

Hikma launches Indomethacin Suppositories in the US

London, 20 December 2024 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Indomethacin Suppositories, in a 50mg dose, in the US. Hikma is the second generic on the market and we are pleased to expand our portfolio with this launch, broadening the choice of medicines available to doctors and patients in the US. The product is indicated for:

- Moderate to severe rheumatoid arthritis including acute flares of chronic disease
- Moderate to severe ankylosing spondylitis
- Moderate to severe osteoarthritis
- Acute painful shoulder (bursitis and/or tendinitis)
- Acute gouty arthritis

According to IQVIA, US sales of Indomethacin Suppositories, 50mg, were approximately \$57 million in the 12 months ending October 2024.

Hikma supplies a broad range of non-injectable products to the US market, and has expertise in complex technologies, such as nasal sprays, where we are one of the largest suppliers in the US. Supporting our portfolio, we have a state-of-the-art manufacturing facility in Columbus, Ohio.

- 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.

Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050

Steven Weiss
US Communications

+1 732 788 8279

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 non-branded generic medicines. Together, our 9,100 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 Indomethacin Suppositories 50mg, for rectal use

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.**
- **Indomethacin is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**

Gastrointestinal Bleeding, Ulceration and Perforation

- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

CONTRAINDICATIONS

Do not use Indomethacin Suppositories:

- If you are allergic to indomethacin.
- If you have had an asthma attack, hives or other allergic reaction with aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs).
- Right before or after heart surgery called a coronary artery bypass graft (CABG).
- If you have inflammation inside your rectum or recent rectal bleeding.

WARNINGS AND PRECAUTIONS

Indomethacin is a type of medicine called a nonsteroidal anti-inflammatory drug (NSAID). NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.**

This risk may happen early in treatment and may increase with increasing doses of NSAIDs and with longer use of NSAIDs. Do not take NSAIDs right before or after a CABG. Avoid taking NSAIDs after a recent heart attack, unless your doctor tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines.**

This risk may happen anytime during use, without warning symptoms and could cause death. The risk of getting an ulcer or bleeding increases with past history of stomach ulcers or stomach or intestinal bleeding with the use of NSAIDs; taking certain medicines, including corticosteroids, anticoagulants, selective serotonin reuptake inhibitors (SSRIs) or serotonin and norepinephrine reuptake inhibitors (SNRIs); increasing doses of NSAIDs; longer use of NSAIDs; smoking; drinking alcohol; older age; poor health; advanced liver disease and bleeding problems. NSAIDs should only be used exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed.

Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you have liver or kidney problems, high blood pressure or asthma. You should also tell your doctor if you are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare



provider may need to monitor the amount of fluid in your womb around your baby. **You should not take NSAIDs after about 30 weeks of pregnancy.**

Tell your doctor if you are breastfeeding. If you are taking indomethacin, it may be present in your breast milk.

Small studies in women treated with NSAIDs have shown a reversible delay in ovulation.

Using Indomethacin Suppositories with other NSAIDs or aspirin is not recommended. It is important to note that NSAIDs may be present in “over the counter” medications for treatment of colds, fever or insomnia.

Safety and effectiveness in patients ≤ 14 years have not been established.

Elderly patients are at greater risk for certain serious NSAID-associated side effects than younger patients.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

SIDE EFFECTS

Possible side effects of NSAIDs include new or worse high blood pressure, heart failure, liver problems (including liver failure), kidney problems (including kidney failure), low red blood cells (anemia), life-threatening skin reactions, life-threatening allergic reactions, stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.

Get emergency help right away if you have any of the following symptoms: shortness of breath or trouble breathing, chest pain, weakness in one part or side of your body, slurred speech or swelling of the face or throat.

Stop taking your NSAID and call your healthcare provider right away if you have any of the following symptoms: nausea, more tired or weaker than usual, diarrhea, itching, your skin or eyes look yellow, indigestion or stomach pain, flu-like symptoms, vomiting blood, blood in bowel movement (or dark, tarry stools), unusual weight gain, skin rash or blisters with fever or swelling of the arms, hands, legs and feet.

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs. Call your doctor for medical advice about side effects.

For more information, please see the [Full Prescribing Information](#) for Indomethacin Suppositories.

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.

Manufactured by: Bliss GVS Pharma Limited; Dewan Udyog Nagar; Aliyali Village, Palghar; Maharashtra 401404, India (IND)

Distributed by: Hikma Pharmaceuticals USA Inc.; Berkeley Heights, NJ 07922

Document Identification Number: HK-3203-v1