



MCAZ/ EVR/GL -number

GUIDELINE ON PRODUCT INFORMATION AND LABELLING

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1.0 APPLICATION

This guideline applies to all applicants submitting product registration, variation, or renewal applications for human allopathic medicines to the Medicines Control Authority of Zimbabwe (MCAZ). It outlines the requirements for labelling of medicinal products intended for human use, including immediate and outer packaging, package inserts, patient information leaflets (PILs), and/or Summary of Product Characteristics (PI).

2.0 PURPOSE

The purpose of this guideline is to ensure that product labelling provides clear, accurate, and comprehensive information to support the safe and effective use of medicines. It aims to harmonize labelling standards with regional and international best practices, including SADC and WHO recommendations.

3.0 BACKGROUND

Product labelling is a critical component of medicine regulation. It serves as a primary source of information for healthcare professionals, patients, and regulatory authorities. Proper labelling helps prevent medication errors, supports pharmacovigilance, and ensures compliance with legal and regulatory requirements.

This guideline aligns with the SADC harmonized framework and incorporates key elements from the SADC Guideline on Product Information and Labelling (Version 4, June 2019).

4.0 DEFINITIONS

The following definitions are provided to facilitate interpretation of the guidelines.

- 4.1 Applicant: the person or entity by, or on whose behalf, an application for registration is made.
- 4.2 Category for Distribution: Classification of medicines based on their regulatory control (e.g., Prescription Only, Pharmacy Only, Household Remedy).
- 4.3 Immediate Packaging/ Primary packaging: The container or other form of packaging that is in direct contact with the medicine.
- 4.4 Label: All information that appears on any part of the container or packaging.
- 4.5 Manufacturer: A company that carries out operations such as production, packaging, repackaging, labelling, and re-labelling of medical products.
- 4.6 MASCA: Medicines and Allied Substances Control Act Chapter 15:03
- 4.7 Outer Packaging/ secondary packaging: The packaging into which the immediate packaging is placed.
- 4.8 Package Insert (PI): A document intended for healthcare professionals containing detailed scientific and clinical information about the medicine.
- 4.9 Patient Information Leaflet (PIL): A simplified version of the PI intended for patients, written in lay language.
- 4.10 Principal: A person or entity that owns the medicine

- 4.11 Product Information (PI): A comprehensive document that includes both the PI and PIL, as well as regulatory and technical details.
- 4.12 SmPC: Summary of Product Characteristics.
- 4.13 Stakeholders: Entities or individuals affected by or interested in SmPCs, including patients, healthcare providers, and manufacturers.
- 4.14 Unique Identification Number: A globally standardized code (e.g., GTIN or UDI) used to uniquely identify a pharmaceutical product, enabling traceability, authentication, and regulatory compliance across the supply chain.

5.0 GUIDELINES

5.1 Applicant Responsibilities

5.1.1 At Submission

Applicants must submit proposed, package insert (SmpC), PIL, and labels for both immediate and outer packaging as part of the registration dossier. Colour mock-ups and final container samples are required.

5.1.2 Category for distribution

Please note that the Authority reserves the right to determine the appropriate category for distribution of a medicine as set out in the sixth schedule of the Medicines and Allied Substances Control Regulations (Statutory Instrument 150 of 1991).

The categories are:

- a) Narcotic Medicines or Dangerous Drug (abbreviated as “N”) - products containing ingredients stated as such in the legislation and which may be subject to control by the International Narcotics Board.
- b) Prescription Preparations (P.P.) – medicines belonging to this category are available on prescription only.
- c) Prescription Preparations Tenth Schedule (P.P.10) – medicines belonging to this category are available on prescription and are mainly used for chronic conditions and can be given under emergency use cases.
- d) Specially Restricted Preparations (S.R.) - Possession is restricted to pharmacies at central hospitals, and the prescription is to be certified by a Medical Superintendent at such a hospital.
- e) Pharmacist Initiated Medicines (P.I.M.) – medicines that may be initiated and dispensed by a pharmacist without a prescription.
- f) Pharmacy Medicines (P) - these products are available from licensed pharmacies only.
- g) Household Remedies (H.R.) - Medicines in this category are available in pharmacies, dispensaries, and all licensed trade supermarkets.

