

# Managing Menopause with Hormone Therapy



*Angeliq<sup>®</sup>*

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# Managing menopause

## Make the “Change of Life” a change for the better

The menopause is the phase in a woman's life associated with physical changes that signal the end of the reproductive years.<sup>1</sup> Menopause is not a disease, but the hormonal changes that occur at menopause can significantly affect a woman's quality of life.<sup>2</sup>



The menopause will bring with it a number of health challenges.<sup>3</sup> Not uncommonly, women feel overwhelmed and daunted by what they are led to believe may happen during menopause.<sup>3</sup> Yet, provided that women understand the “Change of Life” and their doctors individualise their care, the menopause can be a time of positive change.<sup>3</sup>

It's not that difficult to turn the change into a positive change.

It all depends on you, your attitude and finding the best way to manage your needs.

This booklet has been compiled to tell you more about the important life stage you are currently experiencing or approaching. Read through it and use it as a guideline to ease you through the physical and psychological changes you may experience.

**For more information, please speak to your doctor.**

## How to use this booklet



- 1 The first section of this booklet has been devoted to menopause and hormone therapy in general and will answer many of the questions you may have.
- 2 The second section gives you information on the product your doctor has prescribed for you: Angeliq®.



## Menopause and hormone therapy: Your questions answered

### What is menopause?

Starting in your mid to late 40's, you may experience physical and psychological changes over a space of a few years.<sup>1</sup> Although the menopause,<sup>4</sup> as a single event, refers to your final menstrual period, it is preceded by the premenopausal stage (ages 35 to 45) and the perimenopausal stage (ages 45 to 55).<sup>1</sup> The changes can occur well into your postmenopausal years (age 55 and over).<sup>2</sup>



Women may first notice shortened menstrual cycles, which may be more than 7 days shorter than the usual cycle.<sup>1</sup> Later on, periods may be skipped with intervals of more than 60 days between periods.<sup>1</sup> It is during this time that most women start to experience symptoms of menopause, such as hot flashes. However, there are studies that show that up to 40 % of women report hot flashes and night sweats at least 10 years before their menopause.<sup>1</sup>

On average, women have their last menstrual period at about age 51.<sup>3</sup> You will not be considered past menopause, however, until you haven't had a period for at least one year.

Menopause is really just another phase in your life and if you understand the physical changes that are taking place, you will be better prepared for the psychological changes. The menopause can be a time of positive change.<sup>3</sup>

### **What happens to the body during menopause?**

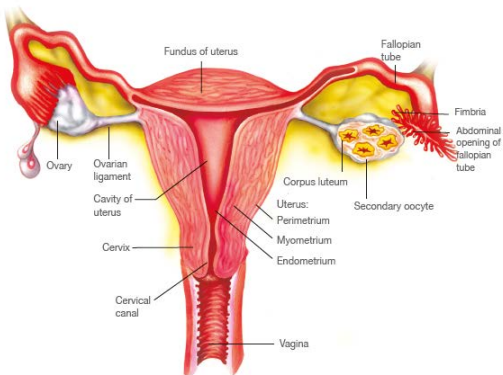
As you get older and go through natural menopause, the ovaries slowly start producing less and less of the hormone estrogen. During menopause, the ovaries stop producing estrogen completely and you stop having your monthly periods. It is the lack of estrogen that causes the symptoms of menopause.<sup>3</sup>

If, on the other hand, the ovaries are removed surgically, your body is deprived of estrogen all at once and you will experience symptoms of menopause suddenly, and possibly, with greater intensity.<sup>4</sup>

## Female hormones and how they work

The following illustration shows the female reproductive system and explains female hormone production during and after menopause. Use it to help you understand this section on hormones and the menstrual cycle.

### FEMALE REPRODUCTIVE SYSTEM<sup>5</sup>



## The menstrual cycle

Hormones are specialized chemicals produced by different organs in the body, regulating the way the body works. The female sex hormone, estrogen, is produced mainly by the ovaries and is responsible for a woman's development from childhood to womanhood.

