



## **PATIENT INFORMATION LEAFLET**

<b>Document No:</b>	<b>FDA/DRI/DER/TP-PIL/2013/02</b>
<b>Date of First Adoption:</b>	<b>1st February 2013</b>
<b>Date of Issue:</b>	<b>1st March 2013</b>
<b>Version No:</b>	<b>02</b>

## **ACKNOWLEDGEMENT**

**The Food and Drugs Authority (FDA) acknowledges the technical support of the World Health Organization (WHO) in the development of this guideline.**

## PATIENT INFORMATION LEAFLET (PIL) TEMPLATE

*<text> signifies text to be selected or deleted as appropriate while {text} refers to information to be added.]*

### PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

**{{(Invented) name strength pharmaceutical form}}<sup>1</sup>**

{Active pharmaceutical ingredient(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 health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.>

#### **In this leaflet:**

1. What {PRODUCT NAME} is and what it is used for
2. Before you <take> <use> {PRODUCT NAME}
3. How to <take> <use> {PRODUCT NAME}
4. Possible side effects
5. How to store {PRODUCT NAME}
6. Further information

#### **1. WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR?**

#### **2. 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 health care provider 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 health care provider 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}**

**3. HOW TO <TAKE> <USE> {PRODUCT NAME}**

<Always <take> <use> {PRODUCT NAME} exactly as your health care provider has told you. You should check with your health care provider 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 health care provider.>

**4. 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 health care provider.

**5. 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.>

## **6. FURTHER INFORMATION**

### **What {PRODUCT NAME} contains:**

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

### **What {PRODUCT NAME} looks like and contents of the pack:**

#### **Manufacturer**

{Name and address}

<{tel}>

<{fax}>

<{email}>

**This leaflet was last approved on {MM/YYYY}.**