5.1.3 Format and Presentation

Labels must be legible, durable, and printed in English.

6.0 PRODUCT LABELLING

The Primary Packaging Label should comply with the Medicines and Allied Substances Control Regulations (S.I. 150 of 1991) with at least the following:

6.1 Primary and secondary packaging

Minimum information on the outer packing (or secondary packaging) and the immediate packaging (primary packaging).

- i. the (brand) name of the medicine;
- ii. the name(s) (generic name) of all active ingredients in the medicine;
- iii. the quantity or proportion of all active ingredient(s) in the medicine per dosage unit; the name of the dosage form;
- iv. the content of the medicine package expressed in the appropriate unit or volume of the medicine;
- v. the batch number of the medicine;
- vi. the manufacturing AND expiry date of the medicine in an un-coded form;
- vii. the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;
- viii. The name and address of the manufacturer;
- ix. the name and address of the principal;
- x. where applicable, the instruction 'Shake the bottle before use';
- xi. where applicable, the statement: 'For external use only';
- xii. in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the authority the warning 'Do not use more than 30 days after opening';
- xiii. the warning: 'Keep out of reach of children';
- xiv. the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;
- xv. the approved name of any anti-oxidant contained in the medicine;
- xvi. in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;
- xvii. if the medicine requires some preparation, such as dissolving, suspending, diluting or reconstituting before use - instructions for its preparation and, where relevant, a statement of the conditions of storage and the maximum period of storage between preparation and use;
- xviii. relevant warning statements, where these are required in relation to a particular medicine e.g. list of excipients known to be a safety concern for some patients i.e.

contains tartrazine, alcohol, sugar etc. any warning should be in a different colour to the colour used for the rest of the text;

- xix. approved indications where practical, for use of the medicine;
- xx. the recommended dosage of the medicine, where practical;
- xxi. For active ingredients that are present as salts, hydrates or solvates, it is recommended that the applicant includes the name of the salt, hydrate or solvate form on the main label;

Example	Recommendation
The active ingredient is present as the salt of a base or acid and it is established that the strength is labelled in terms of the formulated amount of that salt.	Use the name of the salt on all labels (e.g. metformin hydrochloride 500 mg and raloxifene hydrochloride 60 mg).
The active ingredients are present as a hydrate or solvate (such as dapagliflozin propanediol monohydrate), where the strength of the medicine is expressed on the solvent-free basis.	Include the hydrate or solvate in brackets, as in the case for a salt, e.g. dapagliflozin 10 mg (as propanediol monohydrate). If the available label space precludes this, you may omit the name of the solvate (e.g. dapagliflozin 10mg) on labels other than the main label.

- xxii. the registration number of the medicine;
- xxiii. category for distribution.

NOTE: For medicines that differ in strength, but otherwise have the same name, colour must be used to emphasise the strength, so as to differentiate between different labels. When the innovator medicine uses colour differentiation, it is recommended to sponsors of generic medicines to use the same colour scheme as the innovator to differentiate the strengths of their products.

Labels should also be distinct and different from other medical products.

6.1.1 For containers of less than or equal to 10 ml capacity

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container need only contain:

- i. the (brand) name of the medicine;
- ii. the name(s) (generic name) of all active ingredient(s) in the medicine per dosage unit;
- iii. the quantity or proportion of all active ingredients in the medicine;
- iv. the name of the dosage form;

- v. the content of the medicine package expressed in the appropriate unit or volume of the medicine;
- vi. the batch number of the medicine;
- vii. the expiry date of the medicine;
- viii. The name and address of the manufacturer, company or person responsible for placing the product on the market, or a logo that unambiguously identifies the company;
- ix. directions for use, and any warnings or precautions if necessary;
- x. for active ingredients that are present as salts, hydrates or solvates, we recommend that you include the name of the salt, hydrate or solvate form on the main label;

