Slayback Pharma announces FDA approval of Hydroxyprogesterone Caproate Injection, USP 1,250 mg/ 5 mL in a multi-dose vial, the first generic equivalent of Makena® Injection 1,250 mg/ 5 mL multi-dose vial

NEWS PROVIDED BY
Slayback Pharma LLC →
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PRINCETON, N.J., Jan. 2, 2019 /PRNewswire/ -- Slayback Pharma LLC announced today that the U.S. Food and Drug Administration ("FDA") granted approval of its abbreviated new drug application ("ANDA") for Hydroxyprogesterone Caproate Injection, USP 1,250 mg/ 5 ml. This is the first and only ANDA approved by the FDA for Hydroxyprogesterone Caproate Injection in a multi-dose vial. Slayback will commence the commercial launch of this product under its own label shortly.

Ajay Singh, CEO of Slayback Pharma, said: "Slayback's journey has had a singular focus - to develop specialty products, including generics, that are complex; otherwise difficult to develop and/or present other barriers to entry. For many such products, affordable generic options do not exist today because of the inherent technical barriers to entry. Today's approval is a significant milestone in our journey. We are thrilled and honored to have the opportunity to launch the first approved ANDA for such an important product. Slayback is looking forward to a series of approvals for generics that are difficult to develop or provide barriers to entry."

Slayback Pharma's Hydroxyprogesterone Caproate Injection, USP 1,250 mg/ 5 ml was determined by the FDA to be therapeutically equivalent to Makena® (Hydroxyprogesterone Caproate 1,250 mg/ 5 ml) sold in the United States by AMAG Pharmaceuticals, Inc. Hydroxyprogesterone Caproate Injection, USP is available in a 250 mg/ ml, 5 ml multi-dose vial and can be ordered through your wholesaler/distributor. Please contact our customer service team at 1-844-566-2505.

See the following important safety information and refer to the Package Insert for full prescribing information.

Indication

Hydroxyprogesterone caproate (HPC) is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of HPC is based on improvement in the proportion of women who delivered <37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of HPC has been demonstrated only in women with a prior spontaneous singleton preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

Important Safety Information for Hydroxyprogesterone Caproate Injection (HPC)

HPC should not be used in women who have or have had any of the following conditions:

- blood clots or blood clotting problems,
- breast cancer, suspected breast cancer or other hormone-sensitive cancers, or history of these conditions;
- unusual vaginal bleeding not related to your current pregnancy,
- yellowing of the skin due to liver problems during pregnancy,
- liver problems, including liver tumors,
- uncontrolled high blood pressure.

Before you take HPC, tell your healthcare provider about all your medical conditions, including if you have:

- an allergy to HPC, castor oil, or any of the other ingredients in HPC;
- diabetes or prediabetes,
- problems retaining water such as epilepsy, migraine headaches, asthma, heart or kidney problems,
- depression,
- yellowing of the skin or whites of your eyes,
- or high blood pressure.

If any of these medical conditions occur while you are taking HPC, check with your doctor to see if you should continue using it.

Possible side effects: In a clinical study, some complications or new medical conditions associated with pregnancy occurred more often in women who received HPC. These included miscarriage (pregnancy loss), stillbirth (fetal death), hospital admission for preterm labor, preeclampsia (high blood pressure and too much protein in the urine), gestational hypertension (high blood pressure caused by pregnancy), gestational diabetes (diabetes occurring during pregnancy), and oligohydramnios (low amniotic fluid levels).

Two serious side effects were reported in study patients: one developed a pulmonary embolus (blood clot in her lung), and the other developed cellulitis (injection site infection of the skin). HPC may also cause other serious side effects including blood clots, allergic reactions, depression, and yellowing of your skin and the whites of your eyes.

The most common side effects of HPC include hives, itching, nausea, and diarrhea, and injection site reactions (pain, swelling, itching, and development of a hard lump).

You may report an adverse event related to Hydroxyprogesterone Caproate made by Slayback Pharma by calling 1-844-566-2505 or emailing medical@slayback-pharma.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly at fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for Hydroxyprogesterone Caproate Injection (HPC).

References:

Hydroxyprogesterone Caproate Injection prescribing information. Slayback Pharma, 11/2018.

Makena® is a registered trademark of AMAG Pharmaceuticals, Inc.

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