الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Templates for Labelling Information, SPC and PIL

Version 1.3

Date of issue	23 November 2020
Date of implementation	01 March 2021

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Version 1.3

Saudi Food & Drug Authority

Drug Sector

For Inquiries	*SPCPIL@sfda.gov.sa*
For Comments	*Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Executive Directorate of Products Evaluation	4 February 2019	Draft
1.0	Executive Directorate of Products Evaluation	23 November 2020	Final
1.1	Executive Directorate of Products Evaluation	31 January 2021	Update
1.2	Executive Directorate of Regulatory Affairs	05 August 2021	Update
1.3	Executive Directorate of Regulatory Affairs	25 July 2024	Update (Next page shows the updated details)

What is New in version no. 1.3?

Section	Description of change
Appendix 4: Recommended Labeling Statements	**Update:** - Table 1: Recommended labeling statements for finished pharmaceutical products (FPPs) - Table 2: Additional labeling statements for use where the result of the stability testing demonstrates limiting factors

Table of Contents

INTRODUCTION

Objective

This document is intended to provide the applicant a practical advice on how to draw up labeling information, SPC and PIL in order to ensure standardization of product information submitted to the SFDA.

Scope

This guidance is applicable to medicinal products intended for human use.

Related guidelines

This document should be read in conjunction with:

- The GCC guidance for presenting the Labeling information, SPC and PIL
- For Labeling part refer to the following documents:
  - Guidance for Graphic Design of Medication Packaging
  - Drug Barcoding Specifications

BRACKETING CONVENTION USED IN THE TEMPLATES

{text}	Information to be filled in, i.e. normal text.
<text>	Text to be selected or deleted as appropriate.
[Green text]	Guidance and explanatory notes only. To be deleted when using the templates.
[Red text]	Guidance notes in Red cross-refer to the section/information of the SPC which is to be reflected in that particular section of the leaflet.
PAGE SET-UP:	Orientation: Portrait
PAGE LAYOUT:	Section breaks must be avoided. Line breaks or page breaks should only be used if necessary.
MARGINS[1]:	From top of page: 2.0 cm From bottom of page: 2.0 cm From left of page: 2.5 cm From right of page: 2.5 cm Gutter: 0 cm Header: 1.3 Footer: 1.3 cm
FONT[1]:	Font: Times New Roman Size: ≥ 9 Font style: Regular Character spacing: Normal Font color: Black (i.e. the text throughout the annexes should be presented in black font, including figures, tables, pictograms, etc.).
LANGUAGE:	SPC: English only, PIL: Arabic and English
TEXT ALIGNMENT:	Left alignment, except for title pages where the text is centred. Right alignment, except for title pages where the text is centred. (for Arabic text)
LINE SPACING:	Paragraph: single-line spacing (one line before and one line after must not be used). Between paragraphs: one additional single-line spacing.

[1] Applied only on SPC and PIL

	Between headings and text: see information on headings below.
CHARACTER SPACING:	To avoid separation in the text and between figures and units use: - Non-breaking space (Ctrl + Shift + space): e.g. 10 mg - Non-breaking hyphen (Ctrl + Shift + hyphen): e.g. 100-200
INDENTS:	1.0 cm from the left-hand margin for the first indent. 1.0 cm from the right-hand margin for the first indent (for Arabic text).
BULLET POINTS:	Left alignment. Right alignment (for Arabic text) Text indentation: 1.0 cm from the left-hand margin. Text indentation: 1.0 cm from the right-hand margin (for Arabic text).
TITLE PAGES:	Centred, line 24 (**BOLD, CAPITAL LETTERS**). Keep title page as per template, e.g. "**LABELLING**"
HEADINGS:	**1. HEADINGS (BOLD, CAPITAL LETTERS)** (2 single lines before and 1 single line after)
SUBHEADINGS: (SPC only)	**1.1 Subheadings (bold, normal letters)** (1 single line before and 1 single line after)
SUBHEADINGS: (PIL only)	**Subheadings (no numbering, bold, normal letters)** (1 single line before and 1 single line after)
ADDITIONAL SUBHEADINGS:	In the SPC, do not use bold or additional numbering, instead use underline or italics or both and be consistent throughout the document, e.g.: Additional subheading <u>Additional subheading</u> *Additional subheading* *<u>Additional subheading</u>*
HEADINGS NUMBERING:	Must respect the current template. No additional numbering should be created. Do not use automatic numbering insertion.
BOXED HEADINGS:	**1. HEADING** Boxed headings in labelling section provide a structure to facilitate the work of applicants, assessors and reviewers, etc. However, they must NOT appear in the final printed packaging materials (e.g. actual carton, container label) or on the mock-ups and specimens.

	Boxed headings should be created by using “outside borders” and not by inserting a table. Boxed headings should always be kept, even when not applicable.
SCIENTIFIC SYMBOLS:	Insert from the symbol window (normal text), e.g. µ, α, ½, ≤, ±, etc. Do not use AutoCorrect to automatically insert symbols that are included in the built-in list to ensure that the symbols are always readable.
TABLES:	Font: in case the table is too big to fit in the page, a slightly smaller font size may be accepted on a case by case basis, as long as readability is maintained. Borders: single line style, color automatic, width 1/2 pt. Do not use background or shading.
CROSS-REFERENCE:	When cross-referring in the SPC, do not mention the section heading but only the section number and be consistent throughout the text. • Examples: … (see section 5.1) … (see sections 5.1 and 5.3)
SHADED TEXT:	Shaded text can be used by applicants to highlight text which will not be printed in the actual SPC, PL or label. Its use should be limited. • Example in SPC: **5.1 Pharmacodynamic properties** Pharmacotherapeutic group: {group}, ATC code: {code} Not yet assigned • Example in labelling: **12. MARKETING AUTHORISATION NUMBER(S)** 28 tablets 56 tablets 100 tablets

LABELING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

[The data should be presented according to the template below, irrespectively of their sequence on the actual labeling and their position and possible repetition on the individual sides/flaps of the packaging (e.g. top flap, front, back etc.)]