Example	Recommendation
The active ingredient is present as the salt of a base or acid and it is established that the strength is labelled in terms of the formulated amount of that salt.	Use the name of the salt on all labels (e.g. metformin hydrochloride 500 mg and raloxifene hydrochloride 60 mg).
The active ingredients are present as a hydrate or solvate (such as dapagliflozin propanediol monohydrate), where the strength of the medicine is expressed on the solvent-free basis.	Include the hydrate or solvate in brackets, as in the case for a salt, e.g. dapagliflozin 10 mg (as propanediol monohydrate). If the available label space precludes this, you may omit the name of the solvate (e.g. dapagliflozin 10mg) on labels other than the main label.

- xi. general classification for supply i.e. category of distribution/scheduling status or category of distribution.

6.1.2 For blisters, strips, 1ml or 2ml and other similar small containers

For blisters, strips, 1ml or 2ml and other similar small containers as a minimum:

- i. the (brand) name of the medicine
- ii. the name(s) (generic name) of all active ingredients in the medicine
- iii. the quantity or proportion of all active ingredient(s) in the medicine per dosage unit
- iv. the name of the dosage form
- v. the batch number of the medicine
- vi. the expiry date of the medicine

- vii. For active ingredients that are present as salts, hydrates or solvates, we recommend that you include the name of the salt, hydrate or solvate form on the main label.

Example	Recommendation
The active ingredient is present as the salt of a base or acid and it is established that the strength is labelled in terms of the formulated amount of that salt.	Use the name of the salt on all labels (e.g. metformin hydrochloride 500 mg and raloxifene hydrochloride 60 mg).
The active ingredients are present as a hydrate or solvate (such as dapagliflozin propanediol monohydrate), where the strength of the medicine is expressed on the solvent-free basis.	Include the hydrate or solvate in brackets, as in the case for a salt, e.g. dapagliflozin 10 mg (as propanediol monohydrate). If the available label space precludes this, you may omit the name of the solvate (e.g. dapagliflozin 10mg) on labels other than the main label.

- It is recognised that blister strips are often cut up, even if there is no intention for individual dosage units to be supplied in this way. To help ensure the quality and safe use of these medicines, repeating the required information at least once every two dosage units whenever possible is recommended.
- It is also recommended that the particulars on the label remain visible until the last dose is removed. This may best be achieved using a random display where the information appears frequently across the blister strip.

6.1.3 Generic name on labels

For all labelling, the generic name should be clearly visible and legible to ensure accurate identification and safe use of the product.

This means that the generic name must:

- Be easily readable under normal conditions of use, without strain or ambiguity.
- The trade name must appear at least on the main display panel and the information panel (back panel).
- Be printed in a font type, size and colour that provide sufficient contrast with the background.
- Not be obscured, crowded, stylised, faded, blurred or distorted by graphics, branding elements, or packaging design.
- Appear in a prominent and consistent location on the label where healthcare professionals and patients can readily identify it.
- Remain readable throughout the entire shelf life of the product, including after normal handling, storage and transportation.

6.1.4 Statutory requirements on outer labels

The following should appear on all labels:

- i. Provision for Zimbabwean registration details
- ii. Category for distribution
- iii. Provision for Unique Identification Number (Track and trace)

6.1.5 Provision for Unique Identification Number

The inclusion of a Unique Identification Number on product labelling shall be implemented in accordance with the phased approach outlined in the MCAZ/LED/GL-22 Guidelines for Implementing Traceability for Medical Products in Zimbabwe (refer to Page 11 of 12). Applicants are advised to align their submissions with the implementation timelines and technical specifications defined therein.

PRODUCT INFORMATION

7.0 PATIENT INFORMATION LEAFLET (PIL)

7.1 Trade name (proprietary name) in the body of text

For multisource (generic) products, the applicant shall not include the trade name (proprietary name) in the body of text of the package insert unless clinical studies were conducted. Only the generic (non-proprietary) name should be used. Provision for Zimbabwean registration details should be made on the package insert.

