



User Instructions

How to use the calendar pack

1. Set the day reminder

Turn the inner disc to set the day of the week opposite the little plastic tab.

2. How to take the first day's tablet

Break the plastic tab and tip out the first tablet.

3. Move the dial every day

On the next day, simply move the transparent dial clockwise 1 space as indicated by the arrow. Tip out the next tablet. Remember to take only 1 tablet once a day.

You can only turn the transparent dial after the tablet in the opening has been removed.

تعليمات الإستعمال

كيفية إستعمال العبوة المعتمة بأيام الشهر

1) إضبطي التذكير اليومي

أدري الإسطوانة الداخلية لتحديد اليوم من الأسبوع مقابل السنان البلاستيكي الصغير.

2) كيفية تناول قرص اليوم الأول

قومي بكسر السنان البلاستيكي وأخرجي القرص الأول.

3) حركي الإسطوانة بكل يوم

في اليوم التالي، مجرد حركي الإسطوانة الشفافة مكان واحد باتجاه عقارب الساعة، بما يتناسب مع سهم. أخرجي القرص التالي. تذكري تناول قرص واحد فقط بكل اليوم.

بالإمكان تدوير الإسطوانة الشفافة فقط بعد إخراج القرص من العبوة.

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PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

Activelle®

Film-coated tablets

The active ingredients are: **Estradiol 1 mg/ norethisterone acetate 0.5 mg**

Inactive ingredients in the preparation:

see section 6 - Further information.

Read all of this leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine.

If you have any further questions, ask your doctor or pharmacist.

– Keep this leaflet. You may need to read it again.

– This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

– If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is this medicine intended for?

2. Before using the medicine

3. How to use the medicine?

4. Side effects

5. How to store the medicine?

6. Further information

1. What is this medicine intended for?

Activelle® is a continuous combined Hormone Replacement Therapy (HRT). It contains two types of female hormones, an oestrogen and a progestagen. Activelle® is suitable for postmenopausal women with at least 1 year since their last natural period.

Activelle® is used for:

• **Relief of symptoms occurring after menopause** During the menopause, the amount of oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ('hot flushes'). Activelle® alleviates these symptoms after menopause. You will only be prescribed Activelle® if your symptoms seriously hinder your daily life.

• **Prevention of osteoporosis** After the menopause some women may develop fragile bones (osteoporosis).

You should discuss all available options with your doctor. If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Activelle® to prevent osteoporosis after menopause.

Activelle® is prescribed for women who have not had their womb removed, and whose periods stopped more than a year ago. There is only limited experience of treating women older than 65 years with Activelle®.

Therapeutic group: Progestagens and oestrogens.

2. Before using the medicine

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may

decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on Activelle® you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Activelle®.

Go for regular breast screening, as recommended by your doctor.

Do not take the medicine

if any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking Activelle®.

Do not take Activelle®:

• If you are **allergic** (hypersensitive) to **estradiol, norethisterone acetate** or any of the other ingredients of Activelle® (listed in section 6 'Further information').

• If you have, have had or suspect having **breast cancer**.

• If you have, or have had **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it.

• If you have any **unexplained vaginal bleeding**.

• If you have any **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated.

• If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism).

• If you have a **blood clotting disorder** (such as protein C, protein S or antithrombin deficiency).

• If you have or previously have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**.

• If you have or have ever had a **liver disease** and your liver function tests have not returned to normal.

• If you have a **rare blood problem called 'porphyria'** which is passed down in families (inherited).

If any of the above conditions appear for the first time while taking Activelle®, stop taking it at once and consult your doctor immediately.

Special warnings regarding the use of this medicine

Before treatment with Activelle®, tell your doctor if you have ever had any of the following problems, before you start

the treatment, as these may return or become worse during treatment with Activelle®. If so, you should see your doctor more often for check-ups:

• fibroids inside your womb

• growth of the womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)

• increased risk of developing blood clots (see 'Blood clots in a vein (thrombosis)')

• increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)

• high blood pressure

• a liver disorder, such as a benign liver tumour

• diabetes

• gallstones

• migraine or severe headaches

• a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)

• epilepsy

• asthma

• a disease affecting the eardrum and hearing (otosclerosis)

• a very high level of fat in your blood (triglycerides)

• fluid retention due to cardiac or kidney problems

• lactose intolerance.

Stop taking Activelle® and see a doctor immediately

If you notice any of the following when taking HRT:

• any of the conditions mentioned in the 'Do not take the medicine' section

• yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease

• a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)

• migraine-like headaches which happen for the first time

• if you become pregnant

• if you notice signs of a blood clot, such as:

– painful swelling and redness of the legs

– sudden chest pain

– difficulty in breathing.

For more information, see 'Blood clots in a vein (thrombosis)'.

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Activelle® is used for:

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• **Prevention of osteoporosis** After the menopause some women may develop fragile bones (osteoporosis).

You should discuss all available options with your doctor. If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Activelle® to prevent osteoporosis after menopause.

Activelle® is prescribed for women who have not had their womb removed, and whose periods stopped more than a year ago. There is only limited experience of treating women older than 65 years with Activelle®.

Therapeutic group: Progestagens and oestrogens.

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