**PATIENT INFORMATION LEAFLET (PIL) TEMPLATE**

*[Should the product to which a completed patient information leaflet (PIL) refers be prequalified, the completed PIL will form Part 3 of the WHO Public Assessment Report that will be posted on the website of the WHO Prequalification Team: medicines (PQTm).*

*Please also consult the prequalification guidance documents*: Annotated Package Information Leaflet *and* Ensuring Consistency Between Product Information Documents.

*<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}[[1]](#footnote-1)**

{Active pharmaceutical ingredient(s)}

**Read all of this leaflet carefully before you start <taking> <using> this medicine.[[2]](#footnote-2)**

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your health care provider.
3. 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.
4. 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

1. 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}**

1. **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.>

1. **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.

1. **HOW TO STORE {PRODUCT NAME}**

*[For storage condition statements see prequalification guidance:* Section Guidance for Part 3 — Patient Information Leaflet (PIL) — of a WHO Public Assessment Report (WHOPAR).*]*

Keep out of the reach and sight of children.

<Do not store above ºC>, <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.>

1. **FURTHER INFORMATION**

**What {PRODUCT NAME} contains:**

1. The active pharmaceutical ingredient(s) is (are)…
2. The other ingredient(s) is (are)...

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

**Supplier and Manufacturer**

{Name and address}

<{tel}>

<{fax}>

<{email}>

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

|  |  |
| --- | --- |
| **{Country}**{Name}<{Address}XXXX {City}>Tel: + {telephone number}<{preferably functional, i.e. not personalized, email}> |  |

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

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

Detailed information on this medicinal product is available on PQTm’s website (see: <http://www.who.int/prequal>.

1. Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout a WHOPAR the proprietary name is given as an example only. [↑](#footnote-ref-1)
2. The headings and some of the text elsewhere in this template must be formulated slightly differently for paediatric formulations since they will be read and acted upon by the health care provider rather than the patient. [↑](#footnote-ref-2)