5.3 Probable Dementia

Vaginal atrophy due to menopause (1.2)

The Women's Health Initiative (WHI) estrogen plus progestin intervention trial found an increased risk of dementia among women assigned to intervention therapy compared to those assigned to placebo. The relative risk of probable dementia for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of probable dementia increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of probable dementia. The risk of probable dementia for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.4 Hypercalcemia

Hypercalcemia may occur in women treated with estrogen plus progestin. Hypercalcemia may be associated with a variety of symptoms, including polyuria, polydipsia, vomiting, nausea, constipation, back pain, bone pain, and lethargy. The incidence of hypercalcemia increases with increasing estrogen plus progestin doses. Hypercalcemia can develop quickly and may be associated with complications such as renal failure. The risk of hypercalcemia may be reduced by reducing the dose of estrogen plus progestin or discontinuing therapy. If hypercalcemia is confirmed, the estrogen plus progestin must be discontinued and all causes of hypercalcemia must be evaluated.

5.5 Endometrial Cancer

The WHI estrogen plus progestin intervention trial found an increased risk of endometrial cancer in women assigned to estrogen plus progestin versus placebo. The relative risk of endometrial cancer for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of endometrial cancer increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of endometrial cancer. The risk of endometrial cancer for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.6 Stroke

An increased risk of stroke was reported for estrogen plus progestin therapy compared to placebo in WHI Women’s Health Study. The relative risk of stroke for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of stroke increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of stroke. The risk of stroke for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.7 Deep Vein Thrombosis

An increased risk of DVT was reported for estrogen plus progestin therapy compared to placebo in WHI Women’s Health Study. The relative risk of DVT for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of DVT increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of DVT. The risk of DVT for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.8 Hypertension

An increased risk of hypertension was reported for estrogen plus progestin therapy compared to placebo in WHI Women’s Health Study. The relative risk of hypertension for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of hypertension increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of hypertension. The risk of hypertension for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.9 Breast Cancer

An increased risk of breast cancer was reported for estrogen plus progestin therapy compared to placebo in WHI Women’s Health Study. The relative risk of breast cancer for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of breast cancer increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of breast cancer. The risk of breast cancer for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.

5.10 Vaginal Atrophy due to Menopause (1.2)

The Women’s Health Initiative (WHI) estrogen plus progestin intervention trial found an increased risk of breast cancer in women assigned to estrogen plus progestin versus placebo. The relative risk of breast cancer for estrogen plus progestin versus placebo was 1.29 (95% CI 1.04, 1.59) in WHI Women’s Health Study. The absolute risk of breast cancer increased with increasing years of use of estrogen plus progestin therapy. Women 70 years of age or older at the time of randomization or who had a history of cardiovascular disease or dementia (5.2, 5.3) were at increased risk of breast cancer. The risk of breast cancer for estrogen plus progestin therapy is 5.5 times greater than that of placebo, with a rate of 0.5 mg/0.1 mg estrogen plus progestin therapy compared to estrogen-alone therapy (0.5 mg/0.1 mg) for the treatment of moderate to severe vasomotor symptoms due to menopause.
of the breast milk. Detectable amounts of estrogen and progestin are excreted in breast milk. Estrogens and progestins are metabolized in the breast tissue. Estrogens are conjugated with glucuronic acid, sulfate, or glucosamine and then excreted in the breast milk. Progestins are conjugated with glucuronic acid or sulfate and then excreted in the breast milk. Estrogens and progestins may have different effects on the breast and may affect the risk of breast cancer.

8.1 Pregnancy

Estrogens and progestins are metabolized in the breast tissue. Estrogens are conjugated with glucuronic acid, sulfate, or glucosamine and then excreted in the breast milk. Progestins are conjugated with glucuronic acid or sulfate and then excreted in the breast milk. Estrogens and progestins may have different effects on the breast and may affect the risk of breast cancer. Estrogens and progestins may have different effects on the breast and may affect the risk of breast cancer. Estrogens and progestins may have different effects on the breast and may affect the risk of breast cancer.

8.2 Lactation

Estrogens and progestins are metabolized in the breast tissue. Estrogens are conjugated with glucuronic acid, sulfate, or glucosamine and then excreted in the breast milk. Progestins are conjugated with glucuronic acid or sulfate and then excreted in the breast milk. Estrogens and progestins may have different effects on the breast and may affect the risk of breast cancer.

7.1 Metabolic Interactions

The effect of hepatic impairment on the pharmacokinetics of Activella was assessed in a study of patients with hepatic impairment. The results showed that the pharmacokinetics of Activella were not significantly affected by hepatic impairment.

7.2 Renal Impairment

The effect of renal impairment on the pharmacokinetics of Activella was assessed in a study of patients with renal impairment. The results showed that the pharmacokinetics of Activella were not significantly affected by renal impairment.

7.3 Impaired Fertility

The effect of impaired fertility on the pharmacokinetics of Activella was assessed in a study of patients with impaired fertility. The results showed that the pharmacokinetics of Activella were not significantly affected by impaired fertility.

7.4 Breastfeeding

The effect of breastfeeding on the pharmacokinetics of Activella was assessed in a study of patients who were breastfeeding. The results showed that the pharmacokinetics of Activella were not significantly affected by breastfeeding.

7.5 Effects on Other Hormones

The effects of Activella on other hormones were assessed in a study of patients taking Activella. The results showed that Activella had no significant effect on other hormones.

7.6 Effects on Breasts

The effects of Activella on the breasts were assessed in a study of patients taking Activella. The results showed that Activella had no significant effect on the breasts.

7.7 Effects on Uterine Bleeding or Spotting

The effects of Activella on uterine bleeding or spotting were assessed in a study of patients taking Activella. The results showed that Activella reduced uterine bleeding or spotting.

8. Steroid Hormones

The steroid hormones are responsible for the development and maintenance of the female reproductive system and secondary sexual characteristics. Estrogens are responsible for the development and maintenance of the female reproductive system, and progestins are responsible for the maintenance of pregnancy.

9.1 Estrogen-Related Receptors

The estrogen-related receptors are responsible for the development and maintenance of the female reproductive system and secondary sexual characteristics. Estrogen-related receptors are responsible for the development and maintenance of the female reproductive system, and progestin-related receptors are responsible for the maintenance of pregnancy.

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