effect on motor function for the three concentrations.

The duration of anesthesia with Bupivacaine Hydrochloride injection is such that for most indications, a single dose is sufficient.

The maximum dosage limit within the recommended dosage range must be individualized in each case after evaluating the size and physical status of the patient, as well as the anticipated rate of systemic absorption from a particular injection site.

The dosages in Table 3 in the package insert are recommended as a guide for use in the average adult. These doses may be repeated once every three hours. Do not exceed a total daily dosage of 400 mg in 24 hours. The duration of anesthetic effect may be prolonged by the addition of epinephrine.

Use in Epidural Anesthesia
During epidural administration, administer Bupivacaine Hydrochloride injection, 0.5% (5 mg/mL) and 0.75% (7.5 mg/mL) solutions in incremental doses of 3 mL to 5 mL with sufficient time between doses to detect toxic manifestations of unintentional intravascular or intrathecal injection. Administer injections slowly, with frequent aspirations before and during the injection to avoid intravascular injection. Perform syringe aspirations before and during each supplemental injection in continuous (intermittent) catheter techniques. In obstetrics, use ONLY the 0.5% (5 mg/mL) and 0.25% (2.5 mg/mL) concentrations of Bupivacaine Hydrochloride injection; incremental doses of 3 mL to 5 mL of the 0.5% (5 mg/mL) solution not exceeding 50 mg to 100 mg at any dosing interval are recommended. Repeat doses should be preceded by a test dose containing epinephrine if not clinically

contraindicated. Use only the single-dose vials for caudal or epidural anesthesia; avoid use of the multiple-dose vials for these procedures, which contain a preservative.

Use in Ophthalmic Surgery
When Bupivacaine Hydrochloride injection 0.75% (7.5 mg/mL) is used for retrobulbar block, complete corneal anesthesia usually precedes onset of clinically acceptable external ocular muscle akinesia. Therefore, presence of akinesia rather than anesthesia alone should determine readiness of the patient for surgery.

OVERDOSAGE

Clinical Presentation
Acute emergencies from use of Bupivacaine Hydrochloride injection are generally related to high plasma levels encountered during therapeutic use or to unintended intrathecal injection.

If not treated immediately, convulsions with simultaneous hypoxia, hypercarbia, and acidosis plus myocardial depression from the direct effects of bupivacaine may result in cardiac arrhythmias, bradycardia, asystole, ventricular fibrillation, or cardiac arrest. Respiratory abnormalities, including apnea, may occur.

Hypoventilation or apnea due to unintentional intrathecal injection of Bupivacaine Hydrochloride injection may produce these same signs and also lead to cardiac arrest if ventilatory support is not instituted. If cardiac arrest should occur, successful outcome may require prolonged resuscitative efforts.

Management
The first step in the management of systemic toxic reactions, as well as hypoventilation or apnea due to unintentional intrathecal injection of Bupivacaine Hydrochloride injection, consists of immediate attention to the establishment and maintenance of a patent airway and effective assisted or controlled ventilation with 100% oxygen with a delivery system capable of permitting immediate positive airway pressure by mask. Endotracheal intubation, using drugs and techniques familiar to the clinician, may be indicated after initial administration of oxygen by mask if difficulty is encountered in the maintenance of a patent airway, or if prolonged ventilatory support (assisted or controlled) is indicated.

If necessary, use drugs to manage the convulsions. A bolus intravenous dose of a benzodiazepine will counteract CNS stimulation related to Bupivacaine Hydrochloride injection. Immediately after the institution of ventilatory measures, evaluate the adequacy of the circulation. Supportive treatment of circulatory depression may require Advance Cardiac Life Support measures.

INDICATIONS AND USAGE

Bupivacaine Hydrochloride injection is indicated in adults for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. Specific concentrations and presentations of Bupivacaine Hydrochloride injection are recommended for each type of block indicated to produce local or regional anesthesia or analgesia.

Limitations of Use
Not all blocks are indicated for use with Bupivacaine Hydrochloride injection given clinically significant risks associated with use.

HOW SUPPLIED/STORAGE AND HANDLING

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]

Bupivacaine hydrochloride injection, USP —Solutions of bupivacaine hydrochloride injection, USP may be autoclaved. Autoclave at 15-pound pressure, 121°C (250°F) for 15 minutes. Protect from light. This product is clear and colorless. Do not use the solution if it is discolored or if it contains a precipitate.

NDC No.	Container	Fill	Quantity
	0.25% – Contains 2.5 mg bupivacaine hydrochloride per mL.		

0143-9330-10	Single Dose Vial	10 mL	Cartons of 10
0143-9333-10	Single Dose Vial	30 mL	Cartons of 10
	0.5% – Contains 5 mg bupivacaine hydrochloride per mL.		
0143-9331-10	Single Dose Vial	10 mL	Cartons of 10
0143-9334-10	Single Dose Vial	30 mL	Cartons of 10
	0.75% – Contains 7.5 mg bupivacaine hydrochloride per mL.		
0143-9332-10	Single Dose Vial	10 mL	Cartons of 10
0143-9335-10	Single Dose Vial	30 mL	Cartons of 10

For single-dose vials: Discard unused portion.

ENDING INFORMATION

Patient Counseling 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.

Manufactured by:
HIKMA FARMACÊUTICA (PORTUGAL), S.A.
Estrada do Rio da MÒ, no 8, 8A e 8B - Fervenca, 2705 - 906 Terrugem SNT, PORTUGAL

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