INFORMATION FOR THE PATIENT

Elleste Solo™ MX 40 micrograms Transdermal Patch.

Transdermal Matrix Patch

1.25 mg estradiol (as hemihydrate)

MEDA

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.

2. Before you use Elleste Solo

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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. Elleste Solo is a transdermal patch containing estradiol as the active ingredient. The estradiol in Elleste Solo is a synthetic version of the body's natural oestrogen. It is made from plant materials. Elleste Solo is used in menopausal women.

The estradiol gradually comes out of the sticky side of the patch and goes through your skin while you are wearing it. You will get about 40 micrograms of estradiol a day from Elleste Solo.

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.

2. Before you use Elleste Solo

Elleste Solo may not be suitable for all women. Before you start using this medicine, please read the following information.

Medical history and regular check-ups

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

Be sure to:

- **go for regular breast screening** and **cervical smear** tests, as recommended by your doctor.

Do not use 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 using 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).
- inflammation of a vein just under the skin (active "thrombophlebitis").
- If you are **allergic** (hypersensitive) to **estradiol** or any of the other ingredients of Elleste Solo (listed in section 6 Further information).

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:

- increased risk of getting a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- High blood pressure
- Diabetes (See Taking other medicines)
- Migraine or severe headaches
- fibroids inside your womb
- Epilepsy
- a liver disorder, such as a benign liver tumour
- Gallstones
- a very high level of fat in your blood (triglycerides)
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- a disease affecting the eardrum and hearing (otosclerosis)
- Asthma.
- Fluid retention due to cardiac or kidney problems.

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 use Elleste Solo' 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)'

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.

Effects of HRT on heart and circulation

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.

> **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

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.

Other things 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, **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**, over 5 years(i.e. an extra 3 cases).
> **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 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 seriously overweight (BMI > 30 kg/m^2)
- if any of your close relatives has ever had a blood clot in the leg, lung or an other organ
- you have had one or more miscarriages
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- 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 have systemic lupus erythematosus (SLE)
- you have known thrombophilic disorders (see Section 2 "Do not use Elleste Solo if you have or have ever had")
- 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).
> **If you get:**
> - painful swelling 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. These may be signs of a blood clot.

HRT and cancer

Breast cancer

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

Evidence suggests that taking combined oestrogen-progestogen and possibly also oestrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

For women who have had their womb removed and who are using oestrogen-only HRT for 5 years, little or no increase in breast cancer risk is shown.

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.

> Compare
> Women aged 50 to 79 who are not taking HRT, on average, 9 to 14 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 20 cases in 1000 users (i.e. an extra 4 to 6 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.

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

Taking oestrogen-only HRT for a long time can increase the risk of cancer of the lining of the womb (endometrium 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.

Your product, **Elleste Solo**, is an oestrogen-only product.

> 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.
> **Unexpected bleeding**
> You will have a bleed once a month (so-called withdrawal bleed) while taking Elleste Solo. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:
> - carries on for more than the first 6 months
> - starts after you have been taking Elleste Solo more than 6 months
> - carries on after you have stopped taking Elleste Solo
>
> **see your doctor as soon as possible.**

Ovarian cancer

Ovarian cancer is rare. A slightly increased risk of ovarian cancer has been reported in women taking HRT for at least 5 to 10 years.

Women aged 50 to 69 who are not taking HRT, on average about 2 women in 1000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be between 2 and 3 cases per 1000 users.

Dementia:

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.

Using other medicines

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 carbamazepin)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)
- drugs that prevent and treat harmful blood clots (such as coumarins)
- drugs that treat Parkinson (such as selegiline)
- Medicines for HIV infection (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- sedatives
- Herbal remedies containing **St John's Wort** (Hypericum perforatum).

If you are taking medicine for diabetes, such as insulin or tablets to reduce blood sugar, tell your doctor or pharmacist as your dose may need to be changed.

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

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.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking Elleste Solo, because this edecine can affect the results of some tests.

Pregnancy and breast-feeding

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

Driving and using machines

Elleste Solo is not expected to affect your ability to drive or use machines.

3. How to use Elleste Solo

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

The usual dose is one Elleste Solo patch twice a week.

Always follow any instructions your doctor gives you.
Check with your doctor or pharmacist if you are unsure.

Keep using Elleste Solo as part of your HRT until your doctor tells you to stop.

Starting treatment

If you are having regular periods then you should start your Elleste Solo treatment within 5 days of the start of your bleeding.

If you are not having regular periods then you can start Elleste Solo treatment at any time.

Changing from another type of HRT

If you are changing from a HRT product that gives you a withdrawal bleed (eg a sequential or cyclic product) then you should finish the treatment cycle and start using Elleste Solo within 5 days of the withdrawal bleed starting.

If you are changing from a HRT product that does not give you a withdrawal bleed then you can start using Elleste Solo on any convenient day.

Putting on a patch

You should stick the patch on dry, unbroken areas of your skin below the waistline such as your lower back or buttocks.
Place your new patch on a fresh area of skin, away from the place you have just used.

Do not put the patch on or near your breasts

When you have chosen the areas where you want to put the patch make sure the area is not red or irritated. Before you apply the patch, wash and dry the area where you are going to put it.

Do not put powder or oil on your skin before you stick on the patch as this might prevent it from sticking properly.

- Take one pack out of the carton and open the pouch.
- Take out the patch.
- Next, take off the smaller piece of shiny backing covering the sticky side of the patch and put the patch on the area of skin you have chosen.
- Gently peel off the rest of the backing while you flatten the surface of the patch with your other hand as you pull. This should give a smooth and wrinkle-free surface. Pressing it for a few seconds will make it stick firmly.