Estrogen causes the breasts to develop and the body to change into its characteristic feminine shape. It also causes the reproductive organs to grow and mature, so that a woman is able to have children.<sup>5</sup>

Every month, estrogen and another sex hormone, progesterone, gradually cause a build-up of the lining of the womb (uterus). An egg (ovum) is released by the ovary every month (ovulation). If this egg is fertilised by a sperm, it attaches to the lining of the uterus (endometrium) and grows into a baby. If the egg is not fertilised, the endometrium breaks down and is shed, causing the monthly period (menstruation or menses).<sup>5</sup>

Estrogen is also important for skin and bones, plus some other organs, helping them remain in a healthy condition.<sup>6</sup>

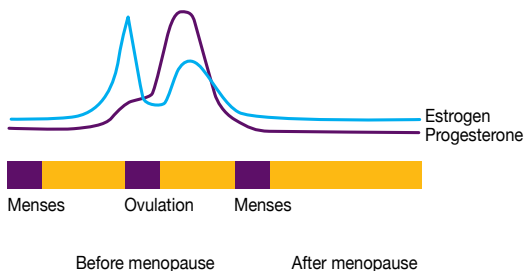
### **Does a hysterectomy affect menopause?<sup>6</sup>**

Usually, when a hysterectomy is performed, the uterus is removed, but not the ovaries. This means the ovaries function normally, as before, and the menopause is the same as for other women.

If the ovaries are also removed, an artificial menopause will follow immediately. Depending on the reason for the operation, some women will receive hormone therapy straight away, while others may not. Your doctor will explain if this applies to you.

If your uterus has been removed surgically, you only need to take estrogen to relieve the symptoms of menopause. *See the section on 'Types of Hormone Therapy' on page 12.*

## THE MENSTRUAL CYCLE



Adapted from Sturdee DW<sup>6</sup>

## SYMPTOMS OF MENOPAUSE



It is the lack of estrogen that causes the symptoms of menopause.<sup>3</sup> The earliest and most overwhelming menopausal symptoms are hot flashes, insomnia, night sweats and mood swings.<sup>3</sup>

Irritability, anxiety, aggression, weepiness and depression are the most common psychological symptoms.<sup>3</sup>

## **In the long term, estrogen deficiency may lead to the following:<sup>6</sup>**

- Your skin may get thinner and wrinkle more easily.
- The bladder lining becomes thinner and more prone to infection. This may be accompanied by less bladder control.
- Vaginal dryness and itching may occur, and sexual intercourse may be painful.

## **There is also a higher risk of osteoporosis and heart disease<sup>6</sup>**



### **Osteoporosis<sup>6</sup>**

Loss of bone mass occurs because calcium is depleted from bones when the supply of estrogen is reduced, making women past the menopause more prone to bone fractures and gradual 'breakdown' of bones. Fractures, which take longer to mend at this stage of life, can lead to complications.

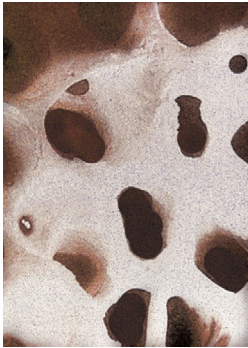


### **Heart disease<sup>6,7</sup>**

The incidence of heart disease and stroke increases after menopause. Before menopause, estrogen produced by the body helps to protect women from heart disease.



## NORMAL BONE VERSUS OSTEOPOROTIC BONE



Normal bone



Osteoporotic bone

## COMMON SITES OF OSTEOPOROTIC FRACTURES



Wrist fracture



Hip fracture



Vertebral fracture

Adapted from Sturdee DW<sup>6</sup>

## The effects of menopause<sup>1,3,6,8</sup>



### Mood or mental<sup>1,3</sup>

- Irritability
- Anxiety
- Aggression
- Depression
- Insomnia
- Weepiness



### Genito-urinary<sup>3</sup>

- Irregular menstrual periods
- Vaginal dryness and itching
- Painful intercourse
- Reduced bladder control
- Frequency and urgency
- Burning with urination



### Bone<sup>6</sup>

- Bone loss
- Higher risk of osteoporosis
- Higher risk of fracture



### Vasomotor<sup>3</sup>

- Hot flushes
- Night sweats



### Skin and hair<sup>6,8</sup>

- Skin dryness and thinning
- Thinning of body hair
- Thinning of scalp hair



### Heart<sup>6</sup>

- Higher risk of heart disease

## What will hormone therapy do for you?

The simple aim of hormone therapy is to replace the estrogen that your ovaries have stopped producing. Hormone therapy is the only therapy that effectively treats the symptoms of menopause while also protecting bone.<sup>1</sup>

There is overwhelming evidence to support the fact that hormone therapy relieves menopausal symptoms more effectively than any other medicine.<sup>3</sup> It therefore follows that women who will benefit the most from hormone therapy are those with symptoms of hot flashes, night sweats, insomnia, vaginal dryness or itching and bone loss.<sup>3</sup>

Hormone therapy can also help to improve vaginal lubrication, enhancing your comfort during, and desire for, sexual intercourse.<sup>9</sup>

