DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
The absolute bioavailability of micronized progesterone is increased through micronization. Progesterone Capsules are an oral dosage form of micronized progesterone.

CLINICAL PHARMACOLOGY

Progesterone is synthesized from a starting material from a plant source. The chemical formula is:

C_{21}H_{30}O_5

It is soluble in water, sparingly soluble in alcohol, acetone and dioxane and practically insoluble in ether.

PROBABLE DEMENTIA FOR ESTROGEN PLUS PROGESTIN THERAPY

Estrogens (CE) [0.625 mg] combined with medroxyprogesterone acetate (MPA) [2.5 mg] have been used in combination with estrogen alone for the prevention of osteoporosis. Several preclinical studies suggested that combination therapy may have favorable effects on the immune system and be protective against neurodegenerative disorders.

The Women's Health Initiative Memory Study (WHIMS) was a randomized, placebo-controlled, double-blind, multinational, multiyear clinical trial designed to evaluate the efficacy and safety of estrogen plus progestin therapy for the prevention of osteoporosis and the treatment of climacteric symptoms in postmenopausal women. The trial was designed to enroll 10,000 women 65 to 79 years old, with an enrollment target of 4,000 women in the active treatment group and 6,000 in the placebo group. The study was stopped early due to an increased risk of cardiovascular disease and breast cancer in the active treatment group.

The Women's Health Initiative Memory Study concluded that estrogen plus progestin therapy was not effective for the prevention of osteoporosis and had a deleterious effect on the cognitive function of postmenopausal women. The absolute excess risk of probable dementia for CE plus MPA versus placebo was 30 percent (p < 0.05).

The discontinuation rate for hyperplasia over the 36 months of treatment was 6 percent in the combination product versus 64 percent in the conjugated estrogens group (64 percent) compared to the conjugated estrogens plus progestin alone group (26 percent). The rate of secretory transformation was evaluated in a multicenter, randomized, double-blind clinical study that included women with intact uteri who received treatment for up to 36 months. The primary endpoint was a complete secretory transformation in the endometrium. All subjects were randomized to one of the following groups: (1) estrogens 0.625 mg alone, (2) estrogens 0.625 mg plus progestin alone, (3) estrogens 0.625 mg plus progestin 0.04 mg, or (4) placebo.

For the discontinuation rate of hyperplasia, the p-value was 0.001 for the combination group versus placebo, 0.001 for the conjugated estrogens plus progestin group versus placebo, and 0.001 for the placebo group versus both treatment groups. For the rate of secretory transformation, the p-value was 0.001 for all comparisons.

The absolute risk of probable dementia for CE plus MPA versus placebo was 30 percent (p < 0.05). This risk was consistent with those seen in postmenopausal women.

In postmenopausal women with documented heart disease (n = 2,763), the discontinuation rate due to hyperplasia in the placebo group was 17 percent. The discontinuation rate due to hyperplasia in the placebo group was 6 percent in the combination product versus 64 percent in the conjugated estrogens group (64 percent) compared to the conjugated estrogens plus progestin alone group (26 percent).
What a large follow-up of 5 years, the estrogen plus progestin group had a relative risk of breast cancer of 1.23, and the estrogen-only group had a relative risk of breast cancer of 1.18. The estrogen plus progestin group showed an increased risk of breast cancer compared to both the placebo group and the estrogen-only group. In the estrogen plus progestin group, the relative risk of breast cancer was 1.23, and in the estrogen-only group, it was 1.18. Both groups showed a higher risk compared to the placebo group, which had a relative risk of breast cancer of 1.00.

In the estrogen plus progestin group, the risk of endometrial cancer was significantly decreased, with a relative risk of 0.71, compared to the estrogen-only group, which had a relative risk of 0.89. This shows that the combination of estrogen and progestin may reduce the risk of endometrial cancer.

Comparisons with the placebo group showed that estrogen plus progestin was associated with an increased risk of blood clots, heart disease, stroke, and death, while estrogen-only was associated with an increased risk of breast cancer.

Further studies have been conducted to explore the risks associated with these treatments. The Women’s Health Initiative (WHI) trial, which included postmenopausal women aged 50-79 years, showed a significant increase in breast cancer risk with estrogen plus progestin compared to placebo, with a relative risk of 1.29. However, there was no significant increase in endometrial cancer risk in the estrogen plus progestin group compared to placebo.

These findings highlight the importance of considering the balance of risks and benefits when choosing hormonal therapy. It is important to discuss these risks with healthcare providers to make informed decisions.

The use of estrogen plus progestin has been studied in relation to a wide range of other outcomes. Some studies have suggested a protective effect on the risk of coronary heart disease, stroke, and dementia. However, the evidence for these effects is not consistent, and further research is needed to clarify the role of hormone therapy in these conditions.

In conclusion, estrogen plus progestin and estrogen-only treatments have been extensively studied, with significant findings in terms of their effects on breast cancer, endometrial cancer, and other outcomes. Healthcare providers should carefully consider the risks and benefits of these treatments, taking into account the individual patient’s medical history and risk factors.

The use of hormone therapy should also be approached with caution. Patients should be informed about the potential risks and benefits, and should be closely monitored for any adverse effects. Regular health check-ups and follow-up appointments are essential to monitor the effectiveness and safety of hormone therapy.

Overall, the findings from these studies emphasize the need for continued research and careful consideration of hormone therapy. Healthcare providers should work closely with their patients to ensure that they make informed decisions about their treatment options.

References: