



BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46200 Petaling Jaya
Selangor Darul Ehsan
MALAYSIA



Tel. : +603-7883 5400
Faks (Fax) : +603-7956 2924
Laman Web (Web) : www.bpfk.gov.my

Ruj. Kami: (24) dlm. BPFK/PPP/07/25 Jld. 1

Tarikh : **29 SEP 2017**

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN (SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

ARAHAN PENGARAH KANAN PERKHIDMATAN FARMASI BILANGAN 19 TAHUN 2017: DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI TESTOSTERON: PENGEMASKINIAN SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP) DENGAN MAKLUMAT KESELAMATAN BERKAITAN KESAN ADVERS SUSULAN PENYALAHGUNAAN DAN KEBERGANTUNGAN UBAT

Adalah saya merujuk kepada Arahan Bilangan 19 Tahun 2017 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 19 Tahun 2017 telah bersetuju untuk menambah maklumat keselamatan berkaitan kesan advers susulan penyalahgunaan dan kebergantungan ubat bagi semua produk yang mengandungi testosteron seperti pada surat arahan Bil. (24) BPFK/PPP/07/25 Jld. 1.

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

Saya yang menurut perintah,

DR RAMLI ZAINAL (RPh 1045)

Pengarah Regulatori Farmasi
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

ra/nb/PPP/NPRA/120917

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SITI AIDA ABDULLAH
Timbalan Pengarah
Pusat Pembangunan Organisasi
Biro Pengawalan Farmaseutikal Kebangsaan
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Non Member Adherence to
Mutual Acceptance
of Data for GLP



**ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN
KAWALAN DADAH DAN KOSMETIK 1984**

BILANGAN 19 TAHUN 2017

**DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI TESTOSTERON:
PENGEMASKINIAN SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT
UNTUK PENGGUNA (RiMUP) DENGAN MAKLUMAT KESELAMATAN
BERKAITAN KESAN ADVERS SUSULAN PENYALAHGUNAAN DAN
KEBERGANTUNGAN UBAT**

TUJUAN

1.1 Arahan ini dikeluarkan oleh Pengarah Kanan Perkhidmatan Farmasi di bawah Peraturan 29 (1) Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984.

1.2 Arahan ini ditujukan kepada semua pemegang pendaftaran semua produk yang mengandungi testosteron bagi mengemaskini sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) dengan maklumat keselamatan berkaitan kesan advers susulan penyalahgunaan dan kebergantungan ubat.

LATAR BELAKANG

2.1 Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke **315** pada **29 Ogos 2017** telah membuat keputusan bagi semua produk yang mengandungi testosteron untuk mengemaskini sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) dengan maklumat keselamatan berkaitan kesan advers susulan penyalahgunaan dan kebergantungan ubat.

PELAKSANAAN

3.1 Oleh itu arahan – arahan berikut perlu dipatuhi untuk semua produk yang mengandungi testosteron seperti berikut:-

3.1.1 Sisip bungkus

Pada bagian *Warnings and Precautions*:

Drug Abuse and Dependence

Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids (AAS). Abuse of testosterone and other AAS are seen in adults and adolescents, including athletes and body builders. Testosterone and AAS abuse can lead to serious adverse outcomes particularly cardiovascular and psychiatric adverse events (See Section Adverse Effects/Undesirable Effects).

If testosterone abuse is suspected, check serum testosterone concentrations to ensure they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and AAS. Conversely, consider the possibility of testosterone and AAS abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.

Continued abuse of testosterone and other AAS may result in dependence and withdrawal symptoms. Individuals taking supratherapeutic doses of testosterone may experience withdrawal symptoms lasting for weeks or months which include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses of testosterone for approved indications has not been documented.

Pada bagian *Overdose*:

Chronic Overdose Caused by Abuse

Chronic overdose caused by abuse of testosterone and other anabolic androgenic steroids (AAS) can lead to serious adverse outcomes particularly cardiovascular and psychiatric adverse events (See Sections Warnings and Precautions and Adverse Effects/ Undesirable Effects).

Pada bagian *Adverse Effects/Undesirable Effects*:

Abuse-Related Adverse Reactions

Serious adverse reactions have been reported in individuals who abuse testosterone and anabolic androgenic steroids (AAS) and include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility and aggression.

The following adverse reactions have also been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidaemias, testicular atrophy, subfertility, and infertility.

The following additional adverse reactions have been reported in women: hirsutism, virilisation, deepening of voice, clitoral enlargement, breast atrophy, male-pattern baldness, and menstrual irregularities.

The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth, and precocious puberty.

Because these reactions are reported voluntarily from a population of uncertain size and may include abuse of other agents, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

3.1.2 Risalah Maklumat Ubat Untuk Pengguna (RiMUP)

Pada bahagian *How to use <product name>*:

If you use too much (overdose):

If you have taken more than the recommended dose of <product name>, contact your doctor immediately or go to the Emergency Department of your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking more than the recommended dose of <product name> for a long period of time can cause serious health problems including effects on the heart, liver, and reproductive functions, as well as serious psychiatric problems.

Pada bahagian *While you are using it*:

Things you must not do:

Do not take more than the recommended dose of <product name>. Individuals who have taken more than the recommended dose for a long period of time may experience withdrawal symptoms lasting for weeks or months after abrupt discontinuation or a significant dose reduction of <product name>. These include: changes in mood and appetite, fatigue, insomnia, decreased sex drive as well as loss of function of the testes and ovaries.

4. Tarikh pelaksanaan keperluan mengemaskini maklumat berkenaan pada semua produk yang mengandungi testosteron bagi:
 - (a) Permohonan baru dan produk yang sedang dalam proses penilaian : **1 Oktober 2017**
 - (b) Produk berdaftar : **1 April 2018**
5. Permohonan pindaan pada sisip bungkusan dan RiMUP bagi produk berdaftar perlu dikemukakan sebagai permohonan variasi.
6. Tarikh kuat kuasa arahan ini ialah mulai **1 Oktober 2017.**

“BERKHIDMAT UNTUK NEGARA”



(DR. SALMAH BT. BAHRI) RPh. 783
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

ra/nd/ppp/NPRA/080017

- s.k.
1. Pengarah Regulatori Farmasi
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia.
 2. Pengarah Amalan dan Perkembangan Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.
 3. Pengarah Penguatkuasa Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia