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Tarikh : 27 SEP 2019

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
ARAHAN PENGARAH KANAN PERKHIDMATAN FARMASI BILANGAN 16 TAHUN 2019: DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI RETINOID YANG DIINDIKASIKAN UNTUK RAWATAN PENYAKIT KULIT (TERMASUK TOPIKAL): PENGEMASKINIAN LABEL, SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP) BAGI MEMPERKUKUHKAN MAKLUMAT KESELAMATAN BERKAITAN KESAN TERATOGENIK SERTA PENYEDIAAN BAHAN-BAHAN PENGAJARAN (*EDUCATIONAL MATERIALS*) BAGI PRODUK YANG MENGANDUNGI ORAL RETINOID YANG DIINDIKASIKAN UNTUK RAWATAN PENYAKIT KULIT

Adalah saya merujuk kepada Arahan Bilangan 16 Tahun 2019 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 16 Tahun 2019 telah bersetuju untuk memperkukuhkan maklumat keselamatan berkaitan kesan teratogenik bagi semua produk yang mengandungi retinoid yang diindikasikan untuk rawatan penyakit kulit (termasuk topikal) serta penyediaan bahan-bahan pengajaran (*educational materials*) bagi produk yang mengandungi oral retinoid yang diindikasikan untuk rawatan penyakit kulit seperti pada surat arahan Bil.(16) BPFK/PPP/07/25 Jld.3.

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATIN DR. FARIDAH ARYANI BINTI MD. YUSOF) **RPh 1197**
Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia
AAG/nb/ppp/NPRA/120919

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 16 TAHUN 2019

i. **DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI RETINOID YANG DIINDIKASIKAN UNTUK RAWATAN PENYAKIT KULIT (TERMASUK TOPIKAL): PENGEMASKINIAN LABEL, SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP) BAGI MEMPERKUKUHKAN MAKLUMAT KESELAMATAN BERKAITAN KESAN TERATOGENIK**

ii. **PENYEDIAAN BAHAN-BAHAN PENGAJARAN (*EDUCATIONAL MATERIALS*) BAGI PRODUK YANG MENGANDUNGI ORAL RETINOID YANG DIINDIKASIKAN UNTUK RAWATAN PENYAKIT KULIT:**
- **BORANG SENARAI SEMAK UNTUK KEGUNAAN PRESKRIBER (*PRESCRIBER CHECKLIST/ ACKNOWLEDGEMENT FORM*)**
- **BORANG SENARAI SEMAK UNTUK KEGUNAAN AHLI FARMASI (*PHARMACIST CHECKLIST*)**
- **KAD PERINGATAN PESAKIT (*PATIENT REMINDER CARD*)**

TUJUAN

1.1 Arahan ini dikeluarkan oleh Pengarah Kanan Perkhidmatan Farmasi di bawah Peraturan 29 (1) Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984.

1.2 Arahan ini ditujukan kepada semua pemegang pendaftaran produk yang mengandungi retinoid yang diindikasikan untuk rawatan penyakit kulit (termasuk topikal) bagi :

(i) Mengemaskini label, sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) bagi memperkukuhkan maklumat keselamatan berkaitan kesan teratogenik.

(ii) Menyediakan bahan-bahan pengajaran (*educational materials*) bagi produk yang mengandungi oral retinoid yang diindikasikan untuk rawatan penyakit kulit:
- Borang senarai semak untuk kegunaan preskriber (*prescriber checklist/ acknowledgement form*)

- Borang senarai semak untuk kegunaan ahli farmasi (*pharmacist checklist*)
- Kad peringatan pesakit (*patient reminder card*)

LATAR BELAKANG

2.1 Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke **338** pada **5 September 2019** telah membuat keputusan bagi semua produk yang mengandungi retinoid yang diindikasikan untuk rawatan penyakit kulit (termasuk topikal) bagi :

(i) Mengemaskini label, sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) bagi memperkukuhkan maklumat keselamatan berkaitan kesan teratogenik.