Hormone therapy can make a significant contribution to your quality of life and normal social activity. It will help your skin look better, retain moisture and maintain its elasticity, giving you a more glowing and radiant complexion. Finally, hormone therapy has been shown to reduce the risk of colon cancer.<sup>10</sup>



Heart disease is the number one killer of women in the Western world.<sup>11</sup> The International Menopause Society has concluded that hormone therapy in healthy women 50 to 59 years of age, does not increase the risk of heart disease and may even decrease the risk in this age group.<sup>11</sup>

It is, however, important to reduce risk factors for heart disease, e.g. avoid smoking, reduce excess weight and undertake some form of aerobic exercise. If you have high blood pressure or raised cholesterol, it may be necessary to use blood pressure medicines and cholesterol-lowering agents as recommended by your doctor to reduce your overall risk of heart disease.<sup>6</sup>

The increase in blood pressure with age is more marked in older women, so that by the age of 60 years, up to 80 % of women will have high blood pressure.<sup>11</sup> It is important for women with high blood pressure to strive for blood pressure control, since even small reductions in blood pressure can reduce the risk of heart disease.<sup>11</sup>

**Hormone therapy needs to be individualised to each woman's needs.<sup>1</sup> Discuss your requirements for hormone therapy with your doctor.**



## WHEN SHOULD HORMONE THERAPY BE STARTED?<sup>3</sup>

Hormone therapy should be started once the typical symptoms of menopause become apparent. These symptoms may occur while you are still having irregular or sporadic periods.<sup>3</sup> Speak to your doctor about your need for hormone therapy when you first start noticing symptoms.



## TYPES OF HORMONE THERAPY<sup>3</sup>

Hormone therapy is available as estrogen only or as a combination of estrogen and progestogen. Estrogens alone are only used in women who have had a hysterectomy. For a woman who still has a uterus in place, she must be given estrogen plus progestogen.<sup>3</sup> This is because estrogen taken alone in a woman with an intact uterus, can increase the risk of cancer of the lining of the uterus (i.e. the endometrium). By adding a progestogen, the risk of this cancer is reduced.

Depending on the availability in your country, hormone therapy is available as oral tablets, skin patches or gel, implants or in the form of vaginal creams or vaginal tablets.



## WHAT ARE THE EFFECTS OF HORMONE THERAPY ON MENSTRUAL PERIODS?<sup>3</sup>

Women who have had a hysterectomy do not have any menstrual periods, as the uterus has been removed.

Women who are still menstruating or if it is only a few months since their last period, it is usual to add cyclical progestogen to the estrogen.



In other words, a progestogen is added to estrogen for the last 10 to 14 days of the treatment cycle. This type of hormone therapy, called ‘cyclical’ or ‘sequential’ hormone therapy, provides a predictable bleeding cycle or ‘period’ at the end of each treatment cycle. These ‘periods’ are usually lighter than normal periods and often diminish with time.<sup>12</sup>

For women who have not had a period for at least one year, it is usual to give hormone therapy containing estrogen and progestogen every day. This continuous combined hormone therapy causes the periods to stop altogether. However, spotting or irregular bleeding can occur in the first few months. Within 6 to 9 months, most women stop having periods when using a continuous combined regimen.<sup>12</sup> To minimise spotting or irregular vaginal bleeding, women should only take a continuous combined regimen if they are at least one year past the menopause.<sup>12</sup>



## HOW LONG SHOULD YOU CONTINUE TAKING HORMONE THERAPY?

It takes about one week after starting hormone therapy for a woman to start noticing symptom relief.<sup>1</sup> After 3 weeks to 3 months of hormone therapy, there is significantly noticeable relief from menopausal symptoms.<sup>1</sup>

Women should see their doctor after 6 months of starting hormone therapy, and then, every year thereafter.<sup>1</sup> Hormone therapy may be continued for 5 years before the need to reassess whether therapy should be continued.<sup>1</sup>

It is very important to remember that regular check-ups by your doctor and a sound knowledge of the benefits and risks of hormone treatment, form an essential part of hormone therapy.

The duration of hormone therapy should be discussed with your doctor, who will individualise your treatment and explain the benefits and the risks to you.



### DOES HORMONE THERAPY DELAY MENOPAUSE?<sup>13</sup>

Hormone therapy does not affect or determine the age-related decline in the function of your ovaries. As such, hormone treatment does not delay menopause.



### DOES HORMONE THERAPY RESTORE FERTILITY?

Hormone therapy will not restore fertility in a menopausal woman.<sup>12</sup> Once you have passed your menopause, you cannot have children. Women who are still having periods before starting hormone therapy, however, need to use a contraceptive, usually a barrier method of contraception e.g. a condom. Hormone therapy is not a contraceptive.<sup>14</sup> Do not take an oral contraceptive while you are on hormone therapy.<sup>9</sup>



### WHAT ABOUT SIDE EFFECTS?<sup>14</sup>

Hormone therapy, like any other medicine, may cause side effects. These include nausea, breast tenderness, headache and dizziness.

