

'Bioidentical' Hormones

Women and health practitioners are constantly being given information about 'hormone imbalance' and how to deal with menopause 'naturally'. This information should be carefully considered, as it is important to understand that companies may just want to sell their products, rather than provide reliable and evidence-based information and treatments. Many women are turning away from approved pharmaceutical hormone replacement therapy (HRT) and are instead using unregulated hormonal preparations called 'bioidenticals'.

What are hormones and why do we have them?

Hormones are chemicals that are made in our body. They help control many body functions such as growth, energy, cell repair, reproduction, digestion and internal body temperature.

As women age, their production of particular sex hormones slows down due to a decrease of eggs in the ovaries (see 'Menopause' fact sheet for more information). These hormones include oestrogen, progesterone and testosterone. When these hormone levels decrease around the time of menopause, many women may experience symptoms such as hot flushes, vaginal dryness, urinary frequency, insomnia and changes in mood and sexual function. Some require hormone therapies to relieve moderate to severe symptoms to improve quality of life.

What are 'bioidentical' hormones?

'Bioidentical hormone replacement therapy' (BHRT) is a term used to describe a medication containing oestrogen, progesterone and sometimes other hormones like testosterone, that claims to be exactly the same as the hormones produced in our bodies. BHRT is prescribed by doctors and made up by particular pharmacists.

The makers of these hormone preparations have stated that they are natural 'bioidentical' hormones. In fact, 'bioidentical' hormones are all manufactured synthetically by a similar process to most hormones, including the pill and regulated HRT.

The issues with taking 'bioidentical' hormones

The problem with 'bioidentical' hormones is that they are 'custom compounded' (custom mixed), which means they are made for the individual woman and her hormone levels.

These medications do not have Therapeutic Goods Administration (TGA) approval. The TGA is a government body that assesses and monitors activities to ensure that therapeutic goods available in Australia are of an acceptable standard. 'Bioidentical' hormones don't have TGA approval because the individually mixed recipes have not been tested to prove that the ingredients are absorbed appropriately or react how they are expected to in the blood and tissue.

Safety and effectiveness

There is no evidence-based research to show that doses of 'bioidentical' hormone preparations made by compounding pharmacists are safe or effective. There is also no long-term research about the side effects or complications for women taking 'bioidentical' hormones. It is misleading to suggest that 'bioidenticals' have advantages over TGA approved pharmaceutical oestrogen therapies.

The US Food and Drug Administration (FDA) has started an action against compounding pharmacies making false and misleading messages and claims about the safety and effectiveness of bioidentical hormones. The FDA has also said that it believes 'bioidentical' to be a marketing term and not one of scientific or medical worth.

Compounded preparations (mixtures)

Compounded 'bioidentical' hormones require a doctor's prescription, like all hormone prescriptions. The difference is they are made up by pharmacists who call themselves 'compounding pharmacists'. There is no further training needed for compounding pharmacists, who are likely to have had the same training as your community pharmacist.

The pharmacists making the 'bioidentical' preparations do not have to follow the rules of the professional pharmaceutical body, Medicines Australia. This means there is limited quality control over the making of these preparations, which could possibly lead to unsafe and unreliable hormone preparations. There has also been no formal research into dosage and the dose prescribed is the responsibility of the prescribing doctor.

Please note: some TGA approved hormone products produced by pharmaceutical companies may also be referred to as 'bioidenticals', e.g. oestradiol patches.

Testing hormone levels

Doctors prescribing 'bioidentical' hormones monitor dosage by performing tests on hormone levels in saliva or blood. However, salivary and blood testing of hormone levels used by custom compounders is meaningless for women at midlife as their hormone levels vary throughout the day, and from day to day. There is also little link between blood hormone levels and menopausal symptom relief.

Differences between 'bioidentical hormone replacement therapy' (BHRT) and approved hormone replacement therapy (HRT):

Approved hormone replacement therapy:

- made by pharmaceutical companies
- strictly regulated
- evidence-based (tried and tested)
- approved for use by the TGA and FDA

Bioidentical hormone replacement therapy:

- made by select pharmacists
- inadequate regulation
- not evidence-based (not tried and tested)
- not approved for use by the TGA or FDA

See 'Hormone Replacement Therapy' fact sheet for more information on HRT.

It is important to be aware that BHRT should be considered as a form of hormone replacement therapy (HRT) and with that, carries the potential risk of developing conditions, such as thrombosis or breast and uterine cancer.

Things to remember

- There is no published evidence that 'bioidentical' hormones are safe to use and have no health risks.
- 'Bioidentical' hormones are not approved by the TGA or FDA and cannot be recommended until quality published research and trials have been conducted and made available.
- It is important when seeking any medical treatment that you consult with a health practitioner **face-to-face**. Receiving advice or a prescription for medication without a consultation is not advised.

If you are experiencing menopause symptoms, it is important to make sure you eat a healthy diet, do regular physical activity, look after your emotional wellbeing, and talk to your health practitioner. Speaking to your health practitioner allows you to discuss all the different options available to you.

Where can I get more information?

www.jeanhailes.org.au

www.tga.gov.au -Therapeutic Goods Administration

www.menopause.org.au – Australasian Menopause Society

www.endo-society.org – The Endocrine Society

www.imsociety.org – International Menopause Society

www.fda.gov –'Bio-Identicals: Sorting Myths and Facts'

This resource was developed with the support of the Australian Department of Health and Ageing

This fact sheet is designed to be informative and educational. It is not intended to provide specific medical advice or replace advice from your health practitioner.

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