(ii) Menyediakan bahan-bahan pengajaran (*educational materials*) bagi produk yang mengandungi oral retinoid yang diindikasikan untuk rawatan penyakit kulit:
- Borang senarai semak untuk kegunaan preskriber (*prescriber checklist/ acknowledgement form*)
- Borang senarai semak untuk kegunaan ahli farmasi (*pharmacist checklist*)
- Kad peringatan pesakit (*patient reminder card*)

PELAKSANAAN

3.1 Oleh itu arahan – arahan berikut perlu dipatuhi untuk semua produk yang mengandungi retinoid yang diindikasikan untuk rawatan penyakit kulit (termasuk topikal) bagi seperti berikut:-

3.1.1 PRODUK ORAL RETINOID

3.1.1.1 LABEL

A boxed warning should be added to the outer packaging as follows:

WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or you think you may be pregnant

3.1.1.2 SISIP BUNGKUSAN

3.1.1.2.1 Pada bahagian *Contraindications*:

- *Pregnant women*

- *Women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met (See Section Warnings & Precautions)*

3.1.1.2.2 Pada bahagian *Warnings & Precautions*:

Teratogenic effects   *[Product name] is a powerful human teratogen inducing a high frequency of severe and life threatening birth defects.*   ***[Product name] is strictly contraindicated in:***   - *Pregnant women*   - *Women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met*

Pregnancy Prevention Programme

[Product name] is contraindicated in women of childbearing potential unless all of the following conditions of the Pregnancy Prevention Programme are met:

- *[approved indications] (See Section Indications)*
- *The potential for pregnancy must be assessed for all female patients.*
- *She understands the teratogenic risk.*
- *She understands the need for frequent follow-up (e.g. on a monthly basis).*
- *She understands and accepts the need for effective contraception, without interruption, 1 month before starting treatment, throughout the entire duration of treatment and for 1 month* [*3 years for acitretin] after the end of treatment. At least one highly effective method of contraception (i.e. a user-independent form) or two complementary user-dependent forms of contraception should be used.*
- *Individual circumstances should be evaluated in each case, when choosing the contraception method, involving the patient in the discussion, to guarantee her engagement and compliance with the chosen measures.*
- *Even if she has amenorrhea she must follow all the advice on effective contraception.*
- *She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy or if she might be pregnant.*
- *She understands the need and accepts to undergo regular pregnancy testing before, ideally monthly during treatment and 1 month after stopping treatment [for acitretin this statement should be - She understands the need and accepts to undergo regular pregnancy testing before, ideally monthly during treatment and*

periodically with 1-3 monthly intervals for a period of 3 years after stopping treatment].

- *She has acknowledged that she has understood the hazards and necessary precautions associated with the use of [product name].*

These conditions also concern women who are not currently sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

The prescriber must ensure that:

- *The patient complies with the conditions for pregnancy prevention as listed above, including confirmation that she has an adequate level of understanding.*
- *The patient has acknowledged the aforementioned conditions.*
- *The patient understands that she must consistently and correctly use one highly effective method of contraception (i.e. a user-independent form) or two complementary user-dependent forms of contraception, for at least 1 month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least 1 month* [*3 years for acitretin] after cessation of treatment.*
- *Negative pregnancy test results have been obtained before, during and 1 month after the end of treatment. The dates and results of pregnancy tests should be documented.*
  [for acitretin this last bullet point should be]
- *Negative pregnancy test results have been obtained before, during and periodically with 1-3 monthly intervals for a period of 3 years after stopping treatment. The dates and results of pregnancy tests should be documented.*

If pregnancy occurs in a woman treated with [product name], treatment must be stopped and the patient should be referred to a physician specialised or experienced in teratology for evaluation and advice.

If pregnancy occurs after stopping treatment there remains a risk of severe and serious malformation of the fetus. This risk persists until the product has been completely eliminated, which is within one month following the end of treatment [*3 years for acitretin].*

Contraception

Female patients must be provided with comprehensive information on pregnancy prevention and should be referred for contraceptive advice if they are not using effective contraception. If the prescribing physician is not in a position to provide such information the patient should be referred to the relevant healthcare professional.

As a minimum requirement, female patients of childbearing potential must use at least one highly effective method of contraception (i.e. a

user-independent form), or two complementary user-dependent forms of contraception. Contraception should be used for at least 1 month prior to starting treatment, throughout treatment and continue for at least 1 month [*3 years for acitretin] after stopping treatment with [product name], even in patients with amenorrhea.*

Individual circumstances should be evaluated in each case, when choosing the contraception method involving the patient in the discussion, to guarantee her engagement and compliance with the chosen measures.

Pregnancy testing

Prior to starting therapy

At least one month after the patient has started using contraception, and shortly (preferably a few days) prior to the first prescription, the patient should undergo a medically supervised pregnancy test. This test should ensure the patient is not pregnant when she starts treatment with [product name].

