

## 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

*[tibolone text in brackets]*

### **Breast cancer**

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

Taking HRT slightly increases the risk of breast cancer; so does having a later menopause. The risk for a post-menopausal woman taking oestrogen-only HRT for 5 years is about the same as for a woman of the same age who's still having periods over that time and not taking HRT. The risk for a woman who is taking oestrogen plus progestogen HRT is higher than for oestrogen-only HRT [and for tibolone] (but oestrogen 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 **oestrogen-only HRT** at age 50 and take it for **5 years**, the figure will be between **33 and 34 in 1000 (ie an extra 1-2 cases)**.

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

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

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

[For women who take **tibolone**, the number of extra cases of breast cancer are similar to the numbers for oestrogen-only HRT. ]

**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 **oestrogen-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 oestrogen helps to lower the extra risk.

**If you still have your womb**, your doctor may [or will usually] prescribe a progestogen as well as oestrogen. If so, these may be prescribed separately, or as a combined HRT product [or tibolone].

**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, *NAME*  contains a progestogen\*  
 is an oestrogen-only product\*

\*(select according to the actual product) – [not to be included in the tibolone PIL]

### 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 oestrogen-only HRT, the number will be 2 to 12 times higher, depending on the dose and how long you take it.

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

[The effect of tibolone on the risk of endometrial cancer is unknown.]

**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 oestrogen-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.

(suggested text for inclusion under side effects)

**Dementia:** 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.