*Information for the patient*

# Elleste Solo™ 1 mg and 2 mg
## (estradiol hemihydrate)

**Read all of this leaflet carefully before you start using this medicine.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Elleste Solo is and what it is used for
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### 1. WHAT ELLESTE SOLO IS AND WHAT IT IS USED FOR

Elleste Solo is a form of hormone replacement therapy (HRT).

It contains the hormone estradiol hemihydrate, and is one of a group of medicines called estrogen-only preparations. It is not an oral contraceptive.

**Why has your doctor given you Elleste Solo?**

Elleste Solo treats the **symptoms of the menopause** (change of life). It is usually given to women who have had a hysterectomy (had their womb removed).

As you approach the menopause, your ovaries gradually produce fewer hormones. This may cause unpleasant symptoms such as hot flushes and sweating. Elleste Solo replaces a hormone which you lose during the menopause and prevents or relieves any unpleasant symptoms. Your doctor will aim to give you the lowest dose required to treat your symptoms.

Other changes in your bones may also take place over a longer time. These changes can lead to an increased risk of your bones breaking or cracking. If you are at an increased risk of fractures due to **osteoporosis** (thinning of the bones) but are unable to take other treatments or if other therapies prove to be ineffective, Elleste Solo 2 mg may also be used for this purpose. Your doctor should discuss all the available options with you.

### 2. BEFORE YOU TAKE ELLESTE SOLO

Elleste Solo may not be suitable for all women. Read the list below.

**DO NOT** take Elleste Solo, if you have, or have ever had:
- a blood clot in a vein in your leg or anywhere else (a "deep vein thrombosis");
- a blood clot that has travelled to your lung or another part of the body (an "embolus");
- narrowed or blocked arteries possibly leading to angina and heart disease;
- breast or womb cancer;
- unexplained vaginal bleeding;
- liver problems, for example, jaundice (yellowing of the skin or eyes);
- porphyria (a rare inherited blood disease);
- untreated endometrial hyperplasia (an overgrowth of the lining of your womb).

Also **do not take** Elleste Solo if you:
- are pregnant or think you could be pregnant;
- are breast-feeding;
- have ever had an allergic reaction to any of the ingredients in Elleste Solo (*see Section 6*).

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.

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

**Safety of HRT**

**As well as benefits, HRT has some risks which you need to consider when you're deciding whether to take it, or whether to carry on taking it.**

#### *Take special care with Elleste Solo Tablets*

Elleste Solo might have an effect on various processes in your body. HRT should only be started for symptoms that reduce your quality of life.

#### *Medical check-ups*

**Before you start taking HRT**, your doctor should ask about your own and your family's medical history. Your doctor may decide to examine your breasts and/or your abdomen, and may do an internal examination - but only if these examinations are necessary for you, or if you have any special concerns.

**Once you've started on HRT**, you should:
- see your doctor for **regular check-ups** (at least once a year). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to take HRT;
- **go for regular breast screening** and **cervical smear tests;**
- **regularly check your breasts** for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

#### *Effects on your heart or circulation*

**Heart disease:**

**HRT is not recommended for women who have heart disease, now or in the past.** If you have ever had heart disease, talk to your doctor to see if you should be taking HRT.

HRT **will not** help to prevent heart disease.

Studies with one type of HRT (containing conjugated estrogen plus the progestogen MPA) have shown that women may be slightly more likely to get heart disease during the first year of taking the medication. For other types of HRT, the risk is likely to be similar, although this is not yet certain.

***If you get:***
- a pain in your chest that spreads to your arm or neck

▸ **See a doctor as soon as possible** and **do not take any more HRT** until your doctor says you can. This pain could be a sign of heart disease.

**Stroke:**

Recent research suggests that HRT slightly increases the risk of having a stroke. Other factors that can increase the risk of stroke include:
- getting older
- high blood pressure
- smoking
- drinking too much alcohol
- an irregular heartbeat.

**If you are worried about any of these things**, or **if you have had a stroke in the past**, talk to your doctor to see if you should take HRT.

***Compare***

Looking at **women in their 50s** who are **not taking HRT** - on average, over a 5-year period, **3 in 1000** would be expected to have a stroke.

For women in their 50s who are **taking HRT**, the figure would be **4 in 1000.**

Looking at **women in their 60s** who are **not taking HRT** - on average, over a 5-year period, **11 in 1000** would be expected to have a stroke.

For women in their 60s who are **taking HRT**, the figure would be **15 in 1000.**

***If you get:***
- unexplained migraine-type headaches, with or without disturbed vision

▸ **See a doctor as soon as possible and do not take any more HRT** until your doctor says you can. These headaches may be an early warning sign of a stroke.

**Blood clots:**

HRT may increase the risk of **blood clots in the veins** (also called **deep vein thrombosis**, or **DVT**), especially during the first year of taking it.

