

Hormonin®



This leaflet contains important information about Hormonin Tablets. Please read it before you take any of the tablets.

About Hormonin

The name of this medicine is Hormonin. Each tablet contains the following active ingredients: 0.27mg estriol, 0.6mg estradiol and 1.4mg estrone. Hormonin Tablets also include lactose, potato starch, magnesium stearate, sunset yellow (E110) and amaranth (E123).

These tablets are supplied to pharmacies in blister packs of 84.

Hormonin Tablets contain three estrogens that are naturally found in a woman. Estrogens are 'female' hormones, and are used for treating the symptoms resulting from estrogen hormone deficiency. Treatments such as this are widely known as Hormone Replacement Therapy (HRT). The symptoms of hormone deficiency may be experienced during and after the menopause, or after the surgical removal of the ovaries. These symptoms can include hot flushes, discomfort when you pass water, dryness of the vagina, feelings of irritability and sweating.

Osteoporosis (brittle bones or thinning of the bones) tends to develop over a period of several years following the menopause. If you are at increased risk of fractures due to osteoporosis but are unable to take other treatments, or if other therapies prove to be ineffective, Hormonin may also be used for this purpose. Your doctor should discuss all the available options with you.

Hormonin is not an oral contraceptive (the pill). If you are still having periods when you start treatment and need family planning advice, talk to your doctor. If you are currently using the pill or another hormonal contraceptive, you will need to use another type of contraceptive. Please discuss this with your doctor.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for this product is held by Amdipharm UK Limited, Capital House, 85 King William Street, London EC4N7BL, UK.

The tablets are manufactured by Recipharm Limited, Vale of Bardsley, Ashton-under-Lyne, Lancashire OL7 9RR.

Before taking Hormonin

Medicines are not always suitable for everyone. If the answer to any of the following questions is 'Yes' you should not take Hormonin. Speak to your doctor or pharmacist for further advice.

- Do you have, or are you being treated for, a blood clot in a vein in your leg or anywhere else (a "deep vein thrombosis")?
- Do you have, or are you being treated for, a blood clot that has travelled to your lung or another part of the body (an "embolus")?
- Do you have, or have you suffered from, porphyria (a rare inherited blood disease)?
- Do you have, or have you suffered from, problems with your arteries, possibly causing angina, a heart attack, or a stroke?
- Do you have vaginal bleeding e.g. unexpected genital bleeding or irregular/heavy periods, which your doctor could not find the cause of?
- Do you have endometrial hyperplasia (thickening of the lining of the womb), which has not been treated?
- Do you have, or have you suffered from, breast cancer?
- Do you have, or have you suffered from, other estrogen dependent cancers, such as womb cancer?
- Do you have liver problems, for example jaundice (yellowing of the skin or eyes)?
- Do you have, or have you suffered from, an allergic reaction to any of the ingredients in Hormonin?

Hormonin tablets contain lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

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.

Be sure to:

- 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, 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.

HRT will not help to prevent heart disease.

Studies with one type of HRT (containing conjugated oestrogen 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 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, 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
- if you have had a blood clot before
- if any of your close family have had blood clots
- if you have had one or more miscarriages
- if you have any blood clotting problem that needs treatment with a medicine such as warfarin
- if you're off your feet for a long time because of major surgery, injury or illness
- if you have a rare condition called SLE.

If any of these things 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**.

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.

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; so does having a later menopause. 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 goes up the longer you take it, but returns to normal within about 5 years after stopping HRT.

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

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 (i.e. an extra 1-2 cases)**.

If they take estrogen-only HRT for **10 years**, the figure will be **37 in 1000 (i.e. 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 (i.e. an extra 6 cases)**.

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

If you notice any changes in your breast, 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.

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.

Your product, Hormonin, is an estrogen-only product.

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 and 65.

For women who **take estrogen-only HRT**, the figure will be between **10 and 60 (i.e. 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.

But 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.

► **Make an appointment to see your doctor.** 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.

Other conditions

Certain diseases or conditions sometimes get worse when you are taking HRT. Your doctor may need to check you more closely if you suffer from any of the following:

- Migraine or severe headache

- Asthma
- Gallstones
- High blood pressure
- Diabetes
- Epilepsy
- You have previously suffered from liver problems
- Endometrial hyperplasia (thickening of the lining of the womb)
- Fibroids in your womb
- Systemic lupus erythematosus (a chronic inflammatory disease affecting the skin and organs)
- Otosclerosis (an inherited form of deafness which sometimes gets worse during pregnancy)
- Endometriosis (where tissue from your womb is found outside the womb)
- An increased risk of blood clots (see previous section on 'Blood clots')
- A family history of breast cancer

Also do not take Hormonin if you could be pregnant, or you are breast-feeding.

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.

While you are taking Hormonin

Hormone therapy may reduce glucose tolerance. If you are diabetic, you should discuss this with your doctor, since it may be necessary to increase the dose of insulin or other anti-diabetic treatments.

