MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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LABELLING OF MEDICINES CONTAINING SUGARS

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. It is not intended as an exclusive approach. Council reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The MCC is committed to ensure that all registered medicines will be of the required quality, safety and efficacy. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website.

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1 Introduction

Regulation 8 (1) (h) (i) of the Medicines and Related Substances Act of 1965 (Act 101 of 1965), requires that the quantity of "sugar" be indicated on the labels of medicines for administration by the oral or parenteral route for all medicines intended for human use. The regulation apparently refers to "sucrose", with the aim of protecting persons with diabetes. However, confusion may arise when taking into account the fact that the definition/meaning of "sugar" chemically includes fructose, galactose, glucose, lactose, mannitol, sorbitol, etc, but often the word "sugar" is ascribed to "sucrose". There is no reference to "sugar" in the Act itself, and no definition of "sugar" in the regulations.

Regulation 9 (1) (c) (v) of the Act requires that the package insert of a medicine for oral administration should include the words "**contains sugar**" or "**sugar free**", whichever is applicable.

Where the product contains sugar, this should be indicated as "contains sugar (name of sugar)" e.g "Contains sugar (lactose)" or "Contains sugar (lactose and sucrose)".

"**Sugar free**" must only be used when the medicine contains **none** of the following sugars: Glucose, honey, invert sugar, lactose, fructose, maltose, and sucrose.

This guideline is intended to provide guidance to applicants on how to label medicines containing "sugar" so as to alert prescribers and users who need to take cognisance of the presence of any sugar in the medicine and to take the necessary steps or decisions.

For the purposes of this guideline, "labelling" refers to the information included on the label (immediate and outer container), package insert (PI) and patient information leaflet (PIL) in accordance with the requirements of the regulations referred to above.

2 Definitions

Sugar

Unless otherwise specifically indicated, the term "sugar" means any of a class of natural, water-soluble crystalline carbohydrates, of relatively low molecular weight, and typically having a sweet taste, and classified as monosaccharides, disaccharides, trisaccharides, etc, depending on the polymeric composition. Examples include sucrose, fructose, glucose, and lactose. This guideline also includes related alcohols such as sorbitol, mannitol, and xylitol.

The simple sugars are referred to as monosaccharides. The more complex sugars comprise between two and ten monosaccharides linked together: The term "table sugar" refers to "sucrose".

This guideline does not include any synthetic substances used as sweeteners or as substitutes for sucrose.

3 Labelling Requirements for Sugars

Sugars required to be declared in the labelling of medicines

Reference to sugar in this guideline includes all sugars and the sugar alcohols. The names of sugars listed under "Ingredient Name(s)" in the table are indicative and do not constitute a complete or formal list. The table below identifies the sugars that must be declared in the labelling. The INN (International Non-proprietary Names) designations have been used unless otherwise indicated.

Ingredient Group or Name	Conditions and Special Labelling Requirements	Ingredient Name(s)
Sugars* - Mono-saccharides & disaccharides (See also Note 1)	Where present *In addition:* ***For lactose*** **Condition:** Lactose forms part of total sugars for the purposes of determining if the sugars will have a significant glycaemic effect and for calculating the total daily dose. **PI: WARNINGS AND SPECIAL PRECAUTIONS** Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take #X **PIL: Important information about some of the ingredients of #X**: #X contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take #X. **PI: WARNINGS AND SPECIAL PRECAUTIONS** ***For galactose*** Contains galactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, or glucose-galactose malabsorption, should not take #X. **PIL: Important information about some of the ingredients of #X:** Patients with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take #X. ****For sucrose*** **PI: WARNINGS AND SPECIAL PRECAUTIONS** Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take #X. **PIL: Important information about some of the ingredients of #X**: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking #X	Glucose Dextrose Honey (as a mixture of sugars) Invert sugar *Lactose Maltose Sucrose **Galactose

Ingredient Group or Name	Conditions and Special Labelling Requirements	Ingredient Name(s)
	****For all sugars* **PI: WARNINGS AND SPECIAL PRECAUTIONS** Contains [name the sugar] which may have an effect on the glycaemic control of patients with diabetes mellitus. **PIL: Important information about some of the ingredients of #X**: #X contains [name the sugar] which may have an effect on the control of your blood sugar if you have diabetes mellitus. #X = Proprietary name	
Sugar alcohols	**Condition:** Where the total sugar alcohol content of the formulation exceeds 10 g per maximum recommended daily dose. *In the package insert and PIL under:* **PI: WARNINGS AND SPECIAL PRECAUTIONS** "Contains (name of sugar alcohol) and may have a laxative effect." **PIL: Important information about some of the ingredients of #X:** #X contains (name of sugar alcohol) and may have a laxative effect. *In addition for **sorbitol / maltitol / lactitol** where present [irrespective of the quantity]*: *In the package insert and PIL under:* **PI: WARNINGS AND SPECIAL PRECAUTIONS** "Patients with the rare hereditary condition of sorbitol / maltitol / lactitol intolerance should not take #X." **PIL: Important information about some of the ingredients of #X:** #X contains (name of sugar alcohol). If you have been told that you have an intolerance to some sugars, you should not take #X	Isomalt Lactitol Maltitol Mannitol Sorbitol Xylitol

Note 1: Sugars - Monosaccharides and disaccharides - some sugar derivatives may not have a significant impact on glycaemic control.

4 Update History

Date	Reason for update	Version & publication
July 2013	Published for comment	Version 1 June 2013
Dec 2015	Published for implementation	Version 1 Dec 2015
	Date of implementation	
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02 Jan 2017	Registered products	