Follow-up visits

Follow-up visits should be arranged at regular intervals, ideally monthly. Follow-up pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.

End of treatment

1 month after stopping treatment, women should undergo a final pregnancy test.
[for acitretin this last paragraph should be]
Women should undergo pregnancy test periodically with 1-3 monthly intervals for a period of 3 years after stopping treatment.

Prescribing and dispensing restrictions

For women of childbearing potential, the prescription duration of [product name] ideally be limited to 30 days in order to support regular follow up, including pregnancy testing and monitoring. Ideally, pregnancy testing, issuing a prescription and dispensing of [product name] should occur on the same day.

This monthly follow-up will allow ensuring that regular pregnancy testing and monitoring is performed and that the patient is not pregnant before receiving the next cycle of medication.

Male patients

The available data suggest that the level of maternal exposure from the semen of the patients receiving [product name] is not of a sufficient magnitude to be associated with the teratogenic effects of [product name]. Male patients should be reminded that they must not share their medication with anyone, particularly females.

Additional precautions

Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment.

Patients should not donate blood during therapy and for 1 month [*3 years for acitretin] following discontinuation of [product name] because of the potential risk to the foetus of a pregnant transfusion recipient.*

Educational material

In order to assist healthcare professionals and patients in avoiding fetal exposure to [product name] the Product Registration Holder will provide educational material to reinforce the warnings about the teratogenicity of [product name], to provide advice on contraception before therapy is started and to provide guidance on the need for pregnancy testing.

Full patient information about the teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Programme should be given by the physician to all patients, both male and female.

3.1.1.3 RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RIMUP)

3.1.1.3.1 Pada bahagian *Before you use [product name]*:

WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant

When you must not use it:

- *If you are pregnant or breast-feeding.*
- *If there is any chance you could become pregnant*

Women must use effective contraception before, during and after taking [product name]:

- *You must agree to use at least one very reliable method of contraception (for example an intrauterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.*
- *You must use contraception for a month before taking [product name], during treatment and for a month* afterwards [*for acitretin should be 3 years].*
- *You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).*

Women must agree to pregnancy testing before, during and after taking [product name]:

- *You must agree to regular follow-up visits, ideally every month.*
- *You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month* after stopping [product name] (unless your doctor decides this is not necessary in your case). {*for acitretin: 'every 1 to 3 months for 3 years after stopping [product name]'}.*
- *You must agree to extra pregnancy tests if your doctor asks you.*
- *You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body.*
  for acitretin this last bullet point should be:
- *You must not get pregnant during treatment or for 3 years afterwards because some medicine may still be left in your body.*

If you get pregnant while taking [product name], stop taking the medicine straight away, and contact your doctor.

Also, if you become pregnant within one month [* 3 years for acitretin] after you stop taking [product name], you should contact your doctor.*

Advice for men

The levels of oral retinoid in the semen of men taking [product name] are too low to harm their partners' unborn baby. However, you must never share your medication with anyone, especially females.

Additional precautions

You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month [*3 years for acitretin] after stopping [product name] because an unborn baby could be harmed if a pregnant patient receives your blood.*

3.1.2 PRODUK TOPIKAL RETINOID

3.1.2.1 SISIP BUNGKUSAN

3.1.2.1.1 Pada bahagian *Contraindications*:

- *Pregnancy (see Section Pregnancy and Lactation)*
- *Women planning a pregnancy*

3.1.2.1.2 Pada bahagian *Pregnancy and Lactation [menggantikan specific labeling requirements – Tretinoin Topical* dalam *Drug Registration Guidance Document]*:

Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result into low systemic exposure due to minimal dermal absorption. However, there could be individual factors (e.g. damaged skin barrier, excessive use) that contribute to an increased systemic exposure.

[Product name] is contraindicated (see Section Contraindications) in pregnancy, or in women planning a pregnancy.

If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

3.1.2.2 RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP)

3.1.2.2.1 Pada bahagian *Before you use [product name]*:

Do not use [product name] if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

3.2 Penyediaan bahan-bahan pengajaran *(education materials)* untuk **oral retinoid** yang diindikasikan untuk rawatan penyakit kulit seperti kad peringatan pesakit, borang senarai semak untuk kegunaan preskriber dan borang senarai semak untuk kegunaan ahli farmasi dengan **maklumat minimum** seperti berikut:

3.2.1 KAD PERINGATAN PESAKIT *(PATIENT REMINDER CARD)*

3.2.1.1 Kad peringatan pesakit perlu dicetak dan dibekalkan oleh syarikat pemegang pendaftaran produk untuk edaran ke fasiliti-fasiliti yang dibekalkan dengan oral retinoid.

