



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Regarding the Patient Information Leaflet, the information to be provided and the accepted format are provided below.

<text> signifies information to be included

Text in black signifies format to be adopted

Text in blue are additional guidance notes to assist applicant/manufacture with the preparation of the PIL

Information in the patient information leaflet (PIL) should be in conformity with the SmPC.

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

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What <Product Name, Strength, dosage form> is and what it is used for
2. What you need to know before you <take><use> <Product Name>
3. How to take <Product Name, strength, dosage form>
4. Possible side effects
5. How to store <Product Name, strength, dosage form>
6. Contents of the pack and other information

1. **WHAT <PRODUCT NAME, STRENGTH, DOSAGE FORM> IS AND WHAT IT IS USED FOR**

The indication of the product and the population or age group that the formulation is applicable to should be stated. The pharmacological class, active ingredient(s), dosage form and mechanism of action of the product should also be stated in simple, easy to understand words.

2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE <PRODUCT NAME, STRENGTH, DOSAGE FORM>**

Do not take<Product Name, strength, dosage form>if you

<Check with your health care provider if you think that applies to you>

Take special care with<product name, strength, dosage form> (if applicable)

Conditions where taking the product would be harmful to the patient or where a potential harm to the patient exists should be stated (e.g. allergies, medical pre-disposition like G6PD, co-morbidity)

Look out for important symptoms

Signs and symptoms to look out for when taking the product which can be indications of serious underlying conditions should be stated.

If there are other possible side effects that could result from taking the product, this should be stated under section 4 and a reference should be made.

Protect other people

If the disease condition is infectious, then information on how to avoid transmitting the infection to other people should be provided if applicable.

<Discuss with your health care provider the precautions needed to avoid infecting other people>

Taking other medicines with <Product Name, strength, dosage form>

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

These medicines should not be used with <Product Name, strength, dosage form>

Other medicines with known interactions with the product should be provided

Pregnancy

Information on the use in pregnancy should be provided.

Breast-feeding

<If a mother wants to breastfeed her baby, she should ask her health care provider for advice on the risks and benefits>

Driving and using machines

<Product Name, strength, dosage form> is <likely> <unlikely> to affect your ability to drive or use machines>

3. HOW TO TAKE <PRODUCT NAME>

<Always take <product name, strength, dosage> as your healthcare provider instructs you to>

Information on how to take the product should be provided e.g. whether tablets should be swallowed whole with water, if crushing is permitted or whether tablet should be taken with or without food.

How much to take

The dosage and frequency of dosing of the product based on body weight should be provided for adults, adolescents, children and infants if applicable should be provided.

If the product is contraindicated in a particular age group, this should be stated under this section.

If you take more <Product Name, strength, dosage form> than you should

The likely effect of taking an overdose of the product should be stated.

<If you take too much <product name, strength, dosage form>, inform your health care provider or contact the nearest hospital for further advice>

If you forget to take <product name, strength, dosage form>

<If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose>

4. POSSIBLE SIDE EFFECTS

<Like all medicines, <Product Name, strength, dosage form> can cause side effects, but not everybody gets them>

Common Side Effects

Common side effects should be stated (affecting 1 in 10 people)

Uncommon Side Effects

Uncommon side effects should be stated (affecting 1 in 100 people)

Rare Side Effects

Rare side effects should be stated (affecting 1 in 1000 people)

Very Rare Side Effects

Very Rare side effects should be stated (affecting 1 in 10,000 people)

If You Get Side Effects

<Tell your healthcare provider if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet>

Other Possible Side Effects

If there are any other possible side effects especially those that can result from combinations with other medications, it should be stated here.

5. HOW TO STORE {PRODUCT NAME}

Keep out of the reach and sight of children.

<Do not store above 0°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, strength, dosage forms} 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.>

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]

[Please refer to "Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution" (CPMP/QWP/159/96/corr).]

<Read the package leaflet before use>.

6. FURTHER INFORMATION

What {product name} contains

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

[List all excipients **except solvents removed during processing**.]

[Grades/standards should **not** be indicated.]

[The ingredients of mixtures (colourants, inks, capsule shells) should be listed. Flavour ingredients do not need to be listed. Only the **solids** of the printing ink should be included, usually shellac and black iron oxide.]

What {product name, strength, dosage form} looks like and contents of the pack

[All pack sizes for this pharmaceutical form and strength should be detailed here; if appropriate indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.]

[The container/closure description should include all parts of the primary packaging including desiccant, void filler or adsorbent cotton filler and dosing device(s) if relevant. Dimensions/volume/capacity may be listed. Shape and colour of the bottle and the cap type (including plastic e.g. PP), should be stated. E.g.: Blisters: colour and transparent/opaque, with number of units per card and cards per box.]

[e.g. sealed LDPE bag, placed inside a round white HDPE bottle with plain PP screw cap and aluminium tagger (packs of 100 Tablets & 1000 Tablets] Note: ensure cap material is indicated.

Supplier and Manufacturer

{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>

<Keep out of the reach and sight of children>