

Package leaflet: Information for the user

Elleste Solo™ 1 mg and 2 mg Tablets
1 mg and 2 mg film-coated tablets
(estradiol)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 Elleste Solo is and what it is used for
2. What you need to know before you take Elleste Solo
3. How to take Elleste Solo
4. Possible side effects
5. How to store Elleste Solo
6. Contents of the pack and other information

1. WHAT ELLESTE SOLO IS AND WHAT IT IS USED FOR

Elleste Solo is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen (estradiol hemihydrate).

Elleste Solo is used for:

Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Elleste Solo alleviates these symptoms after menopause. You will only be prescribed Elleste Solo 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 Elleste Solo 2 mg to prevent osteoporosis after menopause.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ELLESTE SOLO

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 Elleste Solo 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 Elleste Solo.

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

Do not take Elleste Solo

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 Elleste Solo,

Do not take Elleste Solo

- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you have **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 **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 recently 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 you are **allergic to estradiol hemihydrate** or any of the other ingredients of this medicine (listed in section 6)

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

When to take special care with Elleste Solo

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 Elleste Solo. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of 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

- hereditary and acquired angioedema

Stop taking Elleste Solo 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 Elleste Solo' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- 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)'

Note: Elleste Solo is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

Taking a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk. So your doctor will prescribe a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

In women who still have a womb and who are not taking HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

The risk of endometrium cancer when using more than 2 mg Elleste Solo together with a progestogen is not known.

Breast cancer

Evidence shows that taking combined oestrogen-progestogen or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare

Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period.

For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in

1000 users (i.e. an extra 0 to 3 cases).

For women aged 50 who start taking oestrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period.

For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases).

For women aged 50 who start taking oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

• **Regularly check your breasts. See your doctor if you notice any changes such as:**

- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m²)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer

For signs of a blood clot, see “Stop taking Elleste Solo and see a doctor immediately”.

Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

For women in their 50s who have had their womb removed and have been taking oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

Heart disease (heart attack)

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

For women who have had their womb removed and are taking oestrogen-only therapy there is no increased risk of developing a heart disease.

Stroke

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions

- HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Children

Do not give this medicine to children.

Other medicines and Elleste Solo

Some medicines may interfere with the effect of Elleste Solo. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*)

HRT can affect the way some other medicines work:

- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures
- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Elleste Solo contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Elleste Solo with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

Pregnancy and breast-feeding

Elleste Solo is for use in postmenopausal women only. If you become pregnant, stop taking Elleste Solo and contact your doctor.

Driving and using machines

No effects on driving or using machinery have been observed for Elleste Solo.

Elleste Solo 2 mg contains **Sunset yellow colouring** which can cause allergic-type reactions, including asthma. This allergy is more common in people who are allergic to aspirin.

Elleste Solo contains **lactose**.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ELLESTE SOLO

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short a time as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

If you are still having regular periods, take your first tablet on the first day of bleeding.

If you are not having regular periods, you can start straight away.

- Take one tablet each day. You can take the tablet at a time of the day that suits you. But it is best to take it about the same time each day.
- Swallow the tablets whole, with some water.
- Follow the direction of the arrows on the pack and take a tablet each day until the pack is empty. All the tablets are the same.
- The days of the week are marked on the strip to help you to remember to take one each day.
- When you finish a foil strip, start a new strip on the next day.

Changing from another type of HRT

If you are changing from another type of HRT, start taking Elleste Solo when you finish the pack of HRT you are taking at the moment.

If your doctor gives you instructions on changing from another type of HRT you should follow these instructions. If you have any doubts you should contact your doctor.

Will I have periods?

If you have not had a hysterectomy, and you are also taking a progestogen, you will probably have a monthly bleed. In the first few months you may get irregular bleeding. However, if this carries on you should tell your doctor.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking Elleste Solo. You may need to stop taking Elleste Solo about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking Elleste Solo again.

If you forget to take Elleste Solo

Take the tablet as soon as you remember and take the next one at the normal time.

If you have missed your tablet by more than 12 hours, dispose of this tablet safely and take the next one at the normal time. Do not take a double dose to make up for the forgotten tablet. If you have not had a hysterectomy you may experience breakthrough bleeding or spotting.

If you take more Elleste Solo than you should

If you (or someone else) take too many Elleste Solo tablets, you are unlikely to come to any harm. You may feel sick (nauseous), or be sick (vomit), dizzy, drowsy/tired, or may have withdrawal bleeding. No treatment is necessary. But if you are worried, contact your doctor for advice.

Aforementioned information is also applicable for overdosing in children.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see section 2.

The following side effects have been associated with Elleste Solo. Frequencies are defined as follows:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Common: feeling sick, abdominal pain, headache, an increase in size of leiomyoma (benign tumor of the womb), breakthrough bleeding, disturbed menstruation period (metrorrhagia), irregular cycles, Uterine/vaginal bleeding including spotting, changes in weight, oedema (swelling) of legs, breast tenderness and enlargement, mood alterations including anxiety and depressed mood, changes in sex drive, rash, itching.

Uncommon: indigestion, being sick, flatulence, gallstones and gallbladder disease, feeling dizzy,

migraine, vaginal thrush, hypersensitivity reactions, visual impairment, palpitation, urticaria (hives), breast pain, painful reddish skin nodules (erythema nodosum).

Rare: increase in body and facial hair, not being able to wear your contact lenses (contact lens intolerance), acne, muscle cramps, pre-menstrual syndrome (PMS), painful periods (dysmenorrhoea), vaginal discharge.

Other adverse reactions have been reported in association with estradiol treatment (frequency unknown):

Breast cancer, benign or malignant tumours which may be affected by the levels of oestrogens, such as cancer of the womb lining (endometrial cancer), ovarian cancer, increase in size of the musculature of the womb

Worsening of fits (epilepsy), muscle twitches you cannot control (chorea)

Stroke

Blood clots in the arteries (arterial thromboembolism), angina and heart attack

Blood clots in the legs or lungs (venous thromboembolism or pulmonary embolism)

Inflammation of the pancreas (pancreatitis) in women with pre-existing high levels of certain blood fats (hypertriglyceridemia)

Gastroesophageal reflux disease

Abnormal liver function, sometimes with yellowing of the skin (jaundice)

Swelling of the skin around the face and throat, this may cause difficulty in breathing (Angioedema),

Rash with target-shaped reddening or sores (erythema multiforme)

Purplish patches or spots on the skin (vascular purpura)

Discoloration of the skin especially of the face or neck known as “pregnancy patches” (chloasma)

Urinary incontinence

Painful/lumpy breasts (fibrocystic breast disease)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ELLESTE SOLO

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Elleste Solo contains

- Elleste Solo **1 mg** Tablets contain the active substance 1 milligram estradiol (as hemihydrate).
- Elleste Solo **2 mg** Tablets contain the active substance 2 milligrams estradiol (as hemihydrate).

(The estradiol hemihydrate used to make Elleste Solo does not come from animals).

- The tablets also contain: lactose monohydrate, maize starch, povidone, talc, magnesium stearate, macrogol 400, titanium dioxide (E171), and hypromellose (E464).
- Elleste Solo **2 mg** has the extra ingredient sunset yellow (E110) (*see also the warning at the end of section 2*).

What Elleste Solo looks like and contents of the pack

Elleste Solo 1 mg Tablets are white film-coated tablets with an embossing.

Elleste Solo 2 mg Tablets are orange film-coated tablets with an embossing.

They are supplied in packs containing blister strips of 20, 28, 60, 84 or 100 tablets.

Not all packs sizes may be marketed.

Marketing Authorisation Holder

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