3.2.1.2 Kad peringatan pesakit boleh diedarkan oleh golongan ahli profesional kesihatan seperti pakar dermatologi dan ahli farmasi semasa pesakit menerima rawatan oral retinoid.

3.2.1.3 Pesakit perlu dimaklumkan dengan risiko berkaitan oral retinoid dan diingatkan menyimpan kad peringatan pesakit ini dengan cermat.

3.2.1.4 Kad ini perlu disediakan dalam dwi bahasa, iaitu Bahasa Malaysia dan Bahasa Inggeris, dengan saiz yang kecil bagi memudahkan pesakit menyimpan kad tersebut.

PATIENT REMINDER CARD

Important information to know:

- *[Product name] must not be taken during pregnancy. [Product name] can seriously harm an unborn baby if a pregnant woman takes it.*
- *If you become pregnant or think you might be pregnant, stop taking [product name] immediately and contact your doctor.*
- *If you have any questions or concerns about taking [product name], talk to your doctor or pharmacist.*

What you must do:

- *You must use effective contraception before, during and for 1 month* [*for acitretin: 3 years] after stopping treatment with [product name].*
- *You must not become pregnant while taking [product name], or for 1 month* [*for acitretin: 3 years] after stopping treatment.*
- *You must attend regular follow-up visits and have regular pregnancy testing.*

Reminder for Men and Women

Do not share this medication with anybody and return any unused capsules back to the pharmacy. You should not donate blood during treatment with this medicine and for 1 month [*for acitretin: 3 years] after stopping treatment.*

3.2.2 BORANG SENARAI SEMAK UNTUK KEGUNAAN PRESKRIBER *(PRESCRIBER CHECKLIST/ ACKNOWLEDGEMENT FORM)*

3.2.2.1 Borang ini perlu disediakan oleh pemegang pendaftaran produk untuk edaran ke fasiliti-fasiliti yang dibekalkan dengan oral retinoid untuk kegunaan preskriber yang memberikan rawatan kepada pesakit.

3.2.2.2 Borang ini bertujuan untuk memastikan pesakit atau penjaganya telah berbincang dengan preskriber berkaitan rawatan yang diterima dan memahami risiko berkaitan oral retinoid.

3.2.2.3 Satu (1) salinan perlu direkod untuk rujukan preskriber dan 1 (satu) salinan lagi untuk simpanan pesakit.

3.2.2.4 Borang ini perlu dicetak sekurang-kurangnya dalam dua (2) bahasa, iaitu Bahasa Malaysia dan Bahasa Inggeris untuk kegunaan pesakit.

PRESCRIBER CHECKLIST/ ACKNOWLEDGEMENT FORM FOR PRESCRIBING [PRODUCT NAME] TO FEMALE PATIENTS

The potential for pregnancy must be assessed for all female patients prescribed [product name].

A woman has a potential for pregnancy if one of the following applies:
Is a sexually mature woman who:

1. *has not had a hysterectomy or bilateral oophorectomy*
2. *is not in a natural postmenopause for a minimum of 24 consecutive months (i.e., menstruated at a certain point in the last 24 consecutive months).*

Before initiating [product name] in a female patient, the following checklist is to be completed by the prescriber and kept with the patient notes to document compliance with the [product name] Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

[Product name] belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to [product name], even for short periods, presents a high risk of congenital malformations. [Product name] is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the [product name] Pregnancy Prevention Programme are fulfilled.

As the prescriber, you must make sure that the risk of serious harm from drug exposed pregnancy is fully understood by all female patients before treating them with [product name].

This checklist should also be used in all follow-up visits with women of childbearing potential.

Please use the patient reminder card to support your discussion with the patient.

Is the patient a woman of childbearing potential? If No, go to Section 4.

Women of childbearing potential: Review the below statements, explain them to the patient and record confirmation of this and acknowledgment from the patient in this form. If the answer to any of these questions is NO, [product name] must not be prescribed.