These blood clots are not always serious, **but if one travels to the lungs**, it can cause chest pain, breathlessness, collapse or even death. This condition is called **pulmonary embolism**, or **PE.**

DVT and PE are examples of a condition called **venous thromboembolism**, or **VTE.**

**You are more likely to get a blood clot if you:**
- are seriously overweight
- have had a blood clot before or have a close family member who has had blood clots
- have had one or more miscarriages
- have any blood clotting problem that needs treatment with a medicine such as warfarin
- are off your feet for a long time because of major surgery, injury or illness
- have a rare condition called systemic lupus erythematosus (SLE).

**If any of these apply to you**, talk to your doctor to see if you should take HRT.

***Compare***

Looking at **women in their 50s** who are **not taking HRT** - on average, over a 5-year period, **3 in 1000** would be expected to get a blood clot.

For women in their 50s who are **taking HRT,** the figure would be **7 in 1000.**

Looking at **women in their 60s** who are **not taking HRT** - on average, over a 5-year period, **8 in 1000** would be expected to get a blood clot.

For women in their 60s who are **taking HRT**, the figure would be **17 in 1000.**

***The following may be signs of blood clot if you get:***
- painful swellling in your leg
- sudden chest pain
- difficulty breathing

▸ **See a doctor as soon as possible** and **do not take any more HRT** until your doctor says you can.

**If you're going to have surgery**, make sure your doctor knows about it. You may need to stop taking HRT about 4 to 6 weeks before the operation, to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.

#### *Effects on your risk of developing cancer*

**Breast cancer:**

**Women who have breast cancer, or have had breast cancer in the past, should not take HRT.**

Taking HRT slightly increases the risk of breast cancer; as does having a later menopause. Your risk of breast cancer is also higher if you:
- have a close relative (mother, sister or grandmother) who has had breast cancer
- are seriously overweight.

The risk for a post-menopausal woman taking estrogen-only HRT for 5 years is about the same as for a woman of the same age who is still having periods over that time and not taking HRT. The risk for a woman who is taking estrogen plus progestogen HRT is higher than for estrogen-only HRT (but estrogen plus progestogen HRT is beneficial for the endometrium, *see 'Endometrial cancer' below*).

For all kinds of HRT, the extra risk of breast cancer increases the longer you take it, but returns to normal within about 5 years after stopping.

***Compare***

Looking at **women aged 50** who are **not taking HRT** - on average, **32 in 1000** will be diagnosed with breast cancer by the time they reach the age of 65.

For women who start taking **estrogen-only** HRT at age 50 and take it for **5 years**, the figure will be between **33 and 34 in 1000 (ie an extra 1-2 cases).**

If they take **estrogen-only HRT** for **10 years,** the figure will be **37 in 1000 (ie an extra 5 cases).**

For women who start taking **estrogen plus progestogen HRT** at age 50 and take it for **5 years,** the figure will be **38 in 1000 (ie an extra 6 cases).**

If they take **estrogen plus progestogen HRT** for **10 years**, the figure will be **51 in 1000 (ie an extra 19 cases)**

***If you notice any changes in your breasts, such as:***
- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel

▸ **Make an appointment to see your doctor as soon as possible.**

**Endometrial cancer (cancer of the lining of the womb):**

**Taking estrogen-only HRT for a long time can increase the risk of cancer of the lining of the womb** (the endometrium). Taking a **progestogen** as well as the estrogen helps to lower the extra risk.

Elleste Solo is an estrogen-only product.

**If you still have your womb**, your doctor may prescribe a progestogen as well as estrogen. If so, these may be prescribed separately, or as a combined HRT product.

**If you have had your womb removed** (a hysterectomy), your doctor will discuss with you whether you can safely take estrogen without a progestogen.

**If you've had your womb removed because of endometriosis**, any endometrium left in your body may be at risk. So your doctor may prescribe HRT that includes a progestogen as well as an estrogen.

***Compare***

Looking at women who still have a uterus and who are **not taking HRT** - on average **5 in 1000** will be diagnosed with endometrial cancer between the ages of 50-65.

For women who **take estrogen-only HRT**, the figure will be between 10 and 60 in 1000 (ie **an extra 5 to 55 cases**), depending on the dose and how long you take it.

The addition of a progestogen to estrogen-only HRT substantially reduces the risk of endometrial cancer.

**If you get breakthrough bleeding or spotting**, it's usually nothing to worry about, especially during the first few months of taking HRT.

***Make an appointment to see your doctor if the bleeding or spotting:***

- carries on for more than the first few months
- starts after you've been on HRT for a while
- carries on even after you've stopped taking HRT
- It could be a sign that your endometrium has become thicker.

**Ovarian cancer**
Ovarian cancer (cancer of the ovaries) is very rare, but it is serious. It can be difficult to diagnose, because there are often no obvious signs of the disease.

Some studies have indicated that taking estrogen-only HRT for more than 5 years may increase the risk of ovarian cancer. It is not yet known whether other kinds of HRT increase the risk in the same way.

### *While you are taking Elleste Solo*

Certain diseases sometimes get worse when you are taking hormone replacement therapy. Your doctor may need to check you more closely if you have any of the following.

