

Review of testosterone-containing medicines started

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Information on Testosterone containing products

- Testosterone is a natural hormone, known as an androgen, found in men and women. In men with hypogonadism, testosterone levels are abnormally low affecting normal sexual development.
- Testosterone-containing medicines work by replacing the missing testosterone, helping to restore normal testosterone levels to ensure normal sexual development in men. It can also be used in women in combination with oestrogens in the management of menopausal symptoms. The use of testosterone in healthy older men is not an authorised use in the EU, however, research in this area is ongoing.
- Testosterone-containing medicines have been authorised via national procedures under various trade names. They are available in various formulations such as oral capsules, implants to be injected under the skin, transdermal (applied to the skin) patches or as gels and solutions to be applied to the skin.

In Malta the following products are authorised and are prescription-only medicines;

Active Ingredients	Product Name	Authorisation Number
Testosterone 100mg	Testosterone Implant Implants 100mg	AA045/00701
Testosterone propionate 20mg, Testosterone phenylpropionate 40mg, Testosterone isocarproate 40mg	Sustanon 100	AA244/24901
Testosterone Enantate 250mg	Testosterone Enantate Ampoules	AA707/00501
Testosterone undecanoate 40mg	Restandol Testocaps 40mg capsule, soft	MA058/03301
Testosterone 50mg/5g	Testim 50mg Gel	MA832/00901
Testosterone undecanoate 250mg/ml	Nebido	MA 185/02701

Information from the European Medicines Agency about the safety concern

The review was triggered by the Estonian medicines agency, over concerns about side effects of medicines containing testosterone on the heart. The safety concerns were raised following the recent publication of a study¹ suggesting that the use of testosterone increases the risk of myocardial infarction (heart attack) in men aged over 65 years, as well as in younger men with

¹ Finkle et al. "Increased risk of non-fatal myocardial infarction following testosterone therapy prescription in men." PLoS One. 2014 Jan 29; 9(1): e85805.

pre-existing heart disease. This study follows other studies including the Veterans Health Care Study², which suggests that men with pre-existing heart disease who received treatment with testosterone had a higher risk of heart problems than men who did not receive testosterone.

The European Medicines Agency will now review all available data on the benefit-risk balance of testosterone-containing medicines (in men and women), and issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

² Vigen et al. "Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels" JAMA. 2013 Nov 6; 310 (17):1829-1836.

For more information please visit www.ema.europa.eu

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on testosterone containing medicines. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.