Your doctor will individualise your hormone therapy regimen and review your treatment every year at your annual check-up.

## **Thrombosis<sup>10</sup>**

Hormone therapy may be associated with an increased risk of developing a thromboembolism (blood clot formation). If you or anyone in your immediate family has ever had a blood clot in the blood vessels of the legs or lungs, or if you are very overweight, talk to your doctor about this.



## **Breast cancer<sup>15</sup>**

Although breast cancer is 100 times more common in women than men, suggesting that female hormones play an important role in breast cancer, research has shown that there are many other factors involved in a woman's risk of developing breast cancer.<sup>15</sup>

- As women get older, the risk of breast cancer increases.<sup>15</sup>
- A body mass index of more than 30 kg/m<sup>2</sup> or regular consumption of alcohol increases the incidence of breast cancer.<sup>15</sup>
- Having your first period before 12 years of age or having your menopause after age 54 are factors associated with an increased incidence of breast cancer.<sup>15</sup>
- A family history of breast cancer in two first-degree relatives (mother, sister), doubles your risk of developing the disease.<sup>15</sup>





## WHO SHOULD NOT TAKE HORMONE THERAPY?

Hormone therapy should not be prescribed for some women, for instance, those with a history of liver disease, clotting problems, certain types of heart disease or estrogen-dependent cancers, as well as for porphyria sufferers.<sup>14,16</sup>



It is important to bear in mind that the contra-indications for hormone therapy are not the same as for the oral contraceptive pill.<sup>3</sup> Women should be counselled about the benefits and risks of hormone therapy, so that they can make an informed decision about whether or not to take hormone therapy.<sup>3</sup>



## Are the alternative (complementary) medicines for menopause effective?<sup>17</sup>

The herbal therapies used most frequently for menopause are black cohosh, dong quai, ginseng, red clover, evening primrose oil and liquorice. Phytoestrogens are also used. Phytoestrogens are non-steroidal compounds derived from plants that are structurally similar to estradiol. Isoflavones, a class of phytoestrogens, are found in soybeans, soy products, lentils, chickpeas and red clover.<sup>17</sup>

The efficacy of these alternative treatments has been questioned:<sup>17</sup>

### PHYTOESTROGENS<sup>17</sup>

- Several studies have shown negligible or no positive effects with isoflavonoid use.
- Additionally, there is some evidence that soy may contribute to breast cancer risk.
- Evaluating more than 1000 articles published during the past 25 years, it is clear that the proven clinical health benefits of hormone therapy far outweigh those of phytoestrogen.

Furthermore, there is no long-term safety data available for phytoestrogens.



## BLACK COHOSH<sup>17</sup>

- While a number of studies have been completed on black cohosh's therapeutic use, all have been of short duration (maximum 6 months); therefore no long-term safety data exists and bone protection is difficult to assess. Also of concern are three independent reports of black cohosh causing autoimmune hepatitis.<sup>17</sup>

## OTHER<sup>17</sup>

- No benefit has been demonstrated for dong quai, evening primrose oil or ginseng.
- The North American Menopause Society (NAMS) issued a statement on the use of soy foods, isoflavone supplements from soy or red clover, black cohosh or vitamin E alternative therapies for menopause relief, cautioning that, while short-term use is unlikely to do harm, there is insufficient evidence from clinical trials to either support or refute their efficacy.



## **Are bioidentical hormones safer than conventional hormone therapy?<sup>18</sup>**

Bioidentical hormones are derived primarily from plant sources (soy and wild Mexican yam root).<sup>18</sup> The end products (estradiol, estriol, estrone and progesterone) are then used alone, or in combination, to manage menopausal symptoms.<sup>18</sup> Bioidentical hormones have been promoted as potentially safer than conventional hormone therapy. However, there is a lack of data from studies to confirm that bioidentical hormones are safe or effective. Furthermore, compounded bioidentical hormone formulations may be associated with additional risks for variations in quality, purity and batch-to-batch consistency.<sup>18</sup>

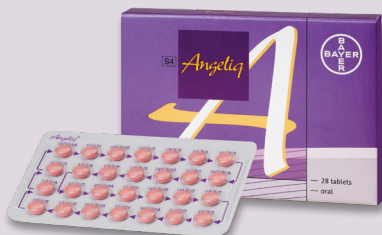
## **Unrealistic expectations**

Hormone therapy should not be regarded as a 'cure-all' or 'elixir of youth'. Some typical menopausal symptoms may be due to other factors such as mood or emotional disorders, partner conflicts, organic diseases etc. and may not be related to a hormonal deficiency at all.