1. NAME OF THE MEDICINAL PRODUCT

{Invented name strength pharmaceutical form}

{Active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

[Special warnings on labelling should be reserved to cases where they are considered very important in order to fulfil a risk minimisation objective (e.g. “Cytotoxic: handle with caution”, “May cause birth defects”, etc.).]

8. MANUFACTURING AND EXPIRY DATE

<{MM/YYYY}>

<{Month YYYY}>

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. MANUFACTURER NAME

12. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

13. BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

<Medicinal product subject to medical prescription.>

<Medicinal product not subject to medical prescription.>

15. DATAMATRIX

[2D barcode carrying the unique identifier included]

16. GLOBAL TRADE ITEM NUMBER

GTIN: {number}

17. SERIAL NUMBER

SN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

3. MANUFACTURING AND EXPIRY DATE

<{MM/YYYY}>

<{month YYYY}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

{Invented name strength pharmaceutical form}

{Active substance(s)}

{Route of administration}

2. METHOD OF ADMINISTRATION

3. MANUFACTURING AND EXPIRY DATE

<{MM/YYYY}>

<{month YYYY}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. SPECIAL STORAGE CONDITIONS

7. OTHER

8. DATAMATRIX

[2D barcode carrying the unique identifier included]

9. GLOBAL TRADE ITEM NUMBER

GTIN: {number}

10. SERIAL NUMBER

SN: {number}

SUMMARY OF PRODUCT CHARACTERISTICS

[ADD: Black Inverted Equilateral Triangle: if applicable]

[For medicinal products subject to additional monitoring ONLY:
The black symbol and the statements should only appear here. The black symbol shall be a black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm.

For the purpose of preparing the product information annexes please use the black triangle as presented in this template (see below).]

< ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See Section 4 for how to report side effects. >

1. Name Of The Medicinal Product

{(Invented) name strength pharmaceutical form}

[No ® ™ symbols attached here and throughout the text; “tablets” and “capsules” in the plural.]

2. Qualitative And Quantitative Composition

{Name of the active substance(s)}

<Excipient(s) with known effect>

<For the full list of excipients, see section 6.1.>

3. Pharmaceutical Form

<The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The score line is not intended for breaking the tablet.>

<The tablet can be divided into equal doses.>

4. Clinical Particulars

4.1 Therapeutic indications

<This medicinal product is for diagnostic use only.> [specified if appropriate.]

<{invented name} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>.>

4.2 Posology and method of administration

Posology

[Additional sub-headings such as "Elderly" or "Renal impairment" can be stated if necessary.]

Pediatric population

[If there is no indication for the product in some or all subsets of the paediatric population, no
posology recommendation can be made, but available information should be summarised using the following standard statements (one or combination of several as appropriate):

<The <safety> <and> <efficacy> of {invented name} in children aged {x to y} <months> <years> [or any other relevant subsets, e.g. weight, pubertal age, gender] <has> <have> not <yet> been established.> [One of the following statements should be added:
<No data are available.>

or <Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>]

<{invented name} should not be used in children aged {x to y} <years> <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] because of <safety> <efficacy> concern(s).> [concern(s) to be stated with cross-reference to sections detailing data (e.g. 4.8 or 5.1).]

<There is no relevant use of {invented name} <in the paediatric population> <in children aged {x to y} <years>, <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] <for the indication of...>.> [specify indication(s).]

<{invented name} is contraindicated in children aged {x to y} <years> <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] <for the indication of...> (see section 4.3).>]

Method of administration

<Precautions to be taken before handling or administering the medicinal product>

[Explanatory illustrations may be included, if necessary, especially for advanced therapy medicinal products.]
<For instructions on <reconstitution> <dilution> of the medicinal product before administration, see section <6.6> <and> <12>.>

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

[Sub-headings (e.g. "Interference with serological testing" "Hepatic impairment", "QT prolongation") should be used where necessary.]

<Paediatric population>

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Paediatric population>

<Interaction studies have only been performed in adults.>

4.6 Fertility, pregnancy and lactation

[For pregnancy and lactation statements, see (Appendix 1 and Appendix 2)]

[Additional sub-headings such as "Women of childbearing potential", "Contraception in males and females" can be stated, as appropriate.]

<Pregnancy>

<Breastfeeding>

<Fertility>

4.7 Effects on ability to drive and use machines

<{(invented) name} has <no or negligible influence> <minor influence> <moderate influence> <major influence> on the ability to drive and use machines.>

<Not relevant.>

4.8 Undesirable effects

4.8.1 adverse reactions:

[MedDRA frequency convention and system organ class database, see Appendix 3.]

[Sub-headings should be used to facilitate identification of information on each selected adverse reaction and on each relevant special population, e.g.: "Summary of the safety profile", "Tabulated list of adverse reactions", "Description of selected adverse reactions" (alternatively the subsection could be named with the name of the relevant adverse reaction), "Other special populations".]

<Paediatric population>

4.8.2 Clinical Studies Experience (upon request from any regulatory Authority in GCC)

4.8.3 Post-marketing Experience (upon request from any regulatory Authority in GCC)

[For ALL medicinal products:

The following should appear at the end of section 4.8:]

To reports any side effect(s):

Saudi Arabia:

- The National Pharmacovigilance Centre (NPC):
  - SFDA Call Center: 19999
  - E-mail: npc.drug@sfda.gov.sa
  - Website: https://ade.sfda.gov.sa/

Other GCC States:

- Please contact the relevant competent authority.

4.8.4 Overdose

[Additional sub-headings, such as "Symptoms" or "Management" can be stated, if necessary.]

<Paediatric population>

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} <not yet assigned>

<{(Invented) name} is a biosimilar medicinal product.>

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Paediatric population>

5.2 Pharmacokinetic properties

<Absorption>

<Distribution>

<Biotransformation>

<Elimination>

<Linearity/non-linearity>

[Additional sub-heading(s), such as "Renal impairment", "Hepatic impairment", "Elderly", Paediatric population" or "Other special populations" (to be specified) should be used, where appropriate.]

