Package leaflet:
Information for the user

PREMARIN® 1.25 mg coated tablets

(conjugated oestrogens)

Read all of this leaflet carefully before you start taking Premarin 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, pharmacist or nurse.
- Premarin 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Premarin 1.25 mg coated tablets but will be referred to as Premarin throughout the remainder of this leaflet.
Your medicine is also available in 0.3 mg and 0.625 mg strengths.

What is in this leaflet

1. What Premarin are and what it is used for
2. What you need to know before you take Premarin
3. How to take Premarin
4. Possible side effects
5. How to store Premarin
6. Contents of the pack and other information

1. What Premarin are and what it is used for

Premarin is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. It is used to treat some of the symptoms and conditions associated with the menopause.
Premarin 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"). Premarin alleviates these symptoms after menopause. You will only be prescribed Premarin if your symptoms seriously hinder your daily life.

Prevention of osteoporosis

After the menopause some women may be at risk of developing fragile bones (osteoporosis). You should discuss all available treatment 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 0.625 mg or 1.25 mg coated tablets of Premarin to prevent osteoporosis after menopause.

Premarin is usually prescribed for women who have had their womb removed (hysterectomy). However, women who have not had this operation can still take Premarin and their doctor may prescribe a second type of tablet containing another hormone called a progestogen to be taken for 12-14 days per month as well as Premarin tablets.

2. What you need to know before you take Premarin

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 Premarin 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 Premarin.

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

Do not take Premarin

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 Premarin.

Do not take Premarin

- If you are allergic (hypersensitive) to conjugated oestrogens or any of the other ingredients of Premarin (listed in section 6).
- 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 lining of the womb (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 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 previously had liver disease.
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited).
- If you are pregnant, or you are breast-feeding.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Premarin 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 Premarin. 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 section 2 "Blood Clots in a vein (thrombosis)" for more detail)
- increased risk of getting oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer) (see section 2 "HRT and cancer")
- high blood pressure
- heart disease
- a liver disorder (e.g. a benign liver tumour)
- kidney disease
- fluid retention due to cardiac or kidney problems
- diabetes
- gallbladder disease or 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)
- low blood calcium levels (hypocalcaemia)
- a very high level of fat in your blood (triglycerides).

Stop taking Premarin 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 Premarin" section
- yellowing of the 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
- have an allergic reaction, signs of which include a rash, itching, shortness of breath, difficulty in breathing and a swollen face
- 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 section titled "Blood Clots in a vein (thrombosis)" below.

Premarin 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.

Premarin's 0.625 mg and 1.25 mg tablets contain a higher dose of oestrogens than other oestrogen-only HRT products. The risk of endometrium cancer when using 0.625 mg and 1.25 mg tablets of Premarin together with a progestogen is not known.

If you still have your womb, your doctor may prescribe a progestogen as well as oestrogen. 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 oestrogen 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 oestrogen.

Your product, Premarin, is an oestrogen-only product.

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 and 65.

For women who take **oestrogen-only HRT**, the number will be **2 to 12 times higher,** depending on the dose and how long you take it. After stopping treatment risk may remain elevated for at least 10 years.
In women with a uterus, use of oestrogen-only HRT is not recommended because it increases the risk of endometrial cancer.

Irregular bleeding
If you get break-through bleeding or spotting, it's usually nothing to worry about, especially during the first 3-6 months of taking HRT.

But if the bleeding or spotting:
- carries on for more than the first 6 months
- starts after you've been taking Premarin for more than 6 months
- carries on even after you've stopped taking Premarin

➢ **Make an appointment to see your doctor. It could be a sign that your endometrium has become thicker.**

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

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.

Your risk of breast cancer is also higher:
- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight.

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 are 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

Ovarian Cancer
Ovarian cancer is rare - much rarer than breast cancer , but it is serious. It can be difficult to diagnose, because there are often no obvious signs of the disease.

The use of oestrogen-only or combined oestrogen-progestogen 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).

Effects of HRT on your heart or circulation

Blood Clots in a vein (thrombosis)
The risk of **blood clots in the veins** (also called **deep vein thrombosis,** or **DVT**), 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, 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 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)
- you have had a blood clot before
- if any of your close family has ever had a blood clot in the leg, lung or another organ
- you are pregnant or in your postpartum period
- you have any blood clotting problem that needs 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 "if you're going to have surgery" below)
- you have a rare condition called SLE (systemic lupus erythematosus)
- you have cancer.

