

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES ON FORMAT AND CONTENT OF PATIENT INFORMATION
LEAFLET FOR MEDICINAL PRODUCTS**

(Made under Section 52 (1) of the Tanzania Food, Drugs and Cosmetics Act, 2003)

**First Edition
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1. GENERAL REQUIREMENTS

(a) The patient information leaflet text

Particulars in the patient information leaflet shall be easily legible, clearly comprehensible and indelible.

(b) Conformity with the Summary of Product Characteristics

The patient information leaflet text should be in conformity with the summary of products characteristics.

(c) Language

The labelling must be presented at least in English and/or Kiswahili.

2. PARTICULARS TO BE INCLUDED ON THE PATIENT INFORMATION LEAFLET

The patient information leaflet shall include the particulars outlined in the template in the following section.

The applicant should complete the template and delete the parts which are not applicable.

3. TEMPLATE FOR PATIENT INFORMATION LEAFLET

{{(Proprietary) name strength pharmaceutical form}}

{Active substance(s)}

Read all of this leaflet carefully before you start <taking><using> this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider><or><pharmacist>.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.>

In this leaflet:

- a) What {product name} is and what it is used for
- b) Before you <take><use> {product name}
- c) How to <take><use> {product name}
- d) Possible side effects
- e) How to store {product name}
- f) Further information

[Delete sections that are not applicable]

a) WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR

b) BEFORE YOU <TAKE><USE> {PRODUCT NAME}

Do not <take><use> {product name}

- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of {product name}.>
- <if ...>

Take special care with {product name}

- <if you ...>
- <when ...>
- <Before treatment with {product name},...>

<Taking><Using> other medicines

<Please tell your <doctor, health care provider><or><pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking><Using> {product name} with food and drink

Pregnancy and breast-feeding

<Ask your <doctor, health care provider><or><pharmacist> for advice before taking any medicine.>

Driving and using machines

- <Do not drive <because...>.>
- <Do not use any tools or machines.>

Important information about some of the ingredients of {product name}

c) HOW TO <TAKE><USE> {PRODUCT NAME}

<Always <take><use> {product name} exactly as your doctor or health care provider has told you. You should check with your <doctor, health care provider><or><pharmacist> if you are not sure.><The usual dose is...>

<Use in children>

If you <take><use> more {product name} than you should

If you forget to <take><use> {product name}

<Do not take a double dose to make up for a forgotten <tablet><dose><...>.>

If you stop <taking><using> {product name}

<If you have any further questions on the use of this product, ask your <doctor, health care provider><or><pharmacist>.>

d) POSSIBLE SIDE EFFECTS

Like all medicines, {product name} can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.

e) HOW TO STORE {PRODUCT NAME}

Keep out of the reach and sight of children.

<Do not store above °C>, <Store in the original <container><carton>>

Do not use {product name} after the expiry date which is stated on the <label><carton><bottle><...><after {abbreviation used for expiry date}>.><The expiry date refers to the last day of that month.>

<Do not use {product name} if you notice {description of the visible signs of deterioration}>.

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

f) FURTHER INFORMATION

What {product name} contains

- The active substance(s) is (are)...
- The other ingredient(s) is (are)...

What {product name} looks like and contents of the pack

Name and full physical address of Marketing Authorization Holder and Manufacturing site:-

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

For any information about this medicinal product, please contact the <local representative of the> supplier:

{Country}

{Name}

<{Address}

B-0000 {City}>

tel: + {telephone number}

<{e-mail}>

{Country}

{Name}

<{Address}

B-0000 {City}>

tel: + {telephone number}

<{e-mail}>

<as appropriate, add additional local representatives to the above table>

This leaflet was last approved in {MM/YYYY}.