

“Bio-identical” hormones

Women and physicians are constantly being given information about “hormone imbalance” and how to deal with menopause “naturally”.

Many are turning away from approved pharmaceutical postmenopausal hormone therapy (HT) available as a tablet, patch, gel, intranasal spray and or implant and using instead hormonal preparations, made up as lozenges or troches. These are sucked and the hormones absorbed through the mouth.

Some people have named these products “bio-identical” hormones.

These preparations require a doctor’s prescription and are made up by “compounding” pharmacies. Any one calling themselves a “compounding” pharmacist has exactly the same training as your usual pharmacist.

These preparations have not been approved by the government regulatory body for pharmaceutical products for Australia.

There has been no research into the safety or effectiveness of these hormonal treatments

There has been no research to identify the best dosage of these products to use.

These formulations are expensive and are no more “bio-identical” than oestrogen therapy available as government (TGA) approved oral and non-oral hormone therapies (patches, implants, gels).

The oestrogen present in many oral and all non-oral hormone therapies is exactly the oestrogen that occurs naturally in the human body- oestradiol. It is therefore misleading to suggest that "bio-identical" products have advantages over all TGA approved therapies.

It has also been suggested that the “bio-identical” preparations provide a unique mix of oestradiol, oestrone and oestriol, but in the body these different types of oestrogen are spontaneously made anyway when a woman uses oestradiol or oestrone as the primary form.

For oestrogen doses commonly given in these preparations, no studies have been conducted to show what is the lowest dose needed to treat symptoms, or what dose of progestin (progesterone) needs to be used to protect the lining of the uterus (endometrium) from over stimulation by oestrogen

There is no evidence from any published study that transdermal (skin) or buccally (mouth) absorbed progesterone will protect the lining of the uterus from conditions such as uterine cancer.

These oestrogen lozenges or troches are also sometimes combined with testosterone or DHEA or each of these is sometimes prescribed alone. DHEA is not approved for use in Australia at all.

Again, there is no evidence that any of the doses of the mixed preparations are safe or effective.

There is no published data on these products, yet some of the compounding pharmacies have issued documents recommending various doses and equivalent doses to TGA approved oestrogen therapies. Evidence for many of these recommendations is lacking

If you have been prescribed this kind of hormonal therapy you need to be aware that these compounds are not approved by the TGA in Australia and that they have not been subjected to rigorous evaluation for safety and effectiveness.