Makena (hydroxyprogesterone caproate) is a Progestin (Infertility Drug).

**Pre-Authorization Criteria:**

VCHCP will authorize Makena (Hydroxyprogesterone Caproate) for FDA indicated treatment to reduce the risk of preterm birth in women with singleton pregnancies who have a history of spontaneous preterm birth (delivery <37 weeks gestation) with previous singleton pregnancies.

VCHCP requires that Makena be prescribed by an Infertility Specialist.

**Dosing: Adult**

*To reduce the risk of preterm birth:* Pregnant females ≥16 years: I.M.: 250 mg once weekly (every 7 days). Treatment may begin between 16 weeks 0 days and 20 weeks 6 days of gestation. Continue weekly administration until 37 weeks gestation or until delivery, whichever comes first.

**Dosage Forms: U.S.**

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Injection, solution:
Makena™: 250 mg/mL (5 mL) [contains benzyl alcohol, benzyl benzoate, castor oil]

**Administration**

For I.M. administration into the upper outer quadrant of the gluteus maximus. Withdraw dose using an 18 gauge needle; inject dose using a 21 gauge 1 1/2 inch needle. Administer by slow injection (≥1 minute). Solution is viscous and oily; do not use if solution is cloudy or contains solid particles. Apply pressure to injection site to decrease bruising and swelling.

**WARNINGS / PRECAUTIONS**

*Concerns related to adverse effects:*

- Thromboembolism: Discontinue if arterial thrombosis, DVT, or thromboembolic events occur. Use is contraindicated with current or history of thrombosis or thromboembolic disorders.

*Disease-related concerns:*

- Carbohydrate intolerance: May have adverse effects on glucose tolerance; use caution in women with diabetes.

- Depression: Use with caution in patients with depression; discontinue if depression occurs.

- Diseases exacerbated by fluid retention: Use with caution in patients with diseases which may be exacerbated by fluid retention, including asthma, epilepsy, migraine, diabetes, pre-eclampsia, cardiac or renal dysfunction.

- Hepatic impairment: Specific studies have not been conducted; elimination may be decreased. Use is contraindicated with hepatic impairment.

- Hypertension: Monitor women who develop hypertension during therapy; consider risk versus benefit of continuation. Use is contraindicated with uncontrolled hypertension.
• Jaundice: Monitor women who develop jaundice during therapy; consider risk vs benefit of continuation. Use is contraindicated in women with cholestatic jaundice of pregnancy.

**DRUG Interactions**

(For additional information: Launch Lexi-Interact™ Drug Interactions Program )

Aminoglutethimide: May increase the metabolism of Progestins. Management: Progestin-containing contraceptives are not recommended; consider the use of alternative, nonhormonal contraceptives. *Risk D: Consider therapy modification*

Conivaptan: May increase the serum concentration of CYP3A4 Substrates. *Risk X: Avoid combination*

CYP2A6 Substrates: CYP2A6 Inducers (Strong) may increase the metabolism of CYP2A6 Substrates. *Risk C: Monitor therapy*

CYP3A4 Inducers (Strong): May increase the metabolism of CYP3A4 Substrates. *Risk C: Monitor therapy*

CYP3A4 Inhibitors (Moderate): May decrease the metabolism of CYP3A4 Substrates. *Risk C: Monitor therapy*

CYP3A4 Inhibitors (Strong): May decrease the metabolism of CYP3A4 Substrates. *Risk D: Consider therapy modification*

Dasatinib: May increase the serum concentration of CYP3A4 Substrates. *Risk C: Monitor therapy*

Deferasirox: May decrease the serum concentration of CYP3A4 Substrates. *Risk C: Monitor therapy*

Herbs (CYP3A4 Inducers): May increase the metabolism of CYP3A4 Substrates. *Risk C: Monitor therapy*

Herbs (Progestogenic Properties) (eg, Bloodroot, Yucca): May enhance the adverse/toxic effect of Progestins. *Risk C: Monitor therapy*
Tocilizumab: May decrease the serum concentration of CYP3A4 Substrates. *Risk C: Monitor therapy*

**REFERENCES**


Select Drug Information from **Lexi-Comp Online™**
Copyright (1978 to present) Lexi-Comp, Inc.

Epocrates 2013-www.epocrates.com

©2013 UpToDate® - www.uptodate.com

**Revision History:**
Date Reviewed/No Updates: 1.16.13 by A. Reeves MD
Date Approved by P&T Committee: 01.31.12 ; 1.29.13
Date Reviewed/No Updates: 01.28.14 by C. Sanders MD
Date Approved by P&T Committee: 01.28.14
Date Reviewed/No Updates: 01.13.15 by C. Sanders, MD
Date Approved by P&T Committee: 01.27.15
Date Reviewed/No Updates: 01.26.16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.26.16
Date Reviewed/No Updates: 01.24.17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.24.17

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Content Revised (Yes/No)</th>
<th>Contributors</th>
<th>Review/Revision Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/17</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

S:\2017\DRUGS POLICIES\VCHCP