For signs of a blood clot, see section 2 Stop taking Premarin 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 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're going to have surgery, make sure your doctor knows about it or tell the surgeon that you are taking Premarin. You may need to stop taking Premarin 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 Premarin again.

Heart Disease (heart attack)
HRT is not recommended for women who have heart disease, or have had heart disease recently. If you have ever had heart disease, talk to your doctor to see if you should be taking HRT.

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

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 having a 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. More recent analysis of risk in women aged 50 to 59 years suggests no increased risk for women taking 0.625 mg tablets of Premarin.

Other things that can increase the risk of stroke include:
- 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, 8 in 1000 would be expected to have a stroke.

For women in their 50s who are taking HRT, the figure would be 11 in 1000 users, over a five year period (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.

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.

Women with hypertriglyceridemia may experience large increases of their plasma triglycerides, which can lead to inflammation of the pancreas (pancreatitis). Symptoms of pancreatitis may include abdominal pain, abdominal swelling, fever and feeling or being sick.

If you are taking thyroid hormone replacement therapy (e.g. thyroxine), your doctor may monitor your thyroid function more often when you start treatment.

HRT may affect some medical tests. If you visit a hospital or clinic for any medical tests, you should tell the doctor concerned that you are taking HRT.

Other medicines and Premarin
Some medicines may interfere with the effect of Premarin. This might lead to irregular bleeding.

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

In particular tell your doctor if you are taking:
- an anticonvulsant (used to treat epilepsy e.g. phenobarbital, phenytoin, carbamazepine)
- an anti-infective e.g. used to treat **tuberculosis** (rifampicin, rifabutin) or **HIV** (nevirapine, efavirenz, ritonavir and nelfinavir)
- other antibiotics or antifungal medicines (e.g. erythromycin, clarithromycin, ketoconazole, itraconazole)
- a herbal preparation such as St. John's wort *(Hypericum perforatum*)
- metyrapone (most commonly used in the treatment of Cushing's syndrome)
- cimetidine (used to treat stomach ulcers and reduce stomach acid)
- dexamethasone (a corticosteroid)

HRT can affect the way some other medicines work:
• A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures.

The way that Premarin works may be altered if other medicines are used at the same time.

Premarin with food and drink
Drinking grapefruit juice may affect the way that your medicine works.

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

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Premarin.

Driving and using machines
There is no evidence to suggest that taking Premarin will affect your ability to drive or to operate machinery.

Premarin contains Lactose monohydrate, Sucrose and the colouring agent Sunset Yellow
Lactose monohydrate and sucrose are sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The colouring agent E110 (sunset yellow), that is used in the yellow tablets (1.25 mg), may cause allergic reactions.

3. How to take Premarin

Starting to take Premarin
Always take Premarin exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is one tablet every day.

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

Take your tablet at the same time each day as this will help to remind you to take your medicine.

If you are not already taking an HRT product or if you are taking an HRT product that does not give you a monthly bleed you may start your first pack of Premarin at any convenient time.

If you are changing from an HRT product that gives you a monthly bleed, start Premarin the day after you finish the course of the previous product, unless instructed otherwise by your doctor.

While you are taking Premarin you will have no tablet-free days. You should start your next pack the day after you finish the previous one.

The recommended dose
For menopausal symptoms the usual dose is one tablet every day. Your doctor will prescribe the lowest dose that will control your symptoms. 0.3 mg of Premarin is the lowest starting dose. If your symptoms are not adequately controlled higher doses of Premarin can be used.

For the treatment of osteoporosis the usual dose is one 0.625 mg tablet every day but your doctor may advise you to use 1.25 mg each day. You and your doctor should review the need for treatment regularly.

Do not try to take off the coating, divide or crush the tablets as this could affect the way Premarin works.

Paediatric population
Safety and effectiveness in paediatric patients have not been established.

While you are taking Premarin
If you have had a hysterectomy you are not expected to have a period.

If you have not had a hysterectomy, you may be taking an additional progestogen tablet for 12-14 days each month, and you will probably have a "period", or withdrawal bleed each month at about the time you finish the additional progestogen tablets. This is caused by the hormones in the HRT and is perfectly natural. Some women taking "combined HRT" (oestrogen plus the additional progestogen) may experience a gradual reduction in withdrawal bleeding and it may eventually stop; this is quite normal. If you experience troublesome bleeding or it continues beyond the first 3 months of treatment discuss this with your doctor (see section 2 **HRT and Cancer).**

If you take more Premarin than you should
If you take too many tablets don't worry. You may feel some nausea (sickness), breast tenderness, dizziness, abdominal pain and drowsiness/fatigue. If you have not had a hysterectomy you may experience a short period of vaginal bleeding, but it is unlikely that serious problems will occur. If you are concerned, talk to your doctor or pharmacist.