<Pharmacokinetic/pharmacodynamic relationship(s)>

5.3 Preclinical safety data

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental Risk Assessment (ERA)>

6. Pharmaceutical Particulars

6.1 List of excipients

[Name of the excipient(s)]

<None.>

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>

6.3 Shelf life

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

6.4 Special precautions for storage

[For storage condition statements, see appendix 4]

<For storage conditions after <reconstitution> <dilution> <first opening> of the medicinal product, see section 6.3>

6.5 Nature and contents of container

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal <and other handling>

<Use in the paediatric population>

<No special requirements <for disposal>.>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

7. Marketing Authorisation Holder

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

8. Date of First Authorisation/Renewal of The Authorisation

<Date of first authorisation: {DD month YYYY}>

<Date of latest renewal: {DD month YYYY}>

9. Date of Revision of The Text

[Leave blank in case of a first Marketing Authorisation.]

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

10.<Dosimetry>

11.Instructions For Preparation Of Radiopharmaceuticals>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

PATIENT INFORMATION LEAFLET

Patient Information Leaflet

[Heading to be printed]

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

[For medicinal products subject to additional monitoring ONLY:

The black symbol and the statements should only appear here. The black symbol shall be a black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm. For the purpose of preparing the product information annexes please use the black triangle as presented in this template (see below).]

< ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See Section 6 for how to report side effects. >

[For medicines available only on prescription:]

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <,> <or> <pharmacist> <or nurse>.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.>

[For OTC medicines:]

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**

- Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.>

In this leaflet

1. What {invented name} is and what it is used for

[Invented name, active substance(s) and pharmacotherapeutic group]

[Therapeutic indications]

[e.g. "{invented name} is used to treat {specify indication} in <adults> <new-born babies> <babies> <children> <adolescents> <aged {x to y}> <years> <months>".]

[Information on the benefits of using this medicine]

<You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.>

2. What you need to know before you <take> <use> {invented name}

[Contraindications]

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

<if you are allergic to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6).>

[Appropriate precautions for use; special warnings]

Warnings and precautions

Talk to your doctor <or> <,> <pharmacist> <or nurse> before <taking> <using> {invented name}

Children <and adolescents>

[e.g. "Do not give this medicine 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>".]

[Interactions with other medicines]

Other medicines and {invented name}

<Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.>

[e.g.: "Do not take {invented name} with Y (a medicine used for Z) as this may result in the <loss of its effect><side effect>"]

[Interactions with food and drink]

{Invented name} with <food> <and> <,> <drink> <and> <alcohol>

[Use by pregnant or breast-feeding women, information on fertility]

Pregnancy <and> <,> breast-feeding <and fertility>

<If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your <doctor> <or> <pharmacist> for advice before taking this medicine.>

[Please note that if the medicine is contraindicated in pregnancy and/or breast-feeding the same information should be presented in both subsections ("Do not take/use {invented

name}" & "Pregnancy, breast-feeding and fertility") of the leaflet and should include information on teratogenicity where this is known.]

[Effects on the ability to drive or to use machines]

Driving and using machines

[Excipients warnings]

<{Invented name} contains {name the excipient(s)}>

3. How to <take> <use> {invented name}

[Dose (SPC section 4.2)]

[For medicines available on prescription only:]

<Always <take> <use> this medicine exactly as your doctor <or pharmacist> has told you. Check with your <doctor> <or> <pharmacist> if you are not sure.>

<The recommended dose is...>

[For OTC medicines:]

<Always <take> <use> this medicine 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.>

<The recommended dose is...>

[When available, information on maximum single, daily and/or total dose should also be included.

Additional sub-headings may be included where the posology varies for different indications or for different populations (e.g. elderly, hepatic impairment, renal impairment). Include the recommended dose and specify, if necessary, the appropriate time(s) at which the medicine may or must be administered.]

<**Use in children <and adolescents**>>

[When the medicine is indicated in different age groups with a different dose, method of administration, frequency of administration or duration of treatment, specific instructions for use for each age group should be clearly identified.

If there are more appropriate strength(s) and/or pharmaceutical form(s) for administration in some or all subsets of the paediatric population (e.g. oral solution for infants), these should be mentioned, e.g. "Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.".]

[Route(s) and/or method of administration (SPC section 4.2)]

[Method of administration: directions for a proper use of the medicine, e.g. "Do not swallow", 'Do not chew", "Shake well before use" (user testing experience has shown it is useful to state the reasons for the inclusion of such a statement, e.g. "Do not break or crush the tablet(s). If you do, there is a danger you could overdose because this medicine will be absorbed into your body too quickly").

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 way.

Where relevant, guidance should always be included to clarify if the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.]

<The score line is only there to help you break the tablet if you have difficulty swallowing it whole.>

<The tablet can be divided into equal doses.>

<The score line is not intended for breaking the tablet.>

[Duration of treatment (SPC section 4.2)]

[If appropriate, especially for OTC medicines, precise statements should be included on:

- the usual duration of the therapy;
- the maximum duration of the therapy;
- the intervals with no treatment;
- The cases in which the duration of treatment should be limited.]

[For some medicines, it may be necessary to include some additional information in this section although this need not be covered in all cases. The following headings can be used as a guide:]

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

[Describe how to recognise symptoms if someone has taken an overdose and what to do as per SPC section 4.9.]

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

[Make clear to patients what they should do after irregular use of a medicine, e.g.: if information is available, try to include information on the maximum interval the missed dose can be caught up as per SPC section 4.2.]

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

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

[Indicate withdrawal effects and how to minimise them as per SPC section(s) 4.2 and/or 4.4.

A statement on the potential consequences of stopping the treatment before finishing the course of treatment and the need for a prior discussion with the treating physician, pharmacist or nurse should be included as appropriate.]

