澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
藥物監督管理局
Instituto para a Supervisão e Administração Farmacêutica

成 藥 登 記 證 書
CERTIFICADO DE REGISTO DE ESPECIALIDADE FARMACÊUTICA

茲證明下列成藥已在澳門特別行政區登記，有關資料如下：
Certifico que a especialidade farmacêutica, abaixo identificada, se encontra registada na Região Administrativa Especial de Macau, de acordo com as seguintes especificações:

(1)商品名稱 : RUXOLITINIB CREAM 15MG/G MAC- 03348
Nome comercial :
(2)成份及含量 : Ruxolitinib 15mg/g
Composição e dose :
(3)劑型 F.Farm : 乳膏劑 Creme (4)每一包裝數量 Apresentação : 100g
(5)申請登記人 : 五洲藥物產品出入口及批發商號
Requerente do registo : Firma de Importação, Exportação e Venda por Grosso de Produtos Farmacêuticos Wuzhou
(6)核准登記人 : 藥物監督管理局副局長 (7)批示日期 : 11/04/2024
Registo autorizado por : Vice-presidente do ISAF Data do despacho :
(8)登記有效期 : 2029 年 04 月 11 日
Validade do registo : 11 / 04 / 2029

日期 : 2024 年 04 月 11 日
Data : 11 / 04 / 2024

藥物監督管理局局長
P' O Presidente do ISAF

李世恩 代行

Lei Sai Ian

按照九月十九日第五九/九零/M 號法令第七條第四款之規定發出
(Emitido ao abrigo do nº4 do artigo 7º do Decreto Lei Nº59/90/M, de 19 de Setembro)

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五洲藥物產品出入口及批發商號
台啓

來函編號 Sua referência	來函日期 Sua comunicação de	發函編號 Nossa referência	澳門郵政信箱3092號 C. Postal 3092 - Macau
		758/VPRA/ISAF/2024	11/04/2024

事由：Assunto **確認 RUXOLITINIB CREAM 15MG/G 藥物訊息**

茲確認藥物 RUXOLITINIB CREAM 15MG/G (澳門藥物登記編號 MAC-03348)的申請登記人、產品准照持有人及製造商的訊息如下：

申請登記人	:	五洲藥物產品出入口及批發商號
申請登記人地址	:	澳門電廠巷 22 號亨達大廈地下 AJ 座
產品准照持有人	:	Incyte Biosciences Distribution B.V.
產品准照持有人地址	:	Paasheuvelweg 25, 1105 BP Amsterdam, Netherlands
製造商	:	Tiofarma B.V.
製造商地址	:	Hermanus Boerhaavestraat 1 Oud-Beijerland, 3261 ME Netherlands

耑此，順頌
台祺

藥物監督管理局副局長

李世恩

澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
藥物監督管理局
Instituto para a Supervisão e Administração Farmacêutica

五洲藥物產品出入口及批發商號
台啓

來函編號 Sua referência	來函日期 Sua comunicação de	發函編號 Nossa referência	澳門郵政信箱3092號 C. Postal 3092 - Macau
		759/VPRA/ISAF/2024	11/04/2024

事由：**確認 RUXOLITINIB CREAM 15MG/G 藥物訊息**
Assunto

茲確認藥物 RUXOLITINIB CREAM 15MG/G (澳門藥物登記編號 MAC-03348)已獲本局核准的產品外包裝及說明書資料，如附件所示。

耑此，順頌

台祺

藥物監督管理局副局長

李世恩

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A-4 規格印件 2023年11月
Formato A-4 Imp. Nov. 2023

澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
藥物監督管理局
Instituto para a Supervisão e Administração Farmacêutica

附件：外包装

Ruxolitinib
Cream
15 mg/g

Cutaneous use

1 tube (100 g)

1 g of cream contains 15 mg of ruxolