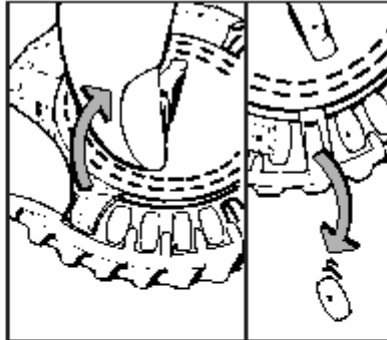


How to use the ACTIVELLA® Dispenser

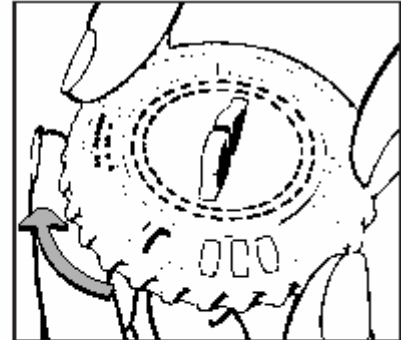
1. Set the Day Reminder

Turn the inner disc so the current day of the week is lined up with the little plastic tab.



2. How to Take the First Tablet

Pull plastic tab up and break off. Tip out the first tablet.



3. Every Day

Turn the outer transparent dial one space clockwise as indicated by the arrow. Tip out the next tablet.

Note: The transparent dial can only be turned after the tablet in the opening has been removed.

**PATIENT INFORMATION
(December 2006)**

**Activella®
(estradiol/norethindrone acetate) tablets
1.0 mg/0.5 mg
0.5 mg/ 0.1 mg**

Read this Patient Information leaflet before you start taking Activella and read what you get each time you refill Activella. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT
Activella (a combination of estrogen and progestin hormones)?**

- Estrogens increase the chance of getting cancer of the uterus.

Report any unusual vaginal bleeding right away while you are taking estrogens. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your health care provider should check any unusual vaginal bleeding to find out the cause.

- Do not use estrogens with or without progestins to prevent heart disease, heart attacks, or strokes.

Using estrogens **with or without progestins** may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots.

- **Do not use estrogens with or without progestins to prevent dementia.**

Using estrogens with or without progestins may increase your risk of dementia.

You and your health care provider should talk regularly about whether you still need treatment with Activella-

What is Activella?

Activella is a medicine that contains estrogen and progestin hormones.

What is Activella used for?

Activella is used after menopause to:

- **Reduce moderate to severe hot flashes**

Estrogens are hormones made by a woman's ovaries. The ovaries normally stop making estrogens when a woman is between 45 to 55 yrs old. This drop in body estrogen levels causes the "change of life" or menopause (the end of monthly menstrual periods). Sometimes, both ovaries are removed during an operation before natural menopause takes place. The sudden drop in estrogen levels causes "surgical menopause."

When the estrogen levels begin dropping, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden strong feelings of heat and sweating ("hot flashes" or "hot flushes"). In some women, the symptoms are mild, and they will not need estrogens. In other women, symptoms can be more severe. You and your health care provider should talk regularly about whether you still need treatment with Activella.

- **Help reduce your chances of getting osteoporosis (thin weak bones)**

Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use Activella only to prevent osteoporosis from menopause, talk with your health care provider about whether a different treatment or medicine without estrogens might be better for you. You and your health care provider should talk regularly about whether you should continue with Activella.

Weight-bearing exercises, like walking or running, and taking calcium and vitamin D supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your health care provider before starting them.

Activella 1.0 mg/0.5 mg is also used after menopause to:

- **Treat moderate to severe dryness, itching, and burning in or around the vagina**

You and your health care provider should talk regularly about whether you still need treatment with Activella 1.0 mg/0.5 mg to control these problems. If you use Activella 1.0 mg/0.5 mg only to treat your dryness, itching, and burning in and around your vagina, talk with your health care provider about whether a topical vaginal product would be better for you.

Who should not take Activella?

Do Not Take Activella If You Have Had Your Uterus Removed (hysterectomy)

Activella contains a progestin to decrease the chances of getting cancer of the uterus. If you do not have a uterus, you do not need a progestin and you should not take Activella.

Do not start taking Activella if you:

- **Have unusual vaginal bleeding**
- **Currently have or have had certain cancers**

Estrogens may increase the chance of getting certain types of cancers, including cancer of the breast or uterus. If you have or have had cancer, talk with your health care provider about whether you should take Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg.

- **Had a stroke or heart attack in the past year**
- **Currently have or have had blood clots**
- **Currently have or have had liver problems**
- **Are allergic to Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg or any of their ingredients**

See section entitled, “What are the ingredients in Activella?” for a list of ingredients in Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg.

- **Think you may be pregnant**

Tell your health care provider:

- **If you are breastfeeding**

The hormones in Activella can pass into your milk.

- **About all of your medical problems**

Your health care provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing); epilepsy (seizures); migraine; endometriosis; lupus; problems with your heart, liver, thyroid, or kidneys; or have high calcium levels in your blood.

- **About all the medicines you take**

This includes prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how Activella works. Activella may also affect how your other medicines work.

- **If you are going to have surgery or will be on bed rest**

You may need to stop taking estrogens.

How should I take Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg?

1. **Take one Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg tablet once a day**
2. Estrogens should be used at the lowest dose possible for your treatment only as long as needed. You and your health care provider should talk regularly (e.g., every 3 to 6 months) about the dose you are taking and whether you still need treatment with Activella.

What are the possible side effects of estrogens?

Less common but serious side effects include:

- **Breast cancer**
- **Cancer of the uterus**
- **Stroke**
- **Heart attack**
- **Blood clots**
- **Dementia**
- **Gallbladder disease**
- **Ovarian cancer**

Some of the warning signs of serious side effects include:

- **Breast lumps**
- **Unusual vaginal bleeding**
- **Dizziness and faintness**
- **Changes in speech**
- **Severe headaches**
- **Chest pain**
- **Shortness of breath**
- **Pains in your legs**
- **Changes in vision**
- **Vomiting**

Call your health care provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

Common side effects include:

- **Headache**
- **Breast pain**
- **Irregular vaginal bleeding or spotting**
- **Stomach/abdominal cramps, bloating**
- **Nausea and vomiting**
- **Mental depression**
- **Back pain**
- **Weight increase**
- **Hair loss**

Other side effects include:

- **High blood pressure**
- **Liver problems**
- **High blood sugar**
- **Fluid retention**
- **Enlargement of benign tumors of the uterus (“fibroids”)**
- **Vaginal yeast infection**
- **Hirsutism**
- **Acne**
- **Weight decrease**
- **Sleep disturbances**
- **Allergic reactions**
- **Nervousness**
- **Mental depression**

These are not all the possible side effects of Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg. For more information, ask your health care provider or pharmacist.

What can I do to lower my chances of a serious side effect with Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg?

- Talk with your health care provider regularly about whether you should continue taking Activella.
- See your health care provider right away if you get vaginal bleeding while taking Activella.
- Have a breast exam and mammogram (breast X-ray) every year unless your health care provider tells you otherwise. If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often.
- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease. Ask your health care provider for ways to lower your chances for getting heart disease.

Have an annual gynecologic exam

General information about the safe and effective use of Activella

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take Activella for conditions for which it was not prescribed. Do not give Activella to other people, even if they have the same symptoms you have. It may harm them.

Keep Activella out of the reach of children

This leaflet provides a summary of the most important information about Activella. If you would like more information, talk with your health care provider or pharmacist. You can ask for information about Activella that is written for health professionals. You can get more information by calling the toll free number 1-866-668-6336.

What are the ingredients in Activella 1.0 mg/0.5 mg?

Each tablet contains 1.0 mg estradiol and 0.5 mg norethindrone acetate. Each 1.0/0.5 mg tablet also contains lactose monohydrate, starch (corn), copovidone, talc, magnesium stearate, hypromellose, and triacetin for oral administration.

What are the ingredients in Activella 0.5 mg/0.1 mg?

Each tablet contains 0.5 mg estradiol and 0.1 mg norethindrone acetate. Each 0.5/0.1 mg tablet also contains lactose monohydrate, starch (corn), hydroxypropylcellulose, talc, magnesium stearate, hypromellose, and triacetin for oral administration.

Activella 1.0 mg/0.5 mg or Activella 0.5 mg/0.1 mg is supplied in a calendar dial pack dispenser containing 28 tablets.

Store in a dry place protected from light. Store at room temperature 25°C (77°F).

Rx only

Activella is a trademark owned by Novo Nordisk FemCare AG

The embossed (Apis) bull symbol on the tablets is a trademark of Novo Nordisk A/S.

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