[Close this section with:]

<If you have any further questions on the use of this medicine, ask your <doctor> <,> <or> <pharmacist>< or nurse>.>

4. Possible side effects

[Description of side effects]

[Begin this section with]

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<Additional side effects in children <and adolescents>>

[Close this section with]

Reporting of side effects

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>

5. How to store {invented name}

Keep this medicine out of the sight and reach of children.

[Expiry date]

[Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.]

Do not use this medicine after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}.>

[Storage conditions]

[Information should be in accordance with section 6.4 of the SPC]

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

[Information should be in accordance with section 6.3 of the SPC.]

[Where appropriate, warnings against certain visible signs of deterioration]

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

<Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.>

6. Further information

[Full statement of the active substance(s) and excipient(s)]

What {invented name} contains

[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in sections 2 and 6.1 of the SPC.]

- The active substance(s) is (are)… [e.g. "Each <tablet> <capsule> contains x <gram> <milligram>…{active substance}".]
- The other <ingredient(s)> <(excipient(s))> is (are)... [e.g. "Each <tablet> <capsule> contains {invented name} <gram> <milligram>…{active substance}".]

[Pharmaceutical form, nature and contents of container in weight, volume or units of dose]

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

[It is recomnded to include a physical description, e.g. shape, colour, texture, imprint, etc. as per section 3 of the SPC.]

[All pack sizes for this pharmaceutical form and strength should be detailed here as per section 6.5 of the SPC, including a reference to any ancillary items included in the pack such as needles, swabs, etc. For multipacks, clearly indicate the pack content, e.g. "{invented name}is available in packs containing Y, Z or W tablets and in multipacks comprising N cartons, each containing M tablets".

If appropriate, indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.]

[Name and address of the marketing authorisation holder and of the manufacturer responsible for batch release, if different]

Marketing Authorisation Holder and Manufacturer

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

[State the name and address of the MAH as per section 7 of the SPC.]

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

To report any side effect(s):

- **Saudi Arabia:**

• The National Pharmacovigilance Centre (NPC): – SFDA Call Center: 19999 – E-mail: npc.drug@sfda.gov.sa – Website: https://ade.sfda.gov.sa/

- **Other GCC States:**

– *Please contact the relevant competent authority.*

Council of Arab Health Ministers

[The following statements issued by the Council of Arab Health Ministers should be printed in the PIL.]

This is a Medicament
– *Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.* – *Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.* – *The doctor and the pharmacist are the experts in medicines, their benefits and risks.* – *Do not by yourself interrupt the period of treatment prescribed for you.* – *Do not repeat the same prescription without consulting your doctor.* – *Keep all medicaments out of reach of children.*

Council of Arab Health Ministers

Union of Arab Pharmacists

This patient information leaflet is approved by {relevant competent authority}.

ARABIC PATIENT INFORMATION LEAFLET

نشرة معلومات المريض

[يُطبع العنوان بالأعلى]

{الاسم المبتكر التركيز الشكل الصيدلاني للمستحضر}

{المادة / المواد الفعالة}

[للأدوية الخاضعة للرقابة الإضافية فقط:

يجب أن يظهر رمز المثلث والعبارات هنا فقط. يجب أن يكون الرمز على هيئة مثلث أسود مقلوب وذو أضلاع متساوية. يجب أن يتناسب الرمز مع حجم الخط للنص الموحد التالي، وأن تكون اضلاع المثلث متساوية بحجم ٥ ملليمتر كحد أدني، وذلك لجميع الحالات. لإعداد الملحقات المتعلقة بمعلومات المنتج، يرجى استخدام المثلث الأسود كما هو موضح في القالب ادناه.]

< ▼هذا الدواء يخضع لرقابة إضافية حتى يتم تحديد معلومات السلامة الجديدة بشكل أسرع. يمكنك المساعدة بالإبلاغ عن أي أعراض جانبية قد تواجهك. راجع القسم (٦) لمعرفة كيفية التبليغ عن الاعراض الجانبية>

[خاص بالأدوية التي يتم صرفها بموجب وصفة طبية (POM):]

<اقرأ هذه النشرة كاملة بعناية تامة قبل القيام <بتناول> <استخدام> هذا الدواء حيث أنها تحتوي على معلومات تهمك:

- احتفظ بهذه النشرة، فقد تحتاج إليها لاحقاً.
- في حال وجود أي استفسارات لديك استشر <الطبيب المعالج >أو <الصيدلي> أو <الممرض >.
- إن هذا الدواء صرف لك بوصفة طبية خاصة بك، ولهذا يجب عدم إعطائه لأي شخص فقد تسبب لهم بالأذى، حتى وإن كان يعاني من نفس الأعراض التي لديك.
- إذا أصبت بأي آثار جانبية، أبلغ <الطبيب المعالج> أو <الصيدلي> أو <الممرض > حتى وإن كانت غير مذكورة في هذه النشرة. راجع القسم (٤).>

[خاص بالأدوية التي يتم صرفها بدون وصفة طبيه (OTC):]

<اقرأ هذه النشرة كاملة بعناية قبل القيام <بتناول> <استخدام> هذا الدواء حيث أنها تحتوي على معلومات تهمك:

- تناول هذا المستحضر بالطريقة التي تم وصفها في هذه النشرة أو حسب إرشادات <الطبيب المعالج > أو <الصيدلي> أو <الممرض>
- لحتفظ بهذه النشرة، فقد تحتاج إليها لاحقاً.
- اسأل الصيدلي في حال احتجت للاستشارة أو لطلب معلومات إضافية.