7.2 Reference documents to be supplied

- An electronic copy (MS Word document) of the SmPC and the PIL should be included in the submission.

7.3 Legibility of the PIL

7.3.1 Print size and type

The information appearing in the package insert to be provided to the patient should be printed in a type having a minimum legibility (i.e. New Time Roman 12).

7.3.2 Syntax

- Lengthy sentences (i.e. more than 20 words) should be avoided.
- Where appropriate, bullet points should be used. A group of bullet points should be introduced with a colon and a single full stop should be placed at the end of the group. A list of bullet points should begin with the uncommon and specific case and end with the common or general case, unless this is inappropriate for the medicine.
- For example:

Tell your doctor or pharmacist if you suffer from:

- tuberculosis of the lungs
- any allergies that affect your lungs
- any chronic lung conditions.
- A minimum number of words should be used in the bullet points and not more than one sentence for each bullet point.
- There should be no more than nine items where the bullet points are simple and no more than five when these are complex.
- Abbreviations should be avoided. Pronouns (e.g. 'it') should be used in preference to repeating the name of the medicine, provided the context clarifies what the pronoun refers to.

7.3.3 Format of the package insert**7.3.3.1 Headings**

- Headings and sub-headings in the package insert and the order of the headings should be in line with the model template.
- Headings and sub-headings should be made conspicuous.
- More than two levels of headings may impair legibility.

7.3.3.2 Content

- The information contained in the patient information leaflet must be in accordance with the SmPC for the medicine
- The text must be phrased so that it is readily intelligible for the patient and address the patient or the caregiver.
- Where a specialised term is used, an explanation should be given.
- Repetition of information can sometimes be avoided by cross-referring to information that is under another heading.
- Information not relevant to the patient should be omitted.

7.3.3.3 Style

- An active and direct style should be used, by placing the verb at the beginning of the sentence,

For example:

- 'take one (1) tablet' instead of '1 tablet should be taken',
- 'you should...' is better than 'it is recommended...'

- ‘give one (1) medicine measureful...’ where a medicine is clearly indicated for children only
- This principle should be adapted as, for example, in the case of ‘If ... then’ instructions, such as: ‘If you feel ill, tell your doctor or pharmacist’.
- This guidance on style may not be appropriate in all languages, nor for all medicines (e.g. those which are not self-administered).
- Pictograms may be used as an additional measure if they make the message clearer to the patient but be without any element of a promotional nature.

7.3.3.4 Product Ranges

- In some instances, there should be a separate package insert for different pharmaceutical forms (e.g. oral and injectables).
- In the event of a medicine falling in two different categories of distribution/schedules, a separate package insert should be submitted for each category of distribution/schedule.

7.4 Model package insert

This section contains a model template for developing a package insert. Applicants are requested to follow the format stipulated in this section.

Explanatory Notes

An example of a model leaflet is presented in this Section, containing headings and text, which should be used together with examples of text formulated in consumer-intelligible language. For the purpose of explaining this model leaflet, the following tools are used:

- ***bold type*** for the headings.
- *normal type* for text which is either mandatory or usually relevant and is not a heading.
- *possible options which applicants should adapt e.g. for the relevant pharmaceutical dosage form, route of administration or population for which the medicine is intended (e.g. the mother of a child) are presented with a slash, e.g. take / give / use / are given / receive / administered. Mandatory statement should be adapted to the dosage form.*
- *text included [in italics] are explanatory notes. When these notes are taken out of the model package insert template, all relevant and mandatory text will remain.*
- *In this model all of the headings are numbered. However, for certain medicines, the headings may not all be relevant. In such instances, the corresponding headings should be omitted.*
- *Throughout the text, “X” indicates the (proprietary) name of the [] medicine.*

CATEGORY FOR DISTRIBUTION/SCHEDULING STATUS

- *[The category for distribution/scheduling status of the medicinal product as it appears in the SmPC]*

