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Slimming using magistral formulas: what are the risks?

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ABSTRACT

Introduction: Magistral formulas (MF) are prepared by the pharmacist for a given patient according to a prescription and following technical and scientific compounding standards. MF are often used in weight loss regimens and contain blends of drugs (D) and plant (P) extracts. Associations potentiate interactions and related adverse effects, compromising effectiveness and risking the patient's health [1,2]. Thus, the purpose of this work is to give an overview of MF intended for slimming, prescribed by doctors, in a perspective of efficacy and safety.

Materials and methods: Slimming MF (prescribed to overweight women, as hard gelatine capsules, once or twice daily) were obtained in pharmacies and analysed in terms of labelled drug/bioactive composition and dosage, therapeutic indication/claim, recommended daily dose (RDD), side effects/interactions and contraindications. Written consent for data use was obtained.

Results: MF did not contain unlawful ingredients [3]. Actives were used mostly in sub therapeutic doses (Table 1). Weight loss is a result of (a) side effect of D-III/IV (off-label use), (b) water loss due to therapeutic action (D-I/IX and P-V/VII/VIII), or (c) claimed appetite reduction (P-VI/X/XI).

Discussion and conclusions: Off-label uses of drugs and efficacy of sub therapeutic doses are questionable. D-II,III present risk of abuse and dependence. Combination of laxatives (MF 1, 2 and 6) is not recommended, increasing the chances of electrolyte imbalance and dehydration, and reducing absorption of ansa diuretics. Clinical data to support the claims and posology of botanicals is scarce and contradictory; moreover, potential side effects/interactions are at times unknown and adulteration/contamination is a risk. Of note is the potential for interaction of P-V (inhibiting several isoenzymes of CYP450) and the association of D-I/P-V may cause hypovolemia and hypocaliemia. Even if no additional interactions were found between molecules, combinations may increase the risk of adverse events. Severe/fatal interactions may occur with other drugs (e.g. D-II + opioids; D-III + MAO inhibitors), so knowledge of patient's clinical history and related medication is of the utmost importance, when prescribing and counselling. Indeed, evaluation of safety and efficacy of MF is a shared responsibility of doctor and pharmacist and requires robust scientific data, especially regarding botanicals. Slimming medication alone, without lifestyle changes, is not effective in the long term and may pose a health risk, as pointed out in this study.

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Table 1. MF labels composition and dose (mg).

Active ingredient (AI)	MF1	MF2	MF3	MF4	MF5	MF6	MF7	Main therapeutic indication / claim	Usual posology in major pathology
Furosemide ^I	20	25		18	18	30		Diuretic	20–80/120 mg/day
Chlordiazepoxide ^{II}	8	8		8	8	10		Anxiolytic	30 mg (3 times/day)
Bupropion ^{III}	120	100		140	150	130		Antidepressant	150 mg (2 times/day)
Metformine ^{IV}	280		250	300	300	260		Antidiabetic	500 mg (2/3 times/day)
Artichoke ^V	110	400						Laxative	500 mg/day*
Bitter orange (<i>Citrus aurantium</i>) ^{VI}	150			200	200	200	200	Appetite reducer	50–100 mg/day*
<i>Centella asiatica</i> L. ^{VII}		400	400				750	Anti-cellulite, venotonic	60–120 mg/day*
Cascara Sagrada (<i>R. purshiana</i>) ^{VIII}		100		130		120		Laxative	150–325 mg/day*
Phenolphthalein ^{IX}	65	100			90	85		Laxative	30–200 mg/day
Glucomannan (<i>A. konjac</i>) ^X							500	Appetite reducer	1000–13,000 mg/day*
Slimalluma (<i>Caralluma fimbriata</i>) ^{XI}		300	250					Appetite reducer	500 mg (2 times/day)*

Roman superscripts identify the substance in the text.

*RDD not well established.

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Polyhexanide and chlorhexidine loaded chitosan wound dressings

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ABSTRACT

Introduction: Wounds may be caused by surgery, trauma, or as a result of diseases such as diabetes. The disruption of the skin/internal tissues and the contact with the external environment may lead to microbial infection. Wound dressings are capable of providing a protective barrier and accelerate the wound healing process [1]. Chitosan is one of the most promising materials for wound dressings, due to its good biocompatibility, low toxicity, haemostatic properties, antibacterial activity and biodegradability [2]. The main goal of this work is to produce chitosan-based hydrogels to be used as efficient and safe drug delivery platforms.

Materials and methods: Two different chitosan-based materials were produced starting from Bioceramed formulations, AbsorKi (suitable for absorbing exudate from the wound) and HemoKi (enhancing haemostasis). The latter was modified by the addition of genipin, a cross-linking agent. The dressings were individually loaded with two different drugs, polyhexamethylene biguanide (PHMB, also called polyhexanide) and chlorhexidine diacetate (CHX), by soaking in solutions containing each drug (24 h, 5 mL, 36 °C, 180 rpm, 0.5 mg/mL for PHMB and 5 mg/mL for CHX). The physical properties (swelling, tensile strength) of the materials were studied prior and upon sterilisation by high hydrostatic pressure (HHP, 600 MPa, 10 min, 70 °C). Surface morphology was analysed by scanning electron microscopy (SEM). *In vitro* drug release studies were performed with a Franz diffusion cell system, combined with UV-Vis absorption spectroscopy for drug quantification. The efficiency of HHP was evaluated by sterility tests. Chorioallantoic membrane (HET-CAM) tests were done to study potential irritation of the skin.

Results: Both dressings present a porous structure and an extremely high swelling capacity (>1700%) before sterilisation. HHP affected the materials in different ways: it increased the swelling capacity of AbsorKi but decreased it for HemoKi. The drug release profiles indicated that the concentrations of PHMB and CHX increased in a sustained way on the first day. HHP increases the amount of drug released, except for AbsorKi with PHMB. Regarding the mechanical properties, sterilisation improved the resistance of both dressings. HET-CAM tests suggest that the produced materials do not lead to irritation.

Discussion and conclusions: HHP revealed an efficient method to ensure the materials sterilisation making the drug loaded wound dressings potentially efficient devices for the absorption of exudate from the wound bed. The combination of chitosan, a natural antibacterial agent, with the studied disinfectant and antiseptic drugs may lead to promising materials to be used as drug delivery platforms. Further studies in animal models are needed to conclude about the safety and clinical usefulness of the developed dressings.

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