If you forget to take Premarin
If you forget to take a tablet don't worry. Take it as soon as you remember and then carry on taking the remaining tablets at the usual time.

Do not take a double dose to make up for a forgotten tablet.

Missed tablets may cause a short period of light bleeding in women who have not had a hysterectomy.

If you have any further questions on the use of Premarin, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Premarin 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.

In addition to those discussed in section 2, the following side effects have been reported in women taking HRT:

- abdominal uterine bleeding such as breakthrough bleeding or spotting, changes in menstrual flow, pelvic pain, vaginal inflammation and vaginal discharge
- a tendency to get thrush
- breast pain, breast tenderness, swollen breasts, discharge from the nipples and changes in breast tissue
- feeling or being sick, a feeling of being bloated, abdominal pain
- headache or migraine
- dizziness
- changes in mood including anxiety, depression and irritability
- joint pain, leg cramps
- changes in your interest in sex (increased or decreased libido)
- visible swelling of the face or ankles
- rash, itchiness, acne and dark or red patches on the skin
- changes in hair growth (loss or increase)
- minor changes to the eye, difficulty wearing contact lenses
- changes in weight (increase or decrease)
- changes in your triglyceride levels (fatty substances in the blood)
- an intolerance to glucose
- memory loss (dementia)
- a worsening of chorea (an existing neurological disorder characterised by involuntary spasmodic movements of the body)
- a worsening of asthma
- a worsening of hypocalcaemia (low blood levels of calcium)
- gallbladder disease or jaundice (e.g. gallstones or yellowing of the skin)
- growth of benign meningioma (a tumour of the membranes around the brain or spinal cord)
- inflammation of the colon (part of the intestine) which may present as lower left sided abdominal pain and/or bloody diarrhoea
- induce or exacerbate symptoms of angioedema, which consists of generalized swelling of parts of the body, most frequently around the face, mouth, tongue and neck areas, particularly in women with hereditary angioedema.

These side effects are usually temporary and should get better over time.

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.

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 Premarin.

5. How to store Premarin

Keep Premarin out of the sight and reach of children.

Do not use Premarin after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

If the tablets become discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

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

6. Contents of the pack and other information

What Premarin contains
Each tablet contains 1.25 mg conjugated oestrogens.
The active substance is a mixture of hormones called conjugated oestrogens.
Premarin tablets are oval shaped, yellow tablets marked with "1.25" in black ink.
The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, hypromellose, sucrose, hydroxypropyl cellulose and polyethylene glycol. The coating on the yellow tablets contains hypromellose, titanium dioxide (E171), quinoline yellow aluminium lake (E104), macrogol, polysorbate and sunset yellow (E110).Ðhe polish on the yellow tablets contains hypromellose and carnauba wax. Ðhe edible ink on the yellow tablets contains iron oxide black, propylene glycol and Hypromellose.
The coating on the yellow tablets contains hypromellose, titanium dioxide, quinoline yellow aluminium lake (E104), sunset yellow FCF aluminium lake (E110), macrogol and polysorbate 80.

These dyes are approved for use as food colourings.

What Premarin looks like and contents of the pack
Each pack contains 84 tablets.

Procured from within the EU for The Product Licence Holder:
IMED Healthcare Ltd, Unit E The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK.

Manufacturer:
Pfizer Italia S.r.l., Località Marino del Tronto, 63100, Ascoli Piceno (AP), Italy.

Repackaged by:
Cast Healthcare Ltd, Unit E The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK.

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Blind or partially sighted? Is this leaflet hard to see or read? Call 028 7962 9988 to obtain the leaflet in a format suitable for you.

Package leaflet:
Information for the user

Conjugated oestrogens 1.25 mg coated tablets

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, pharmacist or nurse.
- Conjugated oestrogens 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Conjugated oestrogens 1.25 mg coated tablets but will be referred to as Conjugated oestrogens throughout the remainder of this leaflet. Your medicine is also available in 0.3 mg and 0.625 mg strengths.