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

- *[The proprietary name of the medicinal product (referred to as X throughout this document) and the active ingredient(s) should be stated here in bold, followed by the strength and pharmaceutical form (i.e. as it appears in the SmPC).*
- *[For medicinal products available only on prescription]*
 - Read all of this leaflet carefully before you start taking / using / are given X
 - Keep this leaflet. You may need to read it again.
 - If you have further questions, please ask your doctor or your pharmacist.
 - X has been prescribed for you personally and you should not share your medicinal product with other people. It may harm them, even if their symptoms are the same as yours. (may be omitted if the medicinal product is not self-administered).
- *[For medicinal products available without a prescription]*
 - Read all of this leaflet carefully because it contains important information for you.
 - X is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use X carefully to get the best results from it.
 - Keep this leaflet. You may need to read it again.
 - Do not share X with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must see a doctor if your symptoms worsen or do not improve after (number of) days.

1. WHAT X IS AND WHAT IT IS USED FOR

- *[Full statement of the active substance(s) and excipient(s)]*
- *[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in the SmPC and in the language of the text: e.g.]*
 - The active substance is...
 - The other ingredients are... [These should be listed alphabetically. This should be in lower case, except at the start of a sentence and when it is a registered proprietary name e.g. Colourant®. If a preservative or alcohol (2 % or more) is present, the content of each must be indicated as required for the SmPC].
- *[The pharmacotherapeutic group or type of activity should be stated here using language intelligible to the patient, followed by brief description of the indications for use of the medicinal product].*

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE/USE X

Do not take / use X / You should not be given / administered X:

- If you are hypersensitive (allergic) to (active substance) or any of the other ingredients of X. [Include reference to residues, excipients, etc., if applicable].
- If you have absolute contraindications, Information on absolute contraindications, in accordance with the SmPC, should be provided here in patient-intelligible language. This should include chronic accompanying diseases (e.g. kidney insufficiency, liver insufficiency, diabetes and other metabolic diseases), contraindications due to interactions with other medicinal products, contraindications due to excipients and specified conditions for certain categories of users, e.g. children or the elderly. Care must be taken to ensure that complex details are not omitted. It is not acceptable to state only the common or major contraindications. Belief that a patient cannot understand a contraindication is not a reason for omitting it.

Warnings and Precautions:

- Tell your doctor or healthcare professional before being given the injection:
- Take special care/Special care should be taken with X
 - if you ...
 - when ...
- *[Information, in patient-understandable language in line with WARNINGS AND SPECIAL PRECAUTIONS in SmPC, on relative contraindications, warnings and appropriate special precautions for use should be provided here. Care must be taken to ensure that complex details are not omitted and that they are expressed in a way that patients can understand. It is not acceptable to include only the more common or major warnings/special precautions.]*
- *[A special precaution should be presented as implying the action a patient should take, rather than as factual information that describes a medical condition. The influence of the medicinal product on the patient's behaviour should be described. A differentiation should be made between the influence on cognitive abilities, reactivity and judgment.]*
 [Example]:
 - If you have asthma (or used to), because X can bring on an attack
 - If you are over 60...
 - If X is given to children...
 - X may make you sleepy
- *[Also describe cases (if any) in which the consumer should only use X after consultation with a medical practitioner. Include (as appropriate and if not mentioned in the previous section) reference to chronic accompanying diseases (renal insufficiency, liver insufficiency diabetes and other metabolic diseases).] [Where applicable, provide information on necessary examinations, which may be carried out by the medical practitioner prior to, or during, the therapy, for example tests carried out in order to exclude contraindications. Provide information (if there is any) about important symptoms which may be masked by the medicinal product or if the medicinal product influences laboratory values. If relevant, reference should be made here to possibilities for intolerance to various materials (e.g. disposable plastic syringes), which must be used as part of the medicinal product.]*

- *[Refer to the need for the avoidance of external influences, such as sunlight after the use of phototoxic medicinal products. Other warnings concerning for example other diseases and the influence of the medicinal product on behaviour should be described. Statements should also include for example, reference to discolorations of underwear as a result of changes in the colour of urine and stool.]*

