Bioidentical hormone therapy

Many women are attracted to the idea of using 'natural' forms of hormones that are identical to those produced by the body before menopause. For this reason, an industry has sprung up selling compounded bioidentical hormone therapies (BHT) with the claim that these are a better source of hormones.

Compounded BHT preparations are handmade by some pharmacists and are marketed as 'safe', natural and superior to conventional, pharmaceutical-grade menopause hormone therapy (MHT). Some marketing even claims the compounded BHTs have 'anti-ageing' effects. The marketing often describes MHT as 'synthetic' when, in fact, many MHTs contain the same hormones as those produced by the body.

As you will read below, these claims are either not true or are inaccurate.

The Australasian Menopause Society does not recommend the use of compounded bioidentical hormone therapy in any form including creams, lozenges and pessaries. If you are having menopausal symptoms, see your doctor to discuss your concerns and treatment options.

Compounded bioidentical hormones are not more 'natural' than MHT

Even if compounded BHTs are produced from plant sources, the hormones must be chemically synthesised in a laboratory, just like conventional MHT.

The oestradiol found in many conventional MHTs is the same hormone produced by ovaries before menopause, so many MHTs could also be described as 'natural' or 'bioidentical'. 'Bioidentical or 'body-identical' hormone therapies are terms which can be applied to pharmaceutical-registered MHT products where the hormones have the same chemical structure as those produced in the human body.

Many conventional MHTs contain hormones identical to those produced in the body

When using MHT, you can be assured the safety and effectiveness of the products has been widely tested and you can avoid the uncertainty and potential dangers of compounded BHTs. In most cases, MHT is also cheaper.

If you wish to use products containing pharmaceutical-grade body-identical hormones, the following approved and regulated products are available in Australia and New Zealand:

If you have any concerns or questions about options to manage your menopausal symptoms, visit your doctor or go to the Find an AMS Doctor service on the AMS website.

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MAIN POINTS

- The Australasian Menopause Society does not recommend the use of compounded bioidentical hormone therapy in any form.
- Many pharmaceutical-grade, approved menopause hormone therapies (MHTs) prescribed by your doctor are 'bodyidentical' – i.e. they contain hormones identical to those produced in the human body.
- Compounded bioidentical hormones (BHTs) are not more 'natural' – even when made from plants, they must be chemically synthesised in a laboratory.
- Compounded BHTs are not tested for quality, safety and negative side effects and they have been associated with cases of endometrial cancer.
- There is no evidence that compounded BHTs are effective and safe to use.
- oestradiol as tablets, transdermal patches or gel and as a vaginal treatment
- progesterone as capsules in Australia ('Prometrium') and NZ ('Utrogestan').

Compounded bioidentical hormones are not safer than MHT

The reputation and use of MHT went into decline after the highly publicised Women's Health Initiative (WHI) studies in 2002 and 2004 led to confusion among women and doctors. This contributed to the rise of the compounded BHT industry.

We now have a much better understanding of the risks and benefits of MHT, as more information has been collected and the WHI studies have been reassessed.

Today, there are many treatment options using regulated MHTs with known and tested quantities of hormones. These are available in many different combinations and forms such as tablets, transdermal patches, gels or vaginal treatments. Doctors can now tailor MHT for each woman's personal health situation to give the best possible results with the lowest possible risk.

In contrast:

- compounded BHT preparations have not been tested for quality, safety or negative side effects
- there is no way to know if compounded BHTs are contaminated with other additives
- compounded BHTs are not regulated and standardised like pharmaceutical-grade MHT.



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Bioidentical hormone therapy continued

Compounded bioidentical hormones have been associated with endometrial cancer

If you still have your uterus, your doctor can prescribe conventional MHT containing progestogens to protect your uterus and reduce the risk of endometrial cancer.

Of concern, compounded BHTs have been associated with cases of endometrial cancer, after the compounded progestogen component did not protect women from endometrial cancer.

Compounded bioidentical hormones do not work better than MHT

There is no evidence that compounded BHTs are more effective than conventional MHT. It is difficult to know the levels of hormones compounded BHTs will produce in your body for a number of reasons:

- Compounded BHTs are handmade for women often based on expensive, saliva testing for hormone levels – these tests are not standardised and are not quality controlled.
- Compounded BHTs are not regulated and standardised like pharmaceutical-grade MHTs.
- It is impossible to know the exact quantities of hormones in a handmade preparation of compounded BHT and it is impossible to know what else has been added or whether it is contaminated.

Even if compounded BHT preparations result in an adequate level of hormones in your body to decrease your menopausal symptoms, you will still have the side effects of those hormone levels and, at the same time, you will have no way of knowing if the compounded BHT is safe (see above).

Compounded bioidentical hormones are sold outside Pharmacy Board Guidelines

Compounded BHTs are sold outside Pharmacy Board Guidelines, which state that medications can be compounded only for research purposes or if a commercial product is not available or not suitable.

As pharmaceutical-grade MHTs are available and can deliver 'body-identical' hormones, this means compounded BHTs are not required and their preparation and sale is outside the guidelines.

Where can you find information about other treatment options?

If your symptoms are bothering you, your doctor can help. Your doctor can tell you about the changes in your body and offer options for managing your symptoms. Other AMS fact sheets about treatment options include:

- What is MHT and is it safe?
- Non-hormonal treatment options
- Complementary medicine options for menopausal symptoms
- Lifestyle and behaviour changes for menopausal symptoms.

Information for your doctor to read includes AMS Information Sheets:

- Custom compounded bioidentical hormone therapy
- Complementary and herbal therapies for hot flushes
- Risks and benefits of MHT/HRT

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