What is in this leaflet

1. What Conjugated oestrogens are and what it is used for
2. What you need to know before you take Conjugated oestrogens
3. How to take Conjugated oestrogens
4. Possible side effects
5. How to store Conjugated oestrogens
6. Contents of the pack and other information

1. What Conjugated oestrogens are and what it is used for

Conjugated oestrogens is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. It is used to treat some of the symptoms and conditions associated with the menopause.
Conjugated oestrogens 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"). Conjugated oestrogens alleviates these symptoms after menopause. You will only be prescribed Conjugated oestrogens if your symptoms seriously hinder your daily life.

Prevention of osteoporosis

After the menopause some women may be at risk of developing fragile bones (osteoporosis). You should discuss all available treatment 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 0.625 mg or 1.25 mg coated tablets of Conjugated oestrogens to prevent osteoporosis after menopause.

Conjugated oestrogens is usually prescribed for women who have had their womb removed (hysterectomy). However, women who have not had this operation can still take Conjugated oestrogens and their doctor may prescribe a second type of tablet containing another hormone called a progestogen to be taken for 12-14 days per month as well as Conjugated oestrogens tablets.

2. What you need to know before you take Conjugated oestrogens

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 Conjugated oestrogens 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 Conjugated oestrogens.

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

Do not take Conjugated oestrogens

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 Conjugated oestrogens.

Do not take Conjugated oestrogens:

- If you are allergic (hypersensitive) to conjugated oestrogens or any of the other ingredients of Conjugated oestrogens (listed in section 6).
- 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 lining of the womb (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 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 previously had liver disease.
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited).
- If you are pregnant, or you are breast-feeding.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Conjugated oestrogens 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 Conjugated oestrogens. 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 section 2 "Blood Clots in a vein (thrombosis)" for more detail)
- increased risk of getting oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer) (see section 2 "HRT and cancer")
- high blood pressure
- heart disease
- a liver disorder (e.g. a benign liver tumour)
- kidney disease
- fluid retention due to cardiac or kidney problems
- diabetes
- gallbladder disease or 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)
- low blood calcium levels (hypocalcaemia)
- a very high level of fat in your blood (triglycerides).

Stop taking Conjugated oestrogens 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 Conjugated oestrogens" section
- yellowing of the 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
- have an allergic reaction, signs of which include a rash, itching, shortness of breath, difficulty in breathing and a swollen face
- 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 section titled "Blood Clots in a vein (thrombosis)" below.

Conjugated oestrogens 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.

Conjugated oestrogens 0.625 mg and 1.25 mg tablets contain a higher dose of oestrogens than other oestrogen-only HRT products. The risk of endometrium cancer when using 0.625 mg and 1.25 mg tablets of Conjugated oestrogens together with a progestogen is not known.

If you still have your womb, your doctor may prescribe a progestogen as well as oestrogen. 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 oestrogen 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 oestrogen.

Your product, Conjugated oestrogens, is an oestrogen-only product.

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 and 65.

For women who take **oestrogen-only HRT**, the number will be **2 to 12 times higher,** depending on the dose and how long you take it. After stopping treatment risk may remain elevated for at least 10 years. In women with a uterus, use of oestrogen-only HRT is not recommended because it increases the risk of endometrial cancer.

Irregular bleeding
If you get break-through bleeding or spotting, it's usually nothing to worry about, especially during the first 3-6 months of taking HRT.

But if the bleeding or spotting:
- carries on for more than the first 6 months
- starts after you've been taking Conjugated oestrogens for more than 6 months
- carries on even after you've stopped taking Conjugated oestrogens

➢ **Make an appointment to see your doctor. It could be a sign that your endometrium has become thicker.**

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

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.

Your risk of breast cancer is also higher:
- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight.

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 are 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

Ovarian Cancer
Ovarian cancer is rare - much rarer than breast cancer , but it is serious. It can be difficult to diagnose, because there are often no obvious signs of the disease.

The use of oestrogen-only or combined oestrogen-progestogen 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).

Effects of HRT on your heart or circulation

Blood Clots in a vein (thrombosis)
The risk of **blood clots in the veins** (also called **deep vein thrombosis,** or **DVT**), 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, 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 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)
- you have had a blood clot before
- if any of your close family has ever had a blood clot in the leg, lung or another organ
- you are pregnant or in your postpartum period
- you have any blood clotting problem that needs 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 "if you're going to have surgery" below)
- you have a rare condition called SLE (systemic lupus erythematosus)
- you have cancer.

For signs of a blood clot, see section 2 Stop taking Conjugated oestrogens 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 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're going to have surgery, make sure your doctor knows about it or tell the surgeon that you are taking Conjugated oestrogens. You may need to stop taking Conjugated oestrogens 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 Conjugated oestrogens again.

Heart Disease (heart attack)
HRT is not recommended for women who have heart disease, or have had heart disease recently. If you have ever had heart disease, talk to your doctor to see if you should be taking HRT.

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

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 having a 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. More recent analysis of risk in women aged 50 to 59 years suggests no increased risk for women taking 0.625 mg tablets of Conjugated oestrogens.

Other things that can increase the risk of stroke include:
- 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, 8 in 1000 would be expected to have a stroke.

For women in their 50s who are taking HRT, the figure would be 11 in 1000 users, over a five year period (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.

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.

Women with hypertriglyceridemia may experience large increases of their plasma triglycerides, which can lead to inflammation of the pancreas (pancreatitis). Symptoms of pancreatitis may include abdominal pain, abdominal swelling, fever and feeling or being sick.

If you are taking thyroid hormone replacement therapy (e.g. thyroxine), your doctor may monitor your thyroid function more often when you start treatment.

HRT may affect some medical tests. If you visit a hospital or clinic for any medical tests, you should tell the doctor concerned that you are taking HRT.

Other medicines and Conjugated oestrogens
Some medicines may interfere with the effect of Conjugated oestrogens. This might lead to irregular bleeding.

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

In particular tell your doctor if you are taking:
- an anticonvulsant (used to treat epilepsy e.g. phenobarbital, phenytoin, carbamazepine)
- an anti-infective e.g. used to treat **tuberculosis** (rifampicin, rifabutin) or **HIV** (nevirapine, efavirenz, ritonavir and nelfinavir)
- other antibiotics or antifungal medicines (e.g. erythromycin, clarithromycin, ketoconazole, itraconazole)
- a herbal preparation such as St. John's wort *(Hypericum perforatum*)
- metyrapone (most commonly used in the treatment of Cushing's syndrome)
- cimetidine (used to treat stomach ulcers and reduce stomach acid)
- dexamethasone (a corticosteroid)

HRT can affect the way some other medicines work:
• A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures.

The way that Conjugated oestrogens works may be altered if other medicines are used at the same time.

Conjugated oestrogens with food and drink
Drinking grapefruit juice may affect the way that your medicine works.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking Conjugated oestrogens, because Conjugated oestrogens can affect the
results of some tests.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Conjugated oestrogens.

Driving and using machines
There is no evidence to suggest that taking Conjugated oestrogens will affect your ability to drive or to operate machinery.

Conjugated oestrogens contains Lactose monohydrate, Sucrose and the colouring agent Sunset Yellow
Lactose monohydrate and sucrose are sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The colouring agent E110 (sunset yellow), that is used in the yellow tablets (1.25 mg), may cause allergic reactions.

3. How to take Conjugated oestrogens

Starting to take Conjugated oestrogens
Always take Conjugated oestrogens exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is one tablet every day.

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

Take your tablet at the same time each day as this will help to remind you to take your medicine.

If you are not already taking an HRT product or if you are taking an HRT product that does not give you a monthly bleed you may start your first pack of Conjugated oestrogens at any convenient time.

If you are changing from an HRT product that gives you a monthly bleed, start Conjugated oestrogens the day after you finish the course of the previous product, unless instructed otherwise by your doctor.

While you are taking Conjugated oestrogens you will have no tablet-free days. You should start your next pack the day after you finish the previous one.

The recommended dose
For menopausal symptoms the usual dose is one tablet every day. Your doctor will prescribe the lowest dose that will control your symptoms. 0.3 mg of Conjugated oestrogens is the lowest starting dose. If your symptoms are not adequately controlled higher doses of Conjugated oestrogens can be used.

For the treatment of osteoporosis the usual dose is one 0.625 mg tablet every day but your doctor may advise you to use 1.25 mg each day. You and your doctor should review the need for treatment regularly.

Do not try to take off the coating, divide or crush the tablets as this could affect the way Conjugated oestrogens works.

Paediatric population
Safety and effectiveness in paediatric patients have not been established.