## **The future**

While you may no longer be able to have children, your life can be as fulfilling, satisfying and productive as you wish it to be. Perhaps now more than ever, it is important to take really good care of your health, give up smoking and alcohol, eat well, exercise regularly and above all, have a positive attitude to life.

Prior to starting Angeliq<sup>®</sup>, please read the professional information, as it contains important and comprehensive product information.



## What is Angeliq<sup>®</sup> and how does it work?<sup>14</sup>

Angeliq<sup>®</sup> contains low-dose estrogen in combination with the progestogen, drospirenone. It is a continuous combined oral regimen, which means that estrogen and drospirenone (combined) are taken every day (continuous). Bleeding is uncommon after 12 months of use.<sup>6</sup>

Angeliq<sup>®</sup> is effective in treating the signs and symptoms of menopause by using a low dose of 1 mg estradiol to restore the hormonal balance. It also contains 2 mg of drospirenone, which protects the lining of the uterus.<sup>14</sup>

## How is Angeliq® different?<sup>19</sup>

Angeliq® is the first and only hormone therapy formulation to contain the unique progestogen, drospirenone. This progestogen is similar to progesterone found in the body.

### DROSPIRENONE:<sup>20</sup>

- reduces water retention
- reduces blood pressure
- reduces cholesterol
- maintains or reduces body weight



## How Angeliq® will help you cope with menopause

Angeliq® will provide you with many important health benefits.



### RELIEF OF MENOPAUSAL SYMPTOMS<sup>21</sup>

Angeliq® provides quick and effective relief of hot flashes, sleep disorders, anxiety, and urogenital symptoms (such as vaginal dryness).



### FREEDOM FROM BLEEDING EPISODES<sup>22</sup>

Angeliq® is a continuous combined hormone therapy preparation that leads to freedom from regular bleeds. During the first few months of treatment, bleeding and spotting are fairly common, but 74 % of women were already without bleeding after 3 months of treatment with Angeliq® and 88-94 % of women had no bleeding after 12 months.



### DOES NOT CAUSE WEIGHT GAIN<sup>19</sup>

The progestogen in Angeliq®, drospirenone, has unique properties that prevent estrogen-induced water retention and weight gain. Women receiving Angeliq® can expect either no weight change, or a small decrease in weight (about 1,2 kg after one year of treatment).



## ENHANCES QUALITY OF LIFE<sup>20,21</sup>

Angeliq® has been shown to enhance quality of life throughout treatment, enhancing mood and sexual functioning while providing relief from hot flushes, sweating, anxiety, concentration problems, menstrual problems and sleep problems.



## PREVENTS POSTMENOPAUSAL OSTEOPOROSIS<sup>22</sup>

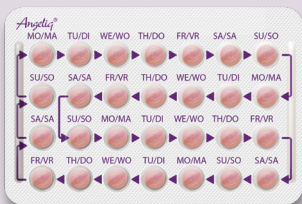
Angeliq® protects against postmenopausal osteoporosis by increasing bone density in the hip and spine and by decreasing bone loss.





## How to take Angeliq®<sup>14</sup>

- Take one tablet daily, following the direction of the arrows.
- Swallow the tablet whole.
- Do not crush, break or chew the tablet.
- Each pack of Angeliq® contains 28 tablets.



- Treatment is continuous. This means that the next pack is started immediately upon completing a pack. In other words, Angeliq® is taken continuously, without a break.
- Women starting hormone therapy for the first time or women switching from another continuous combined product, may start treatment at any time.
- Women switching from sequential or cyclic combined hormone therapy should start treatment at the end of their scheduled bleeding.
- If you miss a tablet, take it as soon as you remember. If, however, you only remember the next day, skip the missed dose and carry on taking Angeliq® tablets as before. Do not take a double dose.

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[S4] Angeliq® film-coated tablets. The pack contains 28 hormonal red film-coated tablets each with estradiol 1,0 mg (as estradiol hemihydrate) and drospirenone 2,0 mg. RSA Reg. No.: 37/21.8.2/0451. Namibia: [NS2] Reg. No.: 04/21.8.2/1466. Botswana: [S2] BOT0901586. Mauritius: PB/13134/07/2019.

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Collaboration Hub, 1st Floor, Waterfall Circle, 9 Country Estate Drive, Waterfall City, 2090, South Africa.

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EMBRACE CHANGE

**All you need to know about Angeliq®**

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