Changing your patch

You should take off each patch after 3 or 4 days, so that you use two each week and you always change them on the same two days. For example, if you start your first patch on Monday, change to your next one on Thursday then change it again on the next Monday and so on.

As long as you have stuck the patch on correctly, it should not come off in the bath or shower. If your patch comes off before the day you regularly change it and you cannot stick it back on, you should put a new patch on. You should change this patch on your usual day and carry on as before.

When the time comes to change the patch, take off the old one and fold it up, with the sticky side inwards, and put it back into an empty pack, and dispose of it safely.

Remember to keep your new and/or used patches where children cannot see or reach them as they still contain medicine.

Do you need to take anything else while using Ellest Solo?

If you have had a hysterectomy (your womb taken out) your HRT will be Elleste Solo only.

If you have not had your womb taken out your doctor will normally also give you a progestogen treatment (another hormone replacement treatment which balances the effect of estradiol on your womb). You will take this for two weeks of each monthly cycle. This is part of your HRT. For more information see "Section 2: Endometrial cancer (cancer of the lining of the womb)".

While you are using Elleste Solo and a progestogen treatment you will probably have either a "period" or some regular bleeding each month. This is quite normal.

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 use more Elleste Solo than you should

It is almost impossible to get an overdose of estradiol from Elleste Solo if you are using the patches properly. However if you are at all worried, take off your patch and see a doctor.

If you forget to use Elleste Solo

If you forget to change your patch at the right time you should change it as soon as possible. But remember to follow your normal schedule for sticking on your next one. You may experience some breakthrough bleeding or spotting.

4. Possible side effects

Like all medicines, **Elleste Solo** 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.

Reasons to stop using Elleste Solo

Stop using Elleste Solo and see your doctor immediately, if you develop any of the conditions listed in "Do not use Elleste Solo" in Section 2 or if any of the following occur:

- Painful swelling in your leg, sudden chest pain or difficulty breathing. These may be signs of a blood clot.
- Numbness that suddenly affects one side or one part of the body.
- Jaundice, (yellowing of the skin or eyes).
- New migraine or severe headache.
- Unexplained epileptic fit.
- Fainting attack or collapse.
- Sudden partial or complete loss of vision.
- Impared hearing.
- You are pregnant or think you may be pregnant.

Also, your doctor may advise you to stop taking your HRT if your blood pressure increases.

Very common side effects, occurring in more than 1 in 10 people using Elleste Solo are:

- Tender breasts.
- Headaches.
- Breakthrough bleeding.

Common side effects, occurring in less than 1 in 10 people might have a mild redness and itching where the patch has been. When this does happen it usually disappears within 3 or 4 days of taking the patch off. If the skin reaction is worse or lasts for longer than this you should tell your doctor.
In general these side-effects do not usually last long. If they do last for a long time or become serious you should tell your doctor or pharmacist.

Rare side effects, occurring in less than 1 in 1000 people are:

- Benign liver tumour.

Very rare side effects, occurring in less than 1 in 10000 people are:

- Malignant liver tumour.

Other side effects that have been reported while using Estrogen therapy include:

- Tenderness to breasts, or unexpected secretions.
- Unexpected vaginal bleeding, itching, discomfort/pain or unpleasant discharge.
- Increased awareness of, or size, of fibroids, aggravation of endometriosis.
- Breast cancer.
  (See Section 2: "Effects on your risk of developing cancer").
- Stroke.
- Blood clot formation, e.g. in the legs or lungs.
- Liver tumours.
- Liver disorders.
- Nausea (feeling sick)or vomiting (being sick).
- Stomach cramp, bloating.
- Skin discolouration or rash.
- Excessive general itching.
- Hair loss, or abnormal distribution of hair growth.
- Muscular cramp or twitching.
- Migraine, serious headache, dizziness.
- Mood change (elation/depression).
- Nervous disorders (such as twitching of arms and legs).
- Dementia.
- Loss of sex drive.
- Visual disturbances.
- Intolerance of contact lenses.
- Change in body weight, water or sodium retention.
- Reduced tolerance to glucose (sugar).
- Premenstrual syndrome.
- Headache following rigorous exercise.
- Inflammation of the pancreas.
- Lipids Abnormal.

The following side effects have been reported with other HRTs:

- Gall bladder disease.
- Various skin disorders:
  - discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma)
  - painful reddish skin nodules (erythema nodosum)
  - rash with target-shaped reddening or sores (erythema multiforme).

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.

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.

If your doctor decides to stop treating you, return any unused patches to the pharmacist who will dispose of them safely.

Do not take Elleste Solo after the 'expiry date' shown on the box.

6. Further information

What Elleste Solo Transdermal patches contain

The active ingredient in each patch is 1.25 mg estradiol (as hemihydrate).

The patch also contains other ingredients which are: acrylic adhesive, diethyltoluamide, polyester laminate and metalised polyester.

What Elleste Solo Transdermal patches look like and contents of the pack

Elleste Solo Transdermal Patches are rectangular in shape with rounded corners. They are packed in a box containing 8, individually wrapped patches. An additional pack containing two patches may be available. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer.

The Marketing Authorisation holder of Elleste Solo is:

Meda Pharmaceuticals Ltd
Skyway House
Parsonage Road
Takeley
Bishop's Stortford
CM22 6PU
UK

The patch is made by:

LTS, Lohmann Therapie Systeme AG
Lohmannstrasse 2
D56626
Andernach
Germany.

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.

This leaflet was last approved in March 2012.

™Elleste Solo is a registered trademark.

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