	Prescriber confirm: I have explained this to my patient		***Patient confirm: I have understood this***	
Is the patient suffering from a severe form of acne, which is resistant to standard therapies? *[for acitretin: Is the patient suffering from a severe form of psoriasis or severe disorder of keratinization ?]*	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
1. Teratogenicity				
The patient understands that [product name] belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. [Product name] also increases the risk of miscarriage when taken during pregnancy.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
2. Contraception				
The patient understands that she must consistently and correctly use at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary methods of birth control (i.e. user-dependent forms such as oral contraceptive and barrier method) before and during treatment.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The patient understands that the risk persists even after the medication is stopped and that she must not get pregnant within 1 month [*for acitretin: 3 years] after stopping treatment.*	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The patient is aware of the risk of contraceptive failure.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
3. Pregnancy Testing & Ideally Monthly Prescriptions				
The first prescription for [product name] can only be given after the patient has had one negative medically supervised pregnancy test. This is to make sure she is not already pregnant before starting treatment.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
Patient understands that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription be limited to 30 days.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
Patient understands the need for and agrees to pregnancy testing before, during and after treatment.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐

	Prescriber confirm: I have explained this to my patient		*Patient confirm: I have understood this*	
Patient understands the need to do a pregnancy test 1 month after stopping treatment [*for acitretin: 1-3 monthly intervals throughout treatment and also for a period of 3 years after stopping treatment] because the drug stays in the body for 1 month* [*for acitretin: 3 years] after the last dose and can damage an unborn baby if pregnancy occurs.*	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The contraceptive methods and pregnancy test results were recorded in the patient's medical records.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The patient knows to contact their doctor if they have unprotected sex, miss their period, become pregnant, or suspect that they have become pregnant during the risk period.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
If pregnancy occurs, treatment must be stopped and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
The patient has received a reminder card and copy of this form.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
4. Other Precautions				
Patient understands that [product name] has been prescribed to her only and must not be shared with others.	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐
Patient understands that she must not donate blood during treatment with [product name] and for one month [*for acitretin: 3 years] after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.*	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐

Prescriber's signature: *Patient's signature:* *Date:*

3.2.3 BORANG SENARAI SEMAK UNTUK KEGUNAAN AHLI FARMASI *(PHARMACIST CHECKLIST)*

3.2.3.1 Borang senarai semak untuk kegunaan ahli farmasi ini perlu dicetak dan dibekalkan oleh syarikat pemegang pendaftaran produk untuk edaran ke fasiliti-fasiliti yang dibekalkan dengan oral retinoid.

3.2.3.2 Borang senarai semak ini boleh diguna oleh ahli farmasi semasa pendispensan oral retinoid.

PHARMACIST CHECKLIST - GUIDANCE FOR DISPENSING [PRODUCT NAME]

[Product name] belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to [product name], even for short periods of time, presents a high risk of congenital malformations and miscarriage.

[Product name] is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions in the Pregnancy Prevention Programme are fulfilled.

Female patient must use effective contraception before, during and for 1 month [*for acitretin: 3 years] after stopping treatment with [product name].*

A negative pregnancy test, issuing a prescription and dispensing [product name] should ideally occur on the same day.

If you are aware that a pregnancy has occurred in a woman treated with [product name], treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within 1 month [*for acitretin: 3 years] of stopping [product name], she should be referred to her prescribing doctor.*

As the pharmacist, you should only dispense [product name] after checking the following information:

For women of child-bearing potential:	
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for [product name] ideally be limited to a 30-day supply.	
All patients should be instructed:	
Never to give the [product name] to another person.	
To return any unused capsules to their pharmacist at the end of treatment.	
Not to donate blood during [product name] therapy and for 1 month [*for acitretin: 3 years] after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.*	

4. Tarikh pelaksanaan keperluan mengemaskini maklumat berkenaan pada semua produk yang mengandungi retinoid yang diindikasikan untuk rawatan penyakit kulit (termasuk topikal) bagi:

(a) Permohonan baru dan produk yang sedang dalam proses penilaian : **1 Oktober 2019.**

(b) Produk berdaftar : **1 April 2020.**

5. Permohonan pindaan pada label, sisip bungkusan dan RiMUP bagi produk berdaftar perlu dikemukakan sebagai permohonan variasi.

6. Tarikh kuat kuasa arahan ini ialah mulai **1 Oktober 2019.**

"BERKHIDMAT UNTUK NEGARA"

(DR. RAMLI BIN ZAINAL) RPh. 1045
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
AAG/nb/ppp/NPRA/100919

s.k. 1. Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

2. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

3. Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia