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Press Release

Hikma launches Dicyclomine Hydrochloride Oral Solution

Receives first Competitive Generic Therapy Exclusivity from FDA

London, May 28, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational generic pharmaceutical company, has launched Dicyclomine Hydrochloride Oral Solution, USP, 10 mg/5 mL, an AA-rated version of Bentyl®[1] Oral Syrup, 10 mg/5 mL in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.

Hikma's Dicyclomine Hydrochloride Oral Solution USP was approved with a Competitive Generic Therapy (CGT) designation from the US Food and Drug Administration. Hikma is the "first approved applicant" for this CGT and therefore is eligible for 180 days of CGT exclusivity which began upon commercial marketing of Hikma's product.

Dicyclomine Hydrochloride Oral Solution is indicated for the treatment of patients with functional bowel/irritable bowel syndrome.

According to IQVIA, US sales of Dicyclomine Hydrochloride Oral Solution USP, 10 mg/5 mL were approximately $3 million in the 12 months ending March 2020.

- ENDS -

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P)

Hikma helps put better health within reach every day for millions of people in more than 50 countries 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

[1] Bentyl® is a registered trademark of Aptalis Pharma Canada ULC.

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

Important Safety Information for Dicyclomine Hydrochloride Oral Solution, USP, 10 mg/5 mL:

CONTRAINDICATIONS
Dicyclomine hydrochloride is contraindicated in infants less than 6 months of age, nursing mothers and in patients with:

- Unstable cardiovascular status in acute hemorrhage
- Myasthenia gravis
- Glaucoma
- Obstructive uropathy
- Obstructive disease of the gastrointestinal tract
- Severe ulcerative colitis
- Reflux esophagitis

WARNINGS AND PRECAUTIONS

Cardiovascular Conditions
Use dicyclomine hydrochloride with caution in patients with conditions characterized by tachyarrhythmia such as thyrotoxicosis, congestive heart failure and in cardiac surgery, where they may further accelerate the heart rate. Investigate any tachycardia before administration of dicyclomine hydrochloride. Care is required in patients with coronary heart disease, as ischemia and infarction may be worsened, and in patients with hypertension.

Peripheral and Central Nervous System (CNS)
Peripheral effects of dicyclomine hydrochloride include dryness of the mouth with difficulty in swallowing and talking, thirst, reduced bronchial secretions, dilatation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhythmias, and difficulty in micturition, as well as reduction in the tone and motility of the gastrointestinal tract leading to constipation.

In the presence of high environmental temperature, heat prostration can occur with drug use. Use with caution in patients with fever. If symptoms occur, the drug should be discontinued and supportive measures instituted. Use with caution in patients with autonomic neuropathy.

CNS signs and symptoms include confusion, disorientation, short-term amnesia, hallucinations, dysarthria, ataxia, coma, euphoria, fatigue, insomnia, agitation and mannerisms and inappropriate affect. Psychosis has been reported in sensitive individuals given anticholinergic drugs.

Dicyclomine hydrochloride may produce drowsiness, dizziness or blurred vision. Warn the patient not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking dicyclomine hydrochloride.

Myasthenia Gravis
With overdosage, a curare-like action may occur. Do not give dicyclomine hydrochloride to patients with myasthenia gravis except to reduce adverse muscarinic effects of an anticholinesterase.

Intestinal Obstruction

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful.

Rarely, development of Ogilvie's Syndrome has been reported.

Toxic Dilatation of Intestinemegacolon
Toxic dilatation of intestine and intestinal perforation is possible when anticholinergic agents are administered in patients with Salmonella dysentery.

Ulcerative Colitis
Use with caution in patients with ulcerative colitis. Large doses may suppress intestinal motility to the point of producing a paralytic ileus and the use of this drug may precipitate or aggravate the serious complication of toxic megacolon. Contraindicated in patients with severe ulcerative colitis.

Prostatic Hypertrophy
Use with caution in patients with known or suspected prostatic enlargement.

Hepatic and Renal Disease
Use with caution in patients with known hepatic and renal impairment.

Geriatric Population
Use with caution in elderly patients who may be more susceptible to its adverse effects.

ADVERSE REACTIONS
The pattern of adverse effects seen with dicyclomine hydrochloride is dose-related and usually reversible when treatment is discontinued.

The most serious adverse reactions reported include cardiovascular and CNS symptoms.

DRUG INTERACTIONS

Antiglaucoma Agents
Anticholinergics antagonize the effects of antiglaucoma agents. Anticholinergic drugs in the presence of increased intraocular pressure may be hazardous when taken concurrently with agents such as corticosteroids. Use of dicyclomine hydrochloride in patients with glaucoma is not recommended.

Other Drugs With Anticholinergic Activity
Amantadine, antiarrhythmic agents of Class I, antihistamines, antipsychotic agents, benzodiazepines, MAO inhibitors, narcotic analgesics, nitrates and nitrites, sympathomimetic agents, tricyclic antidepressants and other drugs having anticholinergic activity may increase certain actions or side effects of anticholinergic drugs, including dicyclomine hydrochloride.

Other Gastrointestinal Motility Drugs
Interaction with other gastrointestinal motility drugs may antagonize the effects of drugs that alter gastrointestinal motility.

Effect of Antacids
Simultaneous use of dicyclomine hydrochloride and antacids should be avoided.

Effect of Absorption of Other Drugs
Anticholinergic agents may affect gastrointestinal absorption of various drugs by affecting gastrointestinal motility, such as slowly dissolving dosage forms of digoxin; increased serum digoxin concentration may result.

Effect on Gastric Acid Secretion
The inhibiting effects of anticholinergic drugs on gastric hydrochloric acid secretion are antagonized by agents used to treat achlorhydria and those used to test gastric secretion.

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category B
Adequate and well-controlled studies have not been conducted with dicyclomine hydrochloride in pregnant women at the recommended doses of 80 to 160 mg/day. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers
Dicyclomine hydrochloride is contraindicated in women who are breastfeeding.

Pediatric Use
Dicyclomine hydrochloride is contraindicated in infants younger than 6 months of age. Safety and effectiveness in other pediatric patients have not been established.

Geriatric Use
Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range in adults, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy.

Because elderly patients are more likely to have decreased renal function, care should be taken to determine the appropriate dose. Renal function should be monitored.

Patients with Renal Impairment
Effects of renal impairment on pharmacokinetics (PK), safety and efficacy of dicyclomine hydrochloride have not been studied. However, dicyclomine hydrochloride is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Administer with caution in these patients.

Patients with Hepatic Impairment
Effects of renal impairment on PK, safety and efficacy of dicyclomine hydrochloride have not been studied. Administer with caution in patients with hepatic impairment.

DOSAGE AND ADMINISTRATION
Dosage must be adjusted to individual patient needs. If efficacy is not achieved within 2 weeks or side effects require doses below 80 mg/day, the drug should be discontinued. Documented safety data are not available for doses above 80 mg/day for periods longer than 2 weeks.

For more information, please see the full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/medwatch or call 1-800-FDA-1088.

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