



Specialty Medicine Compounding Pharmacy

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17 α -Hydroxyprogesterone (17HP) and its Use in Premature Births

Cholesterol is the basic building block of steroids produced in the body. All naturally occurring steroids are made from it including testosterone, estrogen(s), and progesterone. 17HP is a steroid that is naturally produced in the body and is in a subclass of steroids called progestins. It is derived directly from progesterone and is converted in further steps to cortisol, testosterone, estradiol and other steroids.

17HP was originally approved by the FDA for treatment of certain types of uterine cancer and amenorrhea or lack of menstruation.¹ The FDA shut down the production of the drug in 1999. The reason for this was not because of side effects of the drug or lack of efficacy, but because of poor manufacturing process and documentation². Although 17HP has never been approved by the FDA for preventing premature births, it has been

studied in controlled trials and used for that purpose. In the mid-1970's studies were conducted with pregnant women at high risk for premature births. One minor study by Johnson et al published in the New England Journal of Medicine in 1975 showed a significant difference between placebo and active drug in preventing premature birth. The study had a small sample size, but the results were so significant that no major studies were done for a long time because it would be unethical to give someone a placebo when the active drug is known to work.

After 17HP was taken off the market in 1999 a large scale placebo vs. active drug trial was done with 463 pregnant women. The results were published in the New England Journal of Medicine in 2003 showing a clinically effective treatment. There was a decreased difference of

18.6% comparing placebo vs. active drug of premature births.³

When news of this spread the demand for the drug increased and compounding pharmacies have filled the void by making 17HP injections. 17HP is a drug that has been on the market, it is naturally occurring in the body and the dosage for premature birth is much lower than the levels that are produced during pregnancy.¹ Because it is made in the body already and the dosage is much lower than what occurs during pregnancy side effects are low. Possibly side effects are more due to the preparation and occur at the injection site including rash and swelling.

17HP is only indicated and has only been shown effective in patients with high risk for premature delivery. Whether or not you are at high risk and if this is a viable treatment

option for you should be discussed with your doctor.

REFERENCES

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2. *Prevention of Preterm Delivery with Compounded 17 α -Hydroxyprogesterone Caproate*. Reed-Kane, Dana. Kirshbaum, Karen. International Journal of Pharmaceutical Compounding. Vol 10, No. 3 May/June 2006.
3. *Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate*. Meis, Paul J. Kelbanoff, Mark. Thom, Elizabeth. et al. The New England Journal of Medicine. Vol 348, No. 24 June 12, 2003.

Specialty Medicine Compounding Pharmacy

The demands of modern compounding have led to the creation of pharmacies devoted solely to this art. **Specialty Medicine Compounding Pharmacy** has been serving your community for over six years. Here we specialize in bio-identical

hormone replacement therapies and veterinary medicine, to name a few. We have all the facilities and equipment needed to make anything from topicals to capsules and sterile injectables. We do not accept insurance, but do provide claim

forms with prescriptions we fill. So, next time a patient wants a compound you're unsure of - we'd be happy to serve them!



Kenny Walkup, RPh has attended training classes through the American Pharmaceutical Association to give flu shots. Specialty Medicine is a Medicare provider and biller for flu shots for Medicare recipients.