- إذا أصبت بأي آثار جانبية، أبلغ <الطبيب المعالج> أو <الصيدلي> أو <الممرض > حتى وإن كانت غير مذكورة في هذه النشرة. راجع القسم (٤).
- يجب عليك إبلاغ الطبيب <بعد {عدد الأيام}> إذا ساءت حالتك أو لم تشعر بأي تحسن.>

ما الذي تحتويه هذه النشرة:

١. ما هو {اسم المبتكر} وما هي دواعي استعماله

[اسم المبتكر، المادة/المواد الفعالة والشكل الصيدلاني]

[الدواعي الدوائية]

[مثال: "{اسم المبتكر} يستخدم في علاج {اذكر الداعي العلاجي} عند <البالغين> <حديثي الولادة> <الرضع> <الأطفال> <المراهقين> <من عمر {...إلى ...}> <سنوات> <أشهر>".]

[معلومات عن الفائدة من استعمال هذا الدواء]

< يجب عليك إبلاغ الطبيب <بعد {عدد الأيام}> إذا ساءت حالتك أو لم تشعر بأي تحسن.>

٢. ما الذي يجب معرفته قبل <تناول> <استخدام> {اسم المبتكر}.

[التداخلات الدوائية]

موانع <تناول> <استخدام> {اسم المبتكر}

<إن كان لديك حساسية من {المادة/المواد الفعالة} أو أحد مكونات المستحضر (انظر القسم ٦).>

[الاحتياطات اللازمة للاستخدام؛ تحذيرات خاصة]

الاحتياطات عند <تناول> <استخدام> {اسم المبتكر}

أبلغ الطبيب <أو> <الصيدلي> <أو> <الممرض> قبل <تناول> <استخدام> {اسم المبتكر}.

الأطفال <والمراهقين>

[مثال: "لا تعطي هذا الدواء للأطفال من عمر (كذا) إلى (كذا) <سنوات> <أشهر> وذلك بسبب <خطورته على [...]> <انعدام فعاليته> <احتمالية الخطورة أكثر من المنفعة> <أنه من المحتمل أن يكون غير آمن > "]

[التداخلات الدوائية من تناول أدوية أخرى]

التداخلات الدوائية من تناول {اسم المبتكر} مع أي أدوية أخرى أو أعشاب أو مكملات

< أبلغ <الطبيب> <أو> <الصيدلي> إذا كنت <تتناول> <تستخدم> أو <تناولت> <استخدمت> مؤخرا أو تنوي أن <تتناول> <تستخدم> أدوية أخرى.>

[مثال:" لا تتناول {اسم المبتكر} مع ص (دواء يستخدم للمرض ع) لأن هذا قد يؤدي إلى <فقد الدواء لفعاليته> <أعراض جانبية>"]

[التداخلات الدوائية مع الأطعمة والمشروبات]

تناول {اسم المبتكر} مع <الطعام> <و><الشراب> <و><الكحول>

[استخدامه من قبل الحوامل والمرضعات، ومعلومات عن الخصوبة]

الحمل والرضاعة <والخصوبة>

<إذا كنتِ حامل أو مرضع أو تعتقدين أنكِ حامل أو تخططين للحمل استشيري <الطبيب> <أو> <الصيدلي> قبل أخذ الدواء.>

[فضلا إذا كان الدواء يتعارض مع الحمل أو الرضاعة، اعرض نفس المعلومات في قسمي موانع تناول/استخدام {اسم المبتكر} والحمل والرضاعة والخصوبة للنشرة ، أضف أيضا المعلومات المُثبتة عن التشوهات الخُلقية]

[تأثير الدواء على القدرة على القيادة أو استخدام الآلات]

تأثير {اسم المبتكر} على القيادة واستخدام الآلات

[تحذيرات خاصة بالمواد غير الفعالة]

<{اسم المبتكر} يحتوي على { اسم المادة/المواد غير الفعالة}>

٣. ما هي طريقة <تناول> <استخدام> { اسم المبتكر}

[الجرعة من قسم ٤،٢ من SPC]

[خاص بالأدوية التي تصرف بموجب وصفة طبية (POM):]

<دائما <تناول> <استخدم>هذا الدواء تماماً كما أخبرك به الطبيب <أو الصيدلي>. إن لم تكن متأكداً من كيفية الاستخدام ارجع إلى <طبيبك> <أو> <الصيدلي>.>

<الجرعة المقترحة هي..>

[خاص بالأدوية التي تصرف بدون وصفة طبية (OTC):]

<احرص دائمًا على <تناول> <استخدام> هذا الدواء كما هو مذكور في النشرة أو كما أخبرك به <الطبيب> <أو الصيدلي> <أو الممرض>. إن لم تكن متأكدا من كيفية الاستخدام ارجع إلى <طبيبك> <أو> <الصيدلي>.

<الجرعة المقترحة هي..>

[عند توفر المعلومات، اذكر الحد الأقصى للجرعة الواحدة والجرعة اليومية.

يمكن ادراج عناوين فرعية عند اختلاف الجرعات تبعا لاختلاف الدواعي العلاجية أو المرضى (مثال: كبار السن، قصور وظائف الكلى أو الكبد). اذكر الجرعة المقترحة، وحدد الوقت المناسب لأخذ الدواء إذا دعت الحاجة.]

<**استخدامه للأطفال <والمراهقين**>>

[عندما يقرر وصف الدواء لفئات عمرية متفاوتة، وهي مختلفة في الجرعات أو في طرق إعطاء الدواء أو في المدد العلاجية يجب أن يذكر ذلك بوضوح تبعاً لكل فئة عمرية.

وإذا استدعى ذلك استخدام تراكيز أو اشكال صيدلانية معينة لبعض الفئات العمرية في الأطفال (مثال: المحلول الفموي للرضع) يجب أن يُذكر ذلك. مثال: " الأشكال الصيدلانية الأخرى لهذا الدواء مناسبة للأطفال، استشر الطبيب أو الصيدلي]

[طريقة الاستخدام]

[طريقة الإعطاء: أرشد إلى طريقة الاستخدام السليمة للدواء، على سبيل المثال: (لا تبلع)، (لا تمضغ)، (رج جيدا قبل الاستخدام)، حيث أظهرت تجربة اختبار المستخدم إلى أهمية ذكر السبب من ذلك، مثال: "لا تكسر أو تسحق القرص، فهناك خطر من تناول جرعة زائدة؛ لأنه سيتسبب بامتصاص جسمك له بسرعة.