If you need to have a thyroid function test while you are taking these tablets, make sure you tell the hospital you are taking them, since it can affect the results of this test or other laboratory tests.

A few contact lens wearers have reported some eye discomfort as a result of taking hormone based tablets such as HRT or contraceptives. Since this is rare and does not cause damage to the eye, it should not be a reason for any contact lens wearer not to take any of these products. If you were to notice discomfort, you may decide, however, that you don't wish to continue taking the medication.

Some medicines may stop Hormonin from working properly. These include some drugs that treat epilepsy (e.g. phenobarbital, phenytoin, carbamazepine), and some anti-infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz). If your doctor does not know that you are taking these other medicines, tell him or her before you start taking Hormonin. You should also tell your doctor if you are taking any herbal medicines containing St. John's Wort.

How and when to take Hormonin

It is important to take your medicine as directed by the doctor. The pharmacist's label should give you these instructions. Your doctor will probably have started by giving you the lowest daily dose, which is likely to be sufficient to control your symptoms. However, if after a few weeks your symptoms are still troublesome, you should tell your doctor who will consider whether to increase the dose to two tablets daily. If, during treatment, you develop breast tenderness for more than a few days or unexpected menstrual type bleeding, it is possible that the dose is too high. Again, you should see your doctor.

The tablets should be swallowed whole, with water, and taken at approximately the same time each day. Hormonin Tablets can be taken continuously (for all 28 days of the cycle), or cyclically, (for 21 days with 7 tablet-free days). Your doctor will tell you whether you should take the tablets for 28 or 21 days each month.

If you are starting HRT for the first time and have a regular menstrual bleed, start to take Hormonin Tablets within the first five days of the start of your bleed.

If you are starting HRT for the first time and do not have a regular menstrual bleed, start to take Hormonin Tablets on any convenient day.

If you are switching to Hormonin Tablets from another HRT, start to take Hormonin Tablets following the end of the previous HRT cycle.

If you wish to stop Hormonin Tablets, continue until the end of the 21 or 28 day cycle.

If you miss a dose

Take the tablet as soon as you remember, and take the next one at the normal time. However, if you have missed your tablet by more than 12 hours, discard the missed tablet and take the next one at the normal

time. Missing a dose may increase the likelihood of break-through bleeding and spotting.

If anyone takes an overdose of Hormonin

If you accidentally take one or two tablets more than your recommended dose, just return to the correct dose the following day and continue as normal after this.

If anyone takes a large number of these tablets, you should contact your doctor as soon as possible. An overdose of Hormonin is unlikely to cause any harm although it may make the person feel or be sick for a short time.

After taking Hormonin

Like all medicines, it may sometimes cause unwanted effects in some people. The following are unwanted effects that have been noticed by some people who have taken these or similar hormone tablets. If you notice any of them, or any other unwanted effect, tell your doctor.

- Tenderness or enlargement of the breasts, or fluid coming from the nipples (please refer to the earlier section on breast cancer)
- Feeling or being sick, indigestion
- Stomach or back pain, muscle cramps
- Pain or heaviness in the legs or chest, shortness of breath (please refer to the earlier section on your heart and circulation)
- Unexpected vaginal bleeding, painful, irregular or heavy periods
- Increased awareness of or size of fibroids, aggravation of endometriosis, increased vaginal discharge (please refer to the earlier section on endometrial cancer)
- The development of gallstones or jaundice (yellowing of skin and/or eyes)
- Headache, migraine, mood changes (elation or depression), forgetfulness
- Skin problems such as rash, brown patches on the skin, increased hair growth, or loss of scalp hair
- Discomfort of the eyes if contact lenses are used
- Weight change, or possible bloating related to water and sodium retention
- Tiredness, dizziness
- Hot flushes, thrush
- An inability to control your urine
- Increased blood pressure, which you may notice in the form of headaches.

Stop taking Hormonin at once and tell your doctor if:

- You become jaundiced (get yellowing of the skin or eyes) or you have itching all over your body
- You have an unusual, severe, or prolonged headache, or a migraine
- You have signs that you have had a stroke (your sight is affected in any way, you find it difficult to speak or, any part of your body suddenly feels weak or numb)
- You become pregnant
- You answer yes to any of the questions in the 'Before taking Hormonin' section.

Your Doctor may also tell you to stop taking Hormonin if your blood pressure increases.

How to store Hormonin Tablets

In order to protect your medicine from moisture, keep your tablets in the original package. Do not store above 25°C. Keep out of the reach and sight of children. Do not use after the 'use before' date that is printed on the label. Please return unused tablets to your pharmacist.

For further information on osteoporosis, please contact the National Osteoporosis Society, Camerton, Bath BA2 0PJ. Tel: 01761 471 771, Fax: 01761 471 104 or email: info@nos.org.uk.

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PL Holder and Distributor:
Amdipharm UK Limited, Capital House, 85 King William Street,
London EC4N 7BL, UK