Inference with daily activities

- *[Include whether X may be affected with mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.]*
- *[In the case of anaesthetic medicinal products or medicinal products used for conscious sedation, the above applies for 24 hours. The patient should not make any legal or contractual decisions or drink alcohol for that period of time.]*

Competitive Sport

- *[If relevant, include whether the medicinal product may lead to a positive test for a prohibited substance in competitive sport activities.]*

Children <and adolescents>

- *[When the medicinal product is indicated in children, the special warnings and precautions which are specific to this population (and identified as such in 'Special warnings and precautions for use' of the SmPc) should be included under this sub-heading. Where relevant, parents / caregivers should also be alerted in this section of potential children / teenager specific warnings included under "driving and using machines".]*
- *[If there is no indication in some or all subsets of the paediatric population, information should reflect the paediatric subsection of 'Posology and method of administration' of the SmPC], e.g. "Do not give X to children between the ages of x and y <years> <months> because <of the risk of [...]> <it does not work> <the potential benefits are not greater than the risks>, <it is unlikely to be safe>".*

Taking / Giving / Using other medicinal products with X:

- *[The following statement must be included:]*
 - Always tell your healthcare professional if you are taking any other medicinal product. (This includes complementary or traditional medicinal products.)
- *[Describe the effects of other medicinal products on the medicinal product in question and vice versa. Reference should be made to the intensification/weakening and the prolonging/shortening of effects. This information should be in line with the INTERACTIONS as in the SmPC.]*

Taking / Using / Receiving X with food and drink:

- *Interactions not related to medicinal products should be mentioned here. For example, patients should not consume milk in combination with tetracyclines and no alcohol should be consumed during treatment with benzodiazepines and other central nervous system depressants.]*

Pregnancy , Breastfeeding and Fertility:

- *[Include information given in the SmPC, in patient-understandable language. The following additional statement must be included:]*
 - If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicinal product.

Driving and using machines

- *[Include whether the medicinal product may affect mental and / or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment.]*
 - It is not always possible to predict to what extent X may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which X affects them.

Important information about some of the ingredients of X:

- *[If appropriate, details of those excipients for which it is important for the safe and effective use of the medicinal product. Information on intolerances to excipients (e.g. lactose monohydrate), including alcohol should be provided. Indicate “sugar free” if applicable.]*

3. HOW TO TAKE / USE X

- Do not share medicinal products prescribed for you with any other person.
- *[The following statements should be included, where applicable:]*
 - Always take X exactly as your doctor has instructed you. You should check with your doctor, pharmacist, nurse or any other healthcare professional if you are unsure.
 - The usual dose is...
- *[For medicinal products available only with a prescription, a statement such as the following should be included:]*
 - Your doctor will tell you how long your treatment with X will last. Do not stop treatment early because ... If you have the impression that the effect of X is too strong or too weak, tell your doctor or pharmacist.
- *[For medicinal products available without prescription:]*