إذا لزم الأمر، يجب ذكر كيفية فتح العبوات المقاومة للأطفال أو العبوات التي تفتح بطريقة غير مألوفة (يمكن ارفاق رسوم توضيحية).

إذا كان مناسبا، يجب توضيح ما إذا كان يجب تناول الدواء مع الطعام، أو قبل الوجبات، والإشارة بوضوح عن عدم تأثير الأطعمة على الدواء...إلخ.]

< خط تقسيم القرص يساعدك على كسره في حال كنت تعاني من صعوبة في بلع القرص كاملًا>

<يمكن أن تقسم القرص إلى جرعتين متساويين>

<خط تقسيم القرص لا يشير إلى إمكانية كسره>

[المدة العلاجية]

[إذا لزم الأمر، وخاصة للأدوية التي لا يتطلب صرفها وصفة طبية، اذكر التالي بدقة:

- المدة العلاجية المعتادة
- اقصى مدة زمنية للعلاج
- الفترة الزمنية من غير العلاج
- الحالات التي تكون فيها المدة العلاجية محدودة]

<**إذا <تناولت> <استخدمت> {اسم المبتكر} أكثر من اللازم**>

[صف كيف يمكن تمييز الأعراض الناتجة عن تناول المريض لجرعة زائدة وما اللازم عمله وفقًا لما ذكر في قسم ٤,٩ من SPC]

<إذا نسيت أن <تتناول> <تستخدم> {اسم المبتكر}>

[اذكر بوضوح ما يمكن فعله عند عدم الانتظام في استخدام الدواء، مثال: قم بذكر الفترة الزمنية القصوى التي يمكن فيها تعويض الجرعة الفائتة وفقا لما ذكر في قسم ٤,٢ من SPC.]

<لا تقم بأخذ ضعف الجرعة الفائتة لتعويضها>

<إذا توقفت عن <تناول> <استخدام> {اسم المبتكر}>

[اذكر الأعراض الانسحابية للدواء وكيفية تقليلها وفقا لما ذكر في قسمي ٤,٢ أو ٤,٤. من SPC
بيّن احتمالية حدوث العواقب عند ايقاف العلاج قبل انتهاء المدة العلاجية المقررة، وإذا دعت الحاجة لذلك فيجب عليك النقاش مسبقا مع الطبيب أو الصيدلي أو الممرض]

[انهي القسم بـ:]

<إذا كان لديك أي أسئلة أخرى عن استخدام الدواء، اسأل <الطبيب> <أو الصيدلي> <أو الممرض>.>

٤. الأعراض الجانبية المحتملة

[وصف الأعراض الجانبية]

[ابدأ القسم بـ:]

كما هو الحال في كل الأدوية، هذا الدواء يمكن أن يتسبب بأعراض جانبية، بالرغم من أنها قد لا تحدث للجميع.

<أعراض جانبية أخرى لدى الأطفال <والمراهقين>>

[انهي القسم بـ:]

الإبلاغ عن الأعراض الجانبية

إن كان لديك أعراض جانبية أو لاحظت أعراض جانبية غير مذكورة في هذه النشرة، فضلًا ابلغ <الطبيب> <أو> <مقدم الرعاية الصحية> <أو> <الصيدلي>.

٥. طريقة تخزين {اسم المبتكر}

لا تترك الأدوية في متناول الاطفال.

[تاريخ الانتهاء]

[يجب أن تذكر هنا الاختصارات المستخدمة لتاريخ الانتهاء على الملصق الخارجي]

لا تستخدم هذا الدواء بعد تاريخ الانتهاء المذكور على <الملصق الخارجي> <العبوة> <الزجاجة> <...> < بعد {الاختصار المستخدم لتاريخ الانتهاء}.>

[ظروف التخزين]

[يجب أن تكون المعلومات وفقا لقسم ٦,٤ من SPC]

[تُذكر مدة صلاحية المستحضر بعد الحلّ أو التخفيف أو بعد فتح العبوة إذا لزم الأمر]

[يجب أن تكون المعلومات وفقاً لقسم ٦,٣ من SPC]

[تُذكر التحذيرات من التغيرات الظاهرية المتلفة للمستحضر إذا لزم الأمر]

<لا تستخدم هذا الدواء إذا لاحظت {وصف التغيرات الظاهرية التي تتلفه}.>

<لا تتخلص من الدواء عن طريق رميه في مياه الصرف الصحي <أو النفايات المنزلية>. اسأل الصيدلي عن كيفية التخلص من الدواء إذا لم تعد بحاجته. هذه الإجراءات تساعد في حماية البيئة.>

٦. محتويات العلبة ومعلومات إضافية أخرى:

[اسرد جميع المواد الفعالة وغير الفعالة]

ما هي محتويات {اسم المبتكر}

[المادة/المواد الفعالة (صفها نوعاً وكماً) والمكونات الأخرى (صفها نوعاً) يجب أن تُعَرَّف وفقا للأسماء المذكورة في قسمي ٢ و ٦,١ من SPC]

- <المادة> <المواد> الفعالة هي...
- <<المادة> <المواد>غير الفعالة> <المكونات> الأخرى <هي>...

[الشكل الصيدلاني، طبيعة ومحتويات العبوة بوزنها أو كثافتها أو الوحدة للجرعة]

ما هو شكل {اسم المبتكر} ووصفه، وعلى ماذا تحتوي العبوة

[ينصح بذكر الوصف الظاهري مثال: الشكل، اللون، الملمس، الختم... إلخ وفقا لما ذكر في قسم ٣ من SPC.]

