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Regulation of Medicines

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History of Drug Regulation

- **1906: Some medicines had harmful ingredients (eg heroin)**
  - US regulations introduced prohibiting misbranded or adulterated drugs or food
- **1937: Elixir Sulfanilamide Disaster**
  - Regulations revised to require new drugs to undergo safety testing; regulatory approval before marketing; adequate labelling of medicines; prohibition of false therapeutic claims; inspection of manufacturing facilities
- **1962: Thalidomide Disaster**
  - Regulations reviewed to require new medicines proven to be safe and effective; clinical trials adequate and well controlled; regulatory approval for clinical trials; Animal testing of safety of trial participants

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Regulation of Medicines

- **Why have drug regulations?**
  - To assure practitioners and patients about the chemical content efficacy and safety of medicines
  - To balance the requirements of the public for safe medicine with those of the pharmaceutical industry to make a profit
- **What do drug regulations define?**
  - Rules on manufacturing and purity of medicines
  - Animal data required before human studies start
  - Levels of safety and efficacy required for approval for marketing
  - Claims that can be made in drug advertising

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New Zealand Drug Regulation

Medicines control in New Zealand enforced by:

- The Medicines Act of 1981
- Medicines Regulations of 1984
- Misuse of Drugs Act 1972

Impose controls on clinical trials, manufacture, distribution, advertisement and sale of medicines

http://www.medsafe.govt.nz/

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

"Medsafe's mission is to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit."

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Approval for Marketing a Medicine in NZ

- Application to market a new medicine in New Zealand must be made to the Minister of Health by a New Zealand resident or company.
- Applications are reviewed by the Ministry of Health, or advisory committees (Medicines Assessment Advisory Committee).
- Recommendation is made to the Minister.
- Medicine may be distributed and advertised after notice of ministerial consent has been published in the New Zealand Gazette (official newspaper of the New Zealand Government published weekly).
- Minister of Health must be advised of any material change to the existing medicine.

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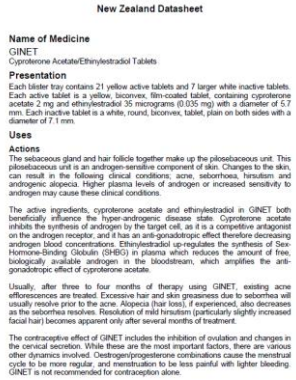
Labelling

- Part of the drug approval process consists of writing a "drug label"
- Contains data on the pharmacological actions, approved use, side effects and dosing of the drug for prescribers
- Content of the label is defined by law



New Zealand Datasheet

Name of Medicine

GINET
Cyproterone Acetate/Ethinylestradiol Tablets

Presentation

Each blister tray contains 21 yellow active tablets and 7 larger white inactive tablets. Each active tablet is a yellow, biconvex, film-coated tablet, containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms (0.035 mg) with a diameter of 5.7 mm. Each inactive tablet is a white, round, biconvex, tablet, plain on both sides with a diameter of 7.1 mm.

Uses

Actions

The sebaceous gland and hair follicle together make up the pilosebaceous unit. This pilosebaceous unit is an androgen-sensitive component of skin. Changes to the skin, can result in the following clinical conditions; acne, seborrhoea, hirsutism and androgenic alopecia. Higher plasma levels of androgen or increased sensitivity to androgen may cause these clinical conditions.

The active ingredients, cyproterone acetate and ethinylestradiol in GINET both beneficially influence the hyper-androgenic disease state. Cyproterone acetate inhibits the synthesis of androgen by the target cell, as it is a competitive antagonist on the androgen receptor, and it has an anti-gonadotropic effect therefore decreasing androgen blood concentrations. Ethinylestradiol up-regulates the synthesis of Sex-Hormone-Binding Globulin (SHBG) in plasma which reduces the amount of free, biologically available androgen in the bloodstream, which amplifies the anti-gonadotropic effect of cyproterone acetate.

Usually, after three to four months of therapy using GINET, existing acne efflorescences are treated. Excessive hair and skin greasiness due to seborrhea will usually resolve prior to the acne. Alopecia (hair loss), if experienced, also decreases as the seborrhea resolves. Resolution of mild hirsutism (particularly slightly increased facial hair) becomes apparent only after several months of treatment.

The contraceptive effect of GINET includes the inhibition of ovulation and changes in the cervical secretion. While these are the most important factors, there are various other dynamics involved. Oestrogen/progesterone combinations cause the menstrual cycle to be more regular, and menstruation to be less painful with lighter bleeding. GINET is not recommended for contraception alone.

http://www.medsafe.govt.nz/profs/Datasheet/DSForm.asp
http://www.medsafe.govt.nz/consumers/educational-material/Hormonal%20Contraceptives.pdf

Slide 7	**Approval of a Clinical Trial in NZ** • Any clinical investigation of an unregistered medicine or registered medicine for a new indication requires approval • submission of all preclinical and clinical data and clinical trial • applications assessed by The Health Research Council Standing Committee of Therapeutical Trials (SCOTT) **Regulation of Drug Distribution in NZ** • Controlled by a series of licences for manufacturers, packers, wholesalers and pharmacies • Inspections are carried out to ensure compliance with manufacturing and distribution regulations • New Zealand dependant on overseas authorities for regulating manufacture of imported medicines	
Slide 8	**Medicines Classification in New Zealand** • Occurs after a medicine is approved for marketing • Classified according to any restriction of its point of sale • Determine by an external advisory committee to the Ministry of Health (Medicines Classification Committee) • According to point of sale: – Prescription medicines, • can only be obtained on a prescription issued by a registered medical practitioner – Restricted medicines, • can only be sold personally by a pharmacist and the sale is recorded – General sales medicines, • available without any restriction on point of sale.	
Slide 9	**Controlled Drugs: Misuse of Drugs Act 1975** • **Class A:** virtually all prohibited, high potential for abuse, not used medically eg. heroin, cocaine, LSD • **Class B:** high potential for abuse but accepted medical use eg. morphine, amphetamine • **Class C:** lower potential for abuse eg. codeine, pholcodine, barbiturates **Misuse of Drugs Regulations 1977** • Class A or B – prescriptions written on special form provided by the Director General of Health – maximum supply 1 month, no repeats • Class C – maximum supply 1 month, 2 repeats • Dispensing of controlled drugs is recorded in a controlled drug register and prescription book	

Slide 10	**Legal Requirement of Prescriptions: Medicines Regulations of 1984** • Legibly and indelibly printed • signed, dated by prescriber • address of prescriber • title, surname, initial, date of birth (if < 13 yrs) of the person for the prescription given • name, strength, amount, dose, frequency of medicine • number of occasions that the medicine will be supplied • quantity not to excess 3 months supply	
Slide 11	**Prescribing Unapproved Medicines** • A medicine for which consent has not been given by the Minister of Health for sale, distribution or marketing **Can you prescribe an unapproved medicine?** **Section 29 of the Medicines Act** allows the sale or supply of unapproved medicines • Supplier must notify the Director-General of Health (via Medsafe) • Detailed records must be kept • The patient should be fully informed **Section 25 of the Medicines Act** allows the use of unapproved medicines	
Slide 12	**PHARMAC: Pharmaceutical Management Agency Ltd** • Manages pharmaceutical subsidies in New Zealand • decides - which pharmaceuticals are subsidised - level of subsidy - whether special authority or guidelines apply • advised by Pharmacology and Therapeutics Advisory Committee (PTAC) **Pharmaceutical Schedule** • Published by PHARMAC to notify of drug subsidies • Lists subsidised medicines, guidelines and conditions	