- <Always <take> <use> [PRODUCT NAME] exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <,> <pharmacist> <or nurse> if you are not sure.>
- *[For medicinal products available without prescription:]*
 - *In particular, and if at all possible, for medicinal products available without a prescription, precise statements should be included on the usual duration of the therapy, the maximum duration of the therapy and intervals with no treatment, together with clear guidance on when to consult a doctor.]*
 - *[The instructions for proper use and the intended dosage ranges (individual and daily doses separately), as well as the maximum daily dose, the frequency, method, route of administration and the duration of treatment, should be stated if relevant. In addition, it may be necessary to explain the route of administration in consumer-intelligible language.]*
- *[Instructions should:*
 - *be used to tell patients what to do. They should not be used to justify or explain an action.*
 - *be described in a practical manner.*
 - *tell patients how to use the medicinal product properly.*
 - *be positive rather than negative, whenever possible. Negative instructions should only be used when the consumer should avoid specific actions.*
 - *be given as separate instructions when the consumer is to carry out two separate actions. Separate actions should not be compressed into a single sentence.*
 - *be numbered and put into the exact order that the consumer should follow.*
 - *usually be intelligible without explanations, so as not to overburden patients with information.] [Explanations should be used to expand on the reasons for instructions and not to give further information. Instructions may be presented in italics or other type with explanations in plain type, so as to give patients a guide as to the significance of the information.]*
- *[When applicable, there should be descriptions (if useful with illustrations) of opening techniques for child-resistant containers and other containers to be opened in an unusual manner.]*
- *[Some examples of statements that may be included here:]*
 - Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)
 - ...one or two tablets (500 to 1 000 mg of paracetamol) three times a day, this means a daily maximum of six tablets (3 000 mg of paracetamol)'
 - ...in the morning, at lunchtime, immediately before meals, with food, after food'
 - Do not swallow
 - Do not chew
 - Shake well before use
 - Dissolve the effervescent tablet in one glass of water. Then drink the contents of the whole glass'
 - Take X once a day, every day, at about the same time each day

- Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets
- Allow to reach room temperature before using (e.g. insulins)
- *[For medicinal products not self-administered] The route of administration should be included; Include*
 - You will not be expected to give yourself X. It will be given to you by a person who is qualified to do so.

If you take / use / more X than you should:

- *[Description of signs and symptoms of over dosage that the patient is able to recognize and actions to be taken]; The following statement must be included:*
 - In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.
- *[For medicinal products not self-administered]; The following may be acceptable:*
 - Since a healthcare professional will administer X, he/she will control the dosage. However, in the event of over dosage your doctor will manage the over dosage.

If you forget to take / missed a dose of X:

- *[Provide clear explanations of what should be done following irregular use of the medicinal product, e.g. Do not take / receive a double dose to make up for forgotten individual doses.*
- *[For medicinal products not self-administered]; The following may be acceptable:*
 - Since a healthcare professional will administer X, it is unlikely that the dose will be missed.

If you stop taking/using X:

- *[Indicate any effects of interruption or ending treatment early, if applicable. Indicate withdrawal effects when the treatment ends, if applicable]*
 - If you have any further question on the use of X ask your doctor, pharmacist, nurse and healthcare professional

4. POSSIBLE SIDE EFFECTS

- *[A description of the side effects should be provided. Begin this section with:]*
 - X can have side effects.
- *[The following statement must be included:]*
 - Not all side effects reported for X are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking X, please consult your doctor, pharmacist or other healthcare professional for advice.
- *[Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently use the term 'immediately'; for less urgent conditions use the phrase 'as soon as possible'.]*

- *[The information given on side effects should be in accordance with the SmPC. Side effects should be subdivided according to seriousness and frequency, or according to symptom type. Wherever possible, for all side effects the frequency with which they occur must be mentioned to allow patients to know the risk. Irrespective of their frequency, very serious, side effects of the medicinal product should be mentioned first or specially emphasized. This applies in particular to side effects where there is an urgent need to take action.]*
- *[The risk (frequency) of side effects may be presented using the terms “frequent” or “less frequent” if the information is available in the corresponding SmPC. Descriptors such as “common”, “rare”, etc. should not be used.]*
- *The following is an example of side effects grouped according to seriousness:]*
- If any of the following happens, stop taking X and tell your doctor immediately or go to the casualty department at your nearest hospital:
 - ‘swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing’,
 - ‘rash or itching’,
 - ‘fainting’
- These are all very serious side effects. If you have them, you may have had a serious reaction to X. You may need urgent medical attention or hospitalization. Tell your doctor, pharmacist, nurse or healthcare professional immediately or go to the casualty department at your nearest hospital if you notice any of the following:
 - chest pain,
 - angina,
 - changes in the way your heart beats, for example, if you notice it beating faster,
 - difficulty breathing,
 - signs of recurrent infections such as fever or sore throat,
 - less urine than is normal for you,
 - yellowing of the skin and eyes, also called jaundice.
- These are all very serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