[كل الاحجام المختلفة للعبوات لهذا الشكل الصيدلاني والتركيز يجب ان تذكر هنا بالتفصيل وفقا لما ذكر في قسم ٦,٥ من SPC، ويتضمن ذلك الإشارة إلى اللوازم الملحقة بالعبوة، مثل: الإبرة والمسحات...إلخ. للحزم متعددة العبوات، اذكر بوضوح محتوياتها، مثال: {اسم المبتكر} يتوفر في العبوات.

اذكر أن ليس جميع العبوات مسوقة، وأشر إلى الأشكال الصيدلانية والتراكيز الأخرى إذا لزم الأمر]

[اسم وعنوان مالك رخصة التسويق والمصنع المسؤول عن إفراج التشغيلات، إذا كانا مختلفين]

اسم وعنوان مالك رخصة التسويق والمصنع

{الاسم والعنوان}

{الهاتف}

{الفاكس}

{البريد الإلكتروني}

[اذكر المعلومات وفقا لما ذكر في قسم ٧ من SPC]

تمت مراجعة هذه النشرة في <الشهر والسنة>

للإبلاغ حول الأعراض الجانبية التي قد تحدث يرجى التواصل عبر العناوين التالية:

- **المملكة العربية السعودية:**

المركز الوطني للتيقظ الدوائي: مركز الاتصال الموحد: 19999 البريد الإلكتروني: npc.drug@sfda.gov.sa الموقع الإلكتروني: https://ade.sfda.gov.sa

- **دول الخليج العربي الأخرى:**

الرجاء الاتصال بالجهات الوطنية في كل دولة

مجلس وزراء الصحة العرب:

[يجب أن تتم طباعة هذا البيان الصادر عن مجلس وزراء الصحة العرب في نشرة المعلومات الداخلية للمستحضر.]

إن هذا الدواء

- الدواء مستحضر يؤثر على صحتك واستهلاكه خلافًا للتعليمات يعرضك للخطر.
- اتبع بدقة وصفة الطبيب، وطريقة الاستعمال المنصوص عليها، وتعليمات الصيدلي الذي صرفها لك.
- الطبيب والصيدلي هما الخبيران في الدواء، وفي نفعه وضرره.
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك.
- لا تكرر صرف الدواء بدون استشارة الطبيب المختص.
- لا تترك الأدوية في متناول الاطفال.

مجلس وزراء الصحة العرب

واتحاد الصيادلة العرب

تمت الموافقة على هذه النشرة من قبل {الجهة التنظيمية في كل دولة}.

APPENDIX 1: Statements for Use in "Pregnancy and Lactation" of SPC

With Respect to "Pregnancy"

1. <Based on human experience [specify] {Active substance} causes <congenital malformations [specify] when administered during pregnancy.> [or] <harmful pharmacological effects during pregnancy and/or on the fetus/newborn child.>

   {Invented name} is contraindicated <during pregnancy><during {trimester} of pregnancy> [this case is a strict contraindication] (see section 4.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).

   <Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after> treatment.>>

2. <Based on human experience [specify] {Active substance} is suggested / suspected to cause congenital malformations [specify] when administered during pregnancy.

- <Studies in animals have shown reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

  [or]

- <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

  {Invented name} should not be used <during pregnancy><during {trimester} of pregnancy> unless the clinical condition of the woman requires treatment with {Active substance}.

  <Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after> treatment.>>

3. <Based on human experience [specify] {Active substance} is suggested / suspected to cause congenital malformations [specify] when administered during pregnancy.

   Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).

   {Invented name} should not be used<during pregnancy><during {trimester} of pregnancy> unless the clinical condition of the woman requires treatment with {Active substance}.

   <Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after)> treatment.>>

4. <There are no or limited amount of data from the use of {Active substance} in pregnant women.

- <Studies in animals have shown reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

  [or]

- <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

  {Invented name} is not recommended <during pregnancy><during {trimester} of pregnancy> and in women of childbearing potential not using contraception.>

5. <There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of {Active substance} in pregnant women.

   Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).

As a precautionary measure, it is preferable to avoid the use of {Invented name} <during pregnancy> <during {trimester} of pregnancy>. >

6. <A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of {Active substance}.

- <Animal studies have shown reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

[or]

- <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

As a precautionary measure, it is preferable to avoid the use of {invented name} <during pregnancy > <during {trimester} of pregnancy.>

7. <A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of {Active substance}.>

Animal studies do not indicate reproductive toxicity (see section 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).

The use of {invented name} may be considered <during pregnancy><during {trimester} of pregnancy>, if necessary.

8. <A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicate no malformative nor feto/ neonatal toxicity of {Active substance}.>

Invented name} can be used <during pregnancy><during {trimester} of pregnancy> if clinically needed.

9. <No effects during pregnancy are anticipated, since systemic exposure to {Active substance} is negligible.>

{Invented name} can be used during pregnancy. [E.g. medicinal products for which negligible systemic exposure/negligible pharmacodynamic systemic activity has been demonstrated in clinical situation]

With Respect to "Lactation"

1. <{Active substance}/metabolites are excreted in human milk and effects have been shown in breastfed newborns/infants of treated women.>

   [or]

   <{Active substance}/metabolites have been identified in breastfed newborns/infants of treated women. <The effect of {Active substance} on newborns/infants is unknown.> [or] <There is insufficient information on the effects of {Active substance} in newborns/infants.>>

   [or]

   <{Active substance}/metabolites are excreted in human milk to such an extent that effects on the breastfed newborns/infants are likely.>

   <{Invented name}<is contraindicated during breast-feeding (see section 4.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part)> [or] <should not be used during breast-feeding>.>

   [or]

   <Breast-feeding should be discontinued during treatment with {Invented name}.>

   [or]

   <A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from {Invented name} therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.>

2. <It is unknown whether {Active substance}/metabolites are excreted in human milk.>

[or]

<There is insufficient information on the excretion of {Active substance}/metabolites in human milk.>

[or]

<There is insufficient information on the excretion of {Active substance}/metabolites in animal milk.>

[or]

<Available pharmacodynamic/toxicological data in animals have shown excretion of {Active substance}/metabolites in milk (for details see 5.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).>

[or]

<Physico-chemical data suggest excretion of {Active substance}/metabolites in human milk.>

A risk to the newborns/infants cannot be excluded.