- Migraine or severe headache
- Asthma
- Gallstones
- Epilepsy
- High blood pressure
- A personal or family history of blood clots
- Diabetes *(see below)*
- Liver problems
- Heart or kidney problems
- Endometrial hyperplasia (overgrowth of the lining of your womb)
- Fibroids in your womb *(see below)*
- Endometriosis (where tissue from your womb is found outside the womb)
- A history of breast cancer in your family
- Systemic lupus erythematosus (SLE; a chronic inflammatory disease affecting the skin and organs)
- Otosclerosis (an inherited form of deafness which sometimes gets worse during pregnancy)
- High levels of lipids in your blood (hypertriglyceridaemia)

Elleste Solo may affect the result of certain **laboratory tests**, so tell the person taking the sample that you are taking Elleste Solo.

If you have:

- **fibroids** (lumps of fibrous and muscular tissue) in your womb, these may increase in size when you are taking Elleste Solo. See your doctor if you have pain or swelling in your abdomen.
- **diabetes**, you may need to change the amount of insulin you take. Check your blood glucose level more often until it is steady.

**Do I need to use contraception while I am taking Elleste Solo ?**

It is important to remember that Elleste Solo is not a contraceptive (the pill).

If you are using the pill or another hormonal contraceptive you will need to use another type of contraceptive. Please discuss this with your doctor.

### *Taking other medicines with Elleste Solo*

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including over-the-counter medicines.

In particular, tell your doctor if you are using any of the following because they may alter the effects of Elleste Solo:

- drugs that treat **epilepsy**, and some anti-infectives (**anti-virals and antibiotics**) and **sedatives**.
- herbal medicines containing **St. John's Wort**.
- **diabetic drugs**, as this product may affect your blood glucose level. If you are being treated for diabetes please let your doctor or pharmacist know that you take Elleste Solo.

If your doctor does not know that you are taking these other medicines, tell him or her before you start taking Elleste Solo.

### *Pregnancy and breast-feeding*

Elleste Solo is for use in post-menopausal women. It should not be taken by pregnant or breast-feeding women.

### *Driving or using machines*

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

### *Important information about some of the ingredients of Elleste Solo Tablets*

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.

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

## *3. HOW TO TAKE ELLESTE SOLO*

**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 forget to take a tablet*

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. If you have not had a hysterectomy you may experience breakthrough bleeding or spotting.

### *If you take more than you should*

There should be no problems, but you may feel sick or actually be sick. If you are worried contact your doctor. Take the usual tablet the following day.

## *4. POSSIBLE SIDE EFFECTS*

Like all medicines, Elleste Solo can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Stop taking the tablets immediately and tell your doctor if:**

- you become jaundiced (yellowing of the skin or eyes);
- you have itching all over your body;
- you have an unusual, severe or prolonged headache;
- your sight is affected in any way;
- you find it difficult to speak;
- any part of your body suddenly feels weak or numb;
- there is a chance that you could be or could become pregnant; or
- you develop any of the conditions listed under "Before you take Elleste Solo".

**During the first few months** you may feel sick, have headaches, or your breasts may be painful or increase in size. These side effects should lessen as your body gets used to the medicine.

You may also get the following side effects:

**Common:** feeling sick, stomach cramps, headache, an increase in size of fibroids in the womb, breakthrough bleeding, changes in weight, oedema (swelling) of legs, breast tenderness and enlargement, mood changes, changes in sex drive.

**Uncommon:** indigestion, being sick, flatulence, gallstones and gallbladder disease, feeling dizzy, migraine, vaginal thrush, increase in blood pressure, leg cramps, breast cancer *(please refer to the earlier section on breast cancer).*

**Rare:** loss of hair from the scalp, increase in body and facial hair, itchiness, rashes, thromboembolic disease *(please refer to the earlier section on the effects of HRT on the heart and circulation).*

**Very rare:** heart disease *(please refer to the earlier section on the effects of HRT on the heart and circulation)*, stroke, chloasma (brown patches on the skin), red swellings on the skin.

HRT will not prevent memory loss. In one study of women who started using combined HRT after the age of 65, a small increase in the risk of dementia was observed.

## *5. HOW TO STORE ELLESTE SOLO*

Keep out of the reach and sight of children.

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

Don't take Elleste Solo after the 'expiry date' shown on the box.

If your tablets are out of date, take them to your pharmacist who will dispose of them safely.

## *6. FURTHER INFORMATION*

**What Elleste Solo contains**

- Elleste Solo **1mg** tablets contain the active ingredient 1 milligram estradiol (as hemihydrate).
- Elleste Solo **2mg** tablets contain the active ingredient 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 2mg 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 1mg tablets are white film-coated tablets with an embossing.

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

They are supplied in three blister strips in each pack. Each strip contains 28 tablets.

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This leaflet was last approved in October 2009.

If you have any comments on the way this leaflet is written, please write to Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU, UK.

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