Frequent side effects:

 - nausea (feeling sick),
 - abdominal cramps or stomach pains,
 - headache,
 - dizziness,
 - tiredness,
 - light-headedness,

Less frequent side effects:

 - dry cough,

- muscle cramps,
 - flatulence or wind,
 - diarrhoea,
 - loss of appetite.
- Should there be side effects that occur at the beginning of the treatment and then subside or that only occur after prolonged treatment, these are to be mentioned here.
 - *[Close this section with:]* If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist, nurse or healthcare professional.
 - **Reporting of side effects**
If you get side effects, talk to your <doctor><or><, ><pharmacist><or nurse>. This includes any possible side effect not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

5. HOW TO STORE X

- *[The following statement must be included in this section:]*
 - Store all medicinal products out of sight and reach of children.
- *[Where applicable, the following statements may be included:] [Storage conditions have to concur with that approved in the SmPC]*
 - Store at or below X 0C [Explain ideal storage environment]
 - Store at 2°C – 8°C (in a refrigerator)
 - Store in a freezer
 - Do not refrigerate / freeze [as appropriate]
 - Store in the original package / container
 - Keep the container in the outer carton
 - Keep the container tightly closed
- *[An additional short explanation of the storage conditions, in patient-friendly terms, should be included when appropriate, e.g.:]*
 - Protect from light / moisture
 - Do not store in a bathroom
 - Do not use after the expiry date stated on the label / carton / bottle
- *[Where applicable, shelf life after reconstitution, dilution or after first opening the container should be indicated]*
- *[Where appropriate, include a warning against any visible signs of deterioration]*
 - Do not use X if you notice (description of the visible signs of deterioration)
- *[Information on how to dispose of unused medicinal product, e.g.:]*
 - Return all unused medicinal product to your pharmacist.

- Do not dispose of unused medicinal product in drains or sewerage systems (e.g. toilets).
6. CONTENTS OF THE PACK AND OTHER INFORMATION What X contains: - The active pharmaceutical ingredient(s) is (are)... - The other ingredient(s) is (are)... What X looks like and contents of the pack: • <i>[A physical description, e.g. shape, colour, texture, imprint, etc., of the dosage form should be included here in accordance with the SmPC Information.]</i> • <i>[In accordance with information provided in the SmPC, include the pharmaceutical form, the number, volume or mass per package unit, pack size and a description of the packaging material, e.g. bottle, blister pack, etc.]</i> Marketing Authorisation Holder and Manufacturer • <i>[As in the SmPc]</i>
7. REGISTRATION NUMBER/MARKET AUTHORISATION NUMBER • <i>[As in the SmPC]</i>
8. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION • <i>[As in the SmPc]</i>
9. DATE OF REVISION OF THE TEXT • <i>[As in the SmPc]</i>

6.0 KEY RELEVANT DOCUMENTS

6.1 Dangerous Drugs

<https://www.mcaz.co.zw/wp-content/uploads/2021/11/Dangerous-Drugs-Act-1.pdf>

6.2 European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use

<https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human>

6.3 Medicines and Allied Substances Control Act Chapter 15:03

<https://www.mcaz.co.zw/wp-content/uploads/2021/11/Medicines-and-Allied-Substances-Control-Act-Chapter-1503-2.pdf>

- 6.4 Medicines and Allied Substances Control General Regulations SI 150 of 1991
<https://www.mcaz.co.zw/wp-content/uploads/2021/11/Medicines-and-Allied-Substances-Control-General-Regulations-1991SI-150-of-1991-1.pdf>
- 6.5 Southern African Development Community (SADC) Guideline On Product Information And Labelling
https://www.mcaz.co.zw/wp-content/uploads/2022/05/DRAFT_SADC_GUIDELINE_ON_PRODUCT_INFORMATION_LABELLING_version_4_26_Jun_2019.pdf

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Date Reviewed: N/A.
N/A	N/A	Reason for Change and Amendments The following changes/amendments were done from Revision ... to Revision N/A