**What is in this leaflet**

1. What product name is used for

 *(product name may be shortened from here onwards, no need to mention strength, e.g. Abcd Ointment)(do not italic product name)*

1. How product name works
2. Before you use product name
3. How to use product name
4. While you are using it
5. Side effects
6. Storage and Disposal of product name
7. Product Description
8. Manufacturer and Product Registration Holder
9. Date of RiMUP revision

**What product name** **is used for**

**How product name works**

**Before you use product name**

* *When you must not use it*

Do not take this medicine if:

• you are allergic to active ingredients or any other ingredients of this medicine (listed in Product Description)

- *Before you start to use it*

Check with your doctor or pharmacist before taking product nameif you:

* xxxx
* xxxx

*Pregnancy and lactation*

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

*(if applicable)*

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

* xxxx
* xxxx

**How to use product name**

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

* *How much to use*
* *When to use it*

 Use as directed by your doctor or pharmacist.

- *How long to use it*

 Use this medicinefor the duration that your doctor recommends.

- *If you forget to use it*

 Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

*For external use products (e.g. cream)*

Apply the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to apply the medicine and skip the missed dose. Do not apply a double dose to make up for the missed dose.

* *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause…………..

**While you are using product name**

* *Things you must do*

Use your medicine exactly as your doctor has told you. *(if applicable)*

Tell all the doctors, dentists and pharmacists treating you that you are using product name.

Tell your doctor immediately if you become pregnant while using this medication*. (if applicable)*

Take product name only with a doctor’s prescription. *(For prescription only medicines)*

* *Things you must not do*

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give product name to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

*Driving and using machines*

This medicine may affect your ability to drive or use machines. If this medicine makes you feel *(insert symptoms as applicable, e.g.* sick, dizzy or tired, or this medicine gives you a headache*)* do not drive or use machines and contact your doctor immediately.

*For eye product (eg: ointment)*

Product name may distort your vision temporarily. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous.

 *If not applicable/ others*

Be careful driving or operating

machinery until you know how product name affects you.

**Side effects**

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

Possible side effects are:

* xxxx
* xxxx

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers 🡪 Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of** product name

* *Storage*

Keep out of the reach and sight of children.

Store below °C.

*For external use products (e.g. cream)*

Do not use this product after the expiry date or if the tube is leaking or the tube nozzle cover is broken. *(red phrase - for products packed in tubes)*

* *Disposal*

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.

**Product Description**

* *What it looks like*
* *Ingredients*
	+ Active ingredient(s)
* xxxx
	+ Inactive ingredients
* xxxx
* xxxx
* *MAL number(s):*

MAL\*\*\*\*\*\*\*\*\*

*(include all if more than one strength)*

**Manufacturer**

Name and address

**Product Registration Holder**

Name and address

**Date of revision**

DD/MM/YYYY

**Serial Number**

**IMPORTANT NOTES**

**Font colours:**

 **Black = compulsory to be included**

**Red = insert relevant information**

**Blue = general statements for reference only and should be chosen for use as appropriate for each product. If your product has more specific information, please ignore the general statements and include the specific information as stated in approved PI**.

**Green = comments/ instructions (please delete before submission)**

**RiMUP Submission Checklist** *(\*please delete before submitting)*

| **No.** |  **Specification** | **Additional notes** | **(√)** |
| --- | --- | --- | --- |
| Before preparing RiMUP |
| 1 | Check that registration information is updated (system and PI) | Ensure information in the PI is up to date especially dosage (Including relevant directives and in DRGD)Section A & PI tally in Quest 3+systemRiMUP information must tally with PI |  |
| Format |
| 1 | Layout | Portrait-orientation, A4 size |  |
| 2 | Compulsory header (right corner)– bold, italic | English: ***Consumer Medication Information Leaflet (RiMUP)***BM: ***Risalah Maklumat Ubat untuk Pengguna (RiMUP)*** |  |
| 3 | Compulsory footer (right corner) | Page number |  |
| 4 | **Title**: Times New Roman, size 24, bold | Use full name as per registered with DCA (no need to include strength)* Must be CAPITALISED
* e.g. If the name is A Tablet 100mg, put as **A TABLET** only (this name will be used throughout RiMUP)
 |  |
| 5 | **Text**: Times New Roman font, size 10 | All text except title |  |
| 6 | Columns and spacing | 3 columns, spacing 1.0 (single), align left Equal width columns, align left  |  |
| 7 | Include all sections listed below | Section headings are boldSub-headings are italic, underlined |  |
| 8 | English and BM versions | Submit as two separate pdf files |  |
| 9 | Length of RiMUP | **Ideal length= 2 pages** per languageMaximum 4 pagesper language |  |
| 10 | Use one leaflet for all different strengths or for second source product (if suitable) | List all the strengths/ MAL numbers/ manufacturers where applicable (must be the same product name) |  |
| **Sections** |
| 1 | Name of product, active ingredient, strength(s) | In RiMUP headingProduct name: Full name as per registered with DCA (no need strength)Active ingredient e.g.: Active Ingredient (5mg, 10mg, 20mg) *or* Active Ingredient 1/Active Ingredient 2 (5mg/200mg) *or* (5% w/v) |  |
| 2 | **What is in this leaflet** | * List all the sections
* Product name may be shortened from here onwards, no need to mention strength
 |  |
| 3 | **What (product name) is used for** | Indication.Information must be same as approved PI but convert to layman terms.Can refer to wording in patient leaflets from reference countries (if relevant). |  |
| 4 | **How (product name) works** | Mention the active ingredient(s) with their mechanism of actions (try to simplify so that consumers can understand) |  |
| 5 | **Before you use (product name)** |  |
|  | *- When you must not use it* | Mention hypersensitivity and other contraindications (in laymen terms) |  |
|  | *- Before you start to use it* | Warnings and precautions (if relevant for before using/taking the medicine) |  |
|  | *- Taking other medicines* | Drug-drug interactions. Mention as, e.g.:- generic name (used to treat xxxx)- If the list is long, try to group according to uses e.g., nifedipine, perindopril (used to treat high blood pressure) Maintain drug names in English for both Eng and BM versions |  |
| 6 | **How to use (product name)** |  |
|  | *- How much to use* | Dose (must be same as registered and approved PI)Mention maximum dose if relevantUse layman terms, e.g. if tablet is 100mg, the dose must be stated as “Take 1 tablet…..”For liquid, state in ml or teaspoon instead of mg for clearer instructionMust make sure the dosage is correlate to the product strength. For example, if the capsule is 150mg, the dose must be in 150, 300, 450mg etc. |  |
|  | *- When to use it* | Frequency: mention maximum frequency if relevantMention if to take before food or with food (if relevant) |  |
|  | *- How long to use it* | Duration: mention maximum duration if relevant |  |
|  | *- If you forget to use it* |  |  |
|  | *- If you use too much (overdose)* | Include the symptoms of overdosage (in layman terms) if relevant |  |
| 7 | **While you are using it** |  |
|  | *- Things you must do* |  |  |
|  | *- Things you must not do* |  |  |
|  | *- Things to be careful of* | Warning and precaution (choose relevant information for “while using” or “after using” the medicine) |  |
| 8 | **Side effects**- Include compulsory statement at the end of this section: | - Do not make the list too long- List down all very common and common ADRs as registered *(follow sequence as per PI)*- For other ADRs that are uncommon to very rare, choose those that are serious and the patients can recognize themselves.- Compulsory statements:**English**: "You may report any side effects or adverse drug reactions directly to the National Center for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].”**BM**: " Anda boleh melaporkan sebarang kesan sampingan atau kesan advers ubat kepada Pusat Pemantauan Kesan Advers Ubat Kebangsaan melalui laman web npra.gov.my [*Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].*” |  |
| 9 | **Storage and Disposal of (product name)** | Must include storage and disposal instructions (if nothing specific, include general instructions) |  |
| 10 | **Product Description** |  |  |
|  | *- What it looks like* | * Shape, colour, scoring
 |  |
|  | *- Ingredients* | * must include active and inactiveingredients
* must be the same as in approved PI
 |  |
|  | *- MAL number* | MAL numbers for each strength |  |
| 11 | **Manufacturer and Product Registration Holder** | * must include at least one Malaysian address
 |  |
| 12 | **Date of revision** | - Must be updated (Format: DD/MM/YYYY) |  |
| 13 | **Serial number** | - Will be provided by officer upon approval of RiMUP |  |
| **Final check before submission** |
| 1 | Content | Insert any compulsory statements as required in DRGD or directives |  |
| 2 | Format | All headings, subheadings and formatting as per guideline |  |
| 3 | Spelling and grammar | Check for any spelling or grammar errors |  |
| 4 | Translation | Correct meaning after translation.Easily understandable laymen terms |  |
| 5 | Spacing and alignment  | Headings/subheadings should not be left hanging at the bottom of pagesAlign left (do not justify)Ensure alignment and tabs are correct |  |
| 6 | During correspondence | Do not blindly follow the amendments requested, but try to understand the remarks. Feel free to provide justification if you do not agree with the remarks.If you do not understand the rejection remarks, do contact the officer in-charge for further clarification. Apply the same amendments on future RiMUPs (if applicable). |  |