While you are taking Conjugated oestrogens
If you have had a hysterectomy you are not expected to have a period. If you have not had a hysterectomy, you may be taking an additional progestogen tablet for 12-14 days each month, and you will probably have a "period", or withdrawal bleed each month at about the time you finish the additional progestogen tablets. This is caused by the hormones in the HRT and is perfectly natural. Some women taking "combined HRT" (oestrogen plus the additional progestogen) may experience a gradual reduction in withdrawal bleeding and it may eventually stop; this is quite normal. If you experience troublesome bleeding or it continues beyond the first 3 months of treatment discuss this with your doctor (see section 2 **HRT and Cancer).**

If you take more Conjugated oestrogens than you should
If you take too many tablets don't worry. You may feel some nausea (sickness), breast tenderness, dizziness, abdominal pain and drowsiness/fatigue. If you have not had a hysterectomy you may experience a short period of vaginal bleeding, but it is unlikely that serious problems will occur. If you are concerned, talk to your doctor or pharmacist.

If you forget to take Conjugated oestrogens
If you forget to take a tablet don't worry. Take it as soon as you remember and then carry on taking the remaining tablets at the usual time.

Do not take a double dose to make up for a forgotten tablet.

Missed tablets may cause a short period of light bleeding in women who have not had a hysterectomy.

If you have any further questions on the use of Conjugated oestrogens, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Conjugated oestrogens 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.

In addition to those discussed in section 2, the following side effects have been reported in women taking HRT:

- abdominal uterine bleeding such as breakthrough bleeding or spotting, changes in menstrual flow, pelvic pain, vaginal inflammation and vaginal discharge
- a tendency to get thrush
- breast pain, breast tenderness, swollen breasts, discharge from the nipples and changes in breast tissue
- feeling or being sick, a feeling of being bloated, abdominal pain
- headache or migraine
- dizziness
- changes in mood including anxiety, depression and irritability
- joint pain, leg cramps
- changes in your interest in sex (increased or decreased libido)
- visible swelling of the face or ankles
- rash, itchiness, acne and dark or red patches on the skin
- changes in hair growth (loss or increase)
- minor changes to the eye, difficulty wearing contact lenses
- changes in weight (increase or decrease)
- changes in your triglyceride levels (fatty substances in the blood)
- an intolerance to glucose
- memory loss (dementia)
- a worsening of chorea (an existing neurological disorder characterised by involuntary spasmodic movements of the body)
- a worsening of asthma
- a worsening of hypocalcaemia (low blood levels of calcium)
- gallbladder disease or jaundice (e.g. gallstones or yellowing of the skin)
- growth of benign meningioma (a tumour of the membranes around the brain or spinal cord)
- inflammation of the colon (part of the intestine) which may present as lower left sided abdominal pain and/or bloody diarrhoea
- induce or exacerbate symptoms of angioedema, which consists of generalized swelling of parts of the body, most frequently around the face, mouth, tongue and neck areas, particularly in women with hereditary angioedema.

These side effects are usually temporary and should get better over time.

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.

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 Conjugated oestrogens.

5. How to store Conjugated oestrogens

Keep Conjugated oestrogens out of the sight and reach of children.

Do not use Conjugated oestrogens after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

If the tablets become discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

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

6. Contents of the pack and other information

What Conjugated oestrogens contains
Each tablet contains 1.25 mg conjugated oestrogens.
The active substance is a mixture of hormones called conjugated oestrogens.
Conjugated oestrogen tablets are oval shaped, yellow tablets marked with "1.25" in black ink.
The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, hypromellose, sucrose, hydroxypropyl cellulose and polyethylene glycol. The coating on the yellow tablets contains hypromellose, titanium dioxide (E171), quinoline yellow aluminium lake (E104), macrogol, polysorbate and sunset yellow (E110).Ðhe polish on the yellow tablets contains hypromellose and carnauba wax. Ðhe edible ink on the yellow tablets contains iron oxide black, propylene glycol and Hypromellose.
The coating on the yellow tablets contains hypromellose, titanium dioxide, quinoline yellow aluminium lake (E104), sunset yellow FCF aluminium lake (E110), macrogol and polysorbate 80.

These dyes are approved for use as food colourings.

What Conjugated oestrogens looks like and contents of the pack
Each pack contains 84 tablets.

Procured from within the EU for The Product Licence Holder:
IMED Healthcare Ltd, Unit E The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK.

Manufacturer:
Pfizer Italia S.r.l., Località Marino del Tronto, 63100, Ascoli Piceno (AP), Italy.

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