**Apakah yang ada pada risalah ini**

1. Apakah kegunaan product name *(product name may be shortened from here onwards, no need to mention strength, e.g. Abcd Ointment)*
2. Bagaimana product name berfungsi
3. Sebelum menggunakan product name
4. Cara menggunakan product name
5. Semasa menggunakan product name
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan product name
8. Maklumat lanjut
9. Pengilang dan Pemegang Pendaftaran Produk
10. Tarikh kemas kini RiMUP

**Apakah kegunaan product name**

**Bagaimana product name berfungsi**

**Sebelum menggunakan** *product name*

* *Bila tidak boleh menggunakan*

Jangan ambil ubat ini jika:

* anda mempunyai alahan terhadap active ingredients atau mana-mana bahan lain yang terkandung dalam ubat ini (disenaraikan dalam Maklumat lanjut).
* *Sebelum menggunakannya*

Dapatkan nasihat doktor atau ahli farmasi sebelum menggunakan product namejika anda:

* xxxx
* xxxx

*Mengandung dan menyusukan anak*

Dapatkan nasihat doktor atau ahli farmasi jika anda mengandung, merancang untuk mengandung atau sedang menyusukan anak sebelum menggunakan sebarang ubat. *(if applicable)*

* *Jika mengambil ubat-ubat lain*

Beritahu doktor jika anda mengambil sebarang ubat lain, termasuk ubat yang dibeli tanpa preskripsi dari farmasi, pasar raya, atau kedai makanan kesihatan.

Maklumkan kepada doktor atau ahli farmasi anda jika anda sedang mengambil:

* xxxx
* xxxx

**Cara menggunakan product name**

Ikut arahan doktor atau ahli farmasi anda dengan teliti. Ia mungkin berbeza dari maklumat di dalam risalah ini. Jika anda tidak memahami arahan pada label ubat anda, sila rujuk kepada doktor atau ahli farmasi.

* *Berapa banyak harus digunakan*
* *Bila perlu digunakan*

Ikut arahan doktor atau ahli farmasi anda.

* *Berapa lama perlu digunakan*

Gunakan ubat ini mengikut tempoh masa yang ditetapkan oleh doktor anda.

* *Jika anda terlupa menggunakan*

Ambil dos yang tertinggal sebaik sahaja anda teringat. Sekiranya sudah hampir masa untuk dos seterusnya, abaikan dos yang tertinggal dan kemudian teruskan mengambil ubat mengikut jadual seperti biasa. Jangan ambil dos berganda untuk menggantikan dos yang tertinggal

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

Sapukan dos yang tertinggal sebaik sahaja anda teringat. Sekiranya sudah hampir masa untuk dos seterusnya, abaikan dos yang tertinggal dan kemudian teruskan menyapu ubat mengikut jadual seperti biasa. Jangan sapukan dos berganda untuk menggantikan dos yang tertinggal

* *Jika menggunakannya secara berlebihan (terlebih dos)*

Hubungi doktor anda dengan segera atau pergi ke Jabatan Kecemasan hospital terdekat, jika dos berlebihan telah digunakan. Ini perlu dilakukan walaupun tiada sebarang kesan keracunan atau rasa tidak selesa. Anda mungkin memerlukan perhatian perubatan segera.

Penggunaan ubat ini secara berlebihan mungkin menyebabkan………

**Semasa menggunakan product name**

* *Perkara yang perlu dilakukan*

Guna ubat anda mengikut arahan doctor. *(if applicable)*

Maklumkan kepada semua doktor, doktor gigi dan ahli farmasi yang merawat anda bahawa anda sedang menggunakan product name.

Beritahu doktor anda dengan segera jika anda menjadi hamil semasa menggunakan ubat ini. *(if applicable)*

Gunakan product namehanya dengan preskripsi doktor. *(For prescription only medicines)*

* *Perkara yang tidak boleh dilakukan*

Jangan berhenti menggunakan ubat ini kecuali diarahkan oleh doktor anda.

Jangan mula menggunakan sebarang ubat baharu tanpa berbincang dengan doktor atau ahli farmasi anda.

Jangan berikan product namekepada sesiapa, walaupun mereka mempunyai simptom atau keadaan yang sama dengan anda.

* *Perkara yang perlu diberi perhatian*

*Memandu dan menggunakan jentera*

Ubat ini mungkin mengganggu keupayaan anda untuk memandu atau mengendalikan jentera. Jika ubat ini menyebabkan anda *(insert sumptoms as applicable, e.g.* terasa loya, pening, letih, atau sakit kepala*)* jangan memandu atau mengendalikan jentera dan hubungi doktor anda dengan segera.

*For eye product (eg: ointment)*

Product name mungkin mengganggu penglihatan anda buat sementara waktu. Pastikan anda tahu bagaimana anda bertindak balas terhadap ubat ini sebelum anda memandu kereta, mengendalikan jentera atau melakukan aktiviti lain yang mungkin berbahaya.

*Others/relevant products*

Berhati-hati semasa memandu atau menggunakan jentera sehingga anda mengetahui tentang kesan product name terhadap anda.

**Kesan-kesan sampingan**

Seperti ubat-ubatan lain, product name boleh menyebabkan kesan sampingan, walaupun bukan semua orang akan mengalaminya.

Kesan sampingan yang mungkin berlaku adalah:

* xxxx
* xxxx

Jumpa doktor atau ahli farmasi anda dengan segera jika anda mengalami sebarang kesan sampingan selepas menggunakan ubat ini.

Anda boleh melaporkan sebarang kesan sampingan atau kesan advers ubat kepada Pusat Pemantauan Kesan *Adverse* Ubat Kebangsaan melalui laman web npra.gov.my [*Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].*

**Cara penyimpanan dan pelupusan**

product name

* *Penyimpanan*

Jauhi semua ubat daripada kanak-kanak.

Simpan pada suhu di bawah °C.

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

Jangan sapu ubat ini selepas tarikh luput atau jika penutup muncung tiub telah rosak atau tiub telah bocor. *(red phrase - for products packed in tubes)*

* *Pelupusan*

Ubat-ubatan tidak harus dilupuskan melalui air buangan atau sisa isi rumah. Sila rujuk kepada ahli farmasi anda mengenai cara yang betul untuk melupuskan ubat yang tidak diperlukan lagi. Langkah-langkah ini dapat membantu melindungi alam sekitar.

**Maklumat lanjut**

* *Rupa dan warna produk*
* *Bahan-bahan kandungan*
  + Bahan aktif
* xxxx
  + Bahan tidak aktif
* xxxx
* xxxx
* *Nombor MAL*

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

(include all if more than one strength)

**Pengilang**

Nama dan alamat

**Pemegang Pendaftaran Produk**

Nama dan alamat

**Tarikh kemas kini RiMUP**

DD/MM/YYYY

**Nombor Siri**

**IMPORTANT NOTES**

**Key:**

**Black = compulsory to be included**

**Red = information to be inserted**

**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**

**Before submission, check for:**

**\*Spelling errors**

**\* Incorrect translation**

**\* Spacing problems**

**\* Unjustify paragraph** (titles/subheadings should not be left hanging at the bottom of pages)

**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+system  RiMUP 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 bold  Sub-headings are italic, underlined |  |
| 8 | English and BM versions | Submit as two separate pdf files |  |
| 9 | Length of RiMUP | **Ideal length= 2 pages** per language  Maximum 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 heading  Product 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 relevant  Use 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 instruction  Must 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 relevant  Mention 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 pages  Align 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). |  |