<{Invented name} <is contraindicated during breast-feeding (see section 4.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part)> [or] <should not be used during breast-feeding>.>

[or]

<Breast-feeding should be discontinued during treatment with {Invented name}.>

[or]

<A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from {Invented name} therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.>

3. <No effects of {Active substance} have been shown in breastfed newborns/infants of treated mothers.>

[or]

<No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to {Active substance} is negligible.>

[or]

<{Active substance}/metabolites have not been identified in plasma of breastfed newborns/infants of treated mothers.>

[or]

<{Active substance}/metabolites are not excreted in human milk.>

[or]

<{Active substance}/metabolites are excreted in human milk, but at therapeutic doses of {Invented name} no effects on the breastfed newborns/infants are anticipated.>

{Invented name} can be used during breast-feeding.

APPENDIX 2: Lactation Statements

1. {Active substance} is not excreted in breast milk. {Invented name} can be used during lactation.
2. {Active substance} is excreted in breast milk. However, at therapeutic doses of {Invented name} no effects on the suckling child are anticipated. {Invented name} can be used during breast-feeding.
3. {Active substance} is excreted in breast milk to such an extent that effects on the suckling child are likely if therapeutic doses of {Invented name} are administered to breast-feeding women.
    - Alternative recommendations (combinations of recommendations may be used):
        - {Invented name} should not be used during breast-feeding.
        - {Invented name} is contraindicated during breast-feeding (must also be contraindicated in 4.3 in the GCC guidance for SPC, PIL and Labeling information, SPC part).
        - Lactation should be discontinued during treatment with {Invented name}.
        - A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from {Invented name} therapy.
    - Additional recommendation (if applicable):
        - Due to the long retention time of {substance} in the body, breast-feeding must not be resumed until x (days, months) after {Invented name} therapy is completed.

4. It is unknown whether {Active substance} is excreted in human breast milk. The excretion of {Active substance} in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.
5. It is unknown whether {active substance} is excreted in human breast milk. Animal studies have shown excretion of (active substance) in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with

{Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

6. It is unknown whether {Active substance} is excreted in human breast milk. Animal studies have not shown excretion of {Active substance} in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

7. There is insufficient/limited information on the excretion of {Active substance} in human or animal breast milk. A risk to the suckling child cannot be excluded. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

8. There is insufficient/limited information on the excretion of (active substance) in human or animal breast milk. Physicochemical and available pharmacodynamic/toxicological data on (active substance) point to excretion in breast milk and a risk to the suckling child cannot be excluded. {Invented name} should not be used during breast-feeding.

9. No effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to {Active substance} is negligible. {Invented name} can be used during breastfeeding.
   - E.g. ear and eye drops and other topical drugs for which negligible systemic exposure has been demonstrated.

10. No effects on the suckling child are anticipated. {Invented name} can be used during breastfeeding.
    - E.g. most vitamin and mineral formulations.

APPENDIX 3: MedDRA Frequency Convention

Ref	[MedDRA frequency convention]
001	<Very common (≥1/10)>
002	<Common (≥1/100 to <1/10)>
003	<Uncommon (≥1/1,000 to <1/100)>
004	<Rare (≥1/10,000 to <1/1,000)>
005	<Very rare (<1/10,000)>
006	<not known (cannot be estimated from the available data)>
[MedDRA- system organ class database]	
007	Infections and infestations
008	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
009	Blood and lymphatic system disorders
010	Immune system disorders
011	Endocrine disorders
012	Metabolism and nutrition disorders
013	Psychiatric disorders
014	Nervous system disorders
015	Eye disorders
016	Ear and labyrinth disorders
017	Cardiac disorders
018	Vascular disorders
019	Respiratory, thoracic and mediastinal disorders
020	Gastrointestinal disorders
021	Hepatobiliary disorders
022	Skin and subcutaneous tissue disorders
023	Musculoskeletal and connective tissue disorders
024	Renal and urinary disorders
025	Pregnancy, puerperium and perinatal conditions
026	Reproductive system and breast disorders
027	Congenital, familial and genetic disorders
028	General disorders and administration site conditions
029	Investigations
030	Injury, poisoning and procedural complications
031	Surgical and medical procedures
032	Social circumstances
033	Product issues

APPENDIX 4: Recommended Labeling Statements:

- Statements that should be used if supported by the stability studies for finished pharmaceutical products (FPPs) are listed in Table 1.

Table 1: Recommended labeling statements for finished pharmaceutical products (FPPs)

Testing condition under which the stability of the FPP has been demonstrated	Recommended labeling statement
30 °C/65% RH (long-term) 40 °C/75% RH (accelerated)	"Store below 30 °C"*
5 °C ± 3 °C	"Store in a refrigerator (2 °C to 8 °C)"
-20 °C ± 5 °C	"Store in freezer"

* "Protect from moisture" should be added as applicable.

- Additional labeling statements that could be used in cases where the result of the stability testing demonstrates limiting factors are listed in Table 2.

Table 2: Additional labeling statements for use where the result of the stability testing demonstrates limiting factors

Limiting factors	Additional labeling statements, where relevant
FPPs that cannot tolerate refrigeration	" Avoid refrigerate or freeze"
FPPs that cannot tolerate freezing	" Avoid freeze"
Light-sensitive FPPs	"Protect from light"
FPPs that cannot tolerate excessive heat, e.g.suppositories	"Store and transport below 30 °C"
Hygroscopic FPPs	"Store in dry condition"

References:

- European Medicines Agency. (2011). *QRD convention to be followed for the EMA-QRD templates*. Retrieved from https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/linguistic-review.

- European Medicines Agency. (2019). *Quality Review of Documents (QRD) product-information annotated template*. Retrieved from https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates.