

## Uniprogestin

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

Abbreviated Prescribing information for **Uniprogestin** (Hydroxyprogesterone Injection IP)  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### **PHARMACOLOGICAL PROPERTIES:**

Hydroxyprogesterone caproate is a synthetic progestin. The mechanism by which hydroxyprogesterone caproate reduces the risk of recurrent preterm birth is not known. Hydroxyprogesterone caproate is an ester of the naturally occurring hydroxyprogesterone and possesses progesterone-like progestogenic effects such as antigonadotropic effects, the secretory transformation of the endometrium and thickening of the cervical mucus. The transformation of the endometrium facilitates the implantation of a fertilized ovum and creates favorable conditions for the maintenance of any pregnancy.

### **INDICATIONS:**

Uniprogestin 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.

- To prevent premature birth and threatened abortion

**DOSAGE AND ADMINISTRATION:** Dosage: As directed by the Physician.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients listed

**WARNINGS & PRECAUTION: Thromboembolic Disorders:** Discontinue Uniprogestin if an arterial or deep venous thrombotic or thromboembolic event occurs. **Allergic Reactions:** Allergic reactions, including urticaria, pruritus and angioedema, have been reported with use of Uniprogestin or with other products containing castor oil. Consider discontinuing the drug if such reactions occur. **Decrease in Glucose Tolerance:** A decrease in glucose tolerance has been observed in some patients on progestin treatment **Fluid Retention, Depression, Jaundice, Hypertension**

**DRUG INTERACTIONS:** Reported In vitro drug-drug interaction studies were conducted with Hydroxyprogesterone caproate. Hydroxyprogesterone caproate has minimal potential for CYP1A2, CYP2A6, and CYP2B6 related drug-drug interactions at the clinically relevant concentrations. In vitro data indicated that therapeutic concentration of hydroxyprogesterone caproate is not likely to inhibit the activity of CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4. The need for oral antidiabetics or insulin may change.

**ADVERSE REACTIONS:** Precaution). The following adverse reactions have been identified following use of hydroxyprogesterone caproate. Body as a whole: Local injection site reactions (including erythema, urticaria, rash, irritation, hypersensitivity, warmth); fatigue; fever; hot flashes/flushes Page 5 of 11 • Digestive disorders: Vomiting • Infections: Urinary tract infection • Nervous system disorders: Headache, dizziness • Pregnancy, puerperium and perinatal conditions: Cervical incompetence, premature rupture of membranes • Reproductive system and breast disorders: Cervical dilation, shortened cervix • Respiratory disorders: Dyspnea, chest discomfort • Skin: Rash

**MARKETED BY:**



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IN/ Uniprogestin 250mg, 500 mg/NOV-19/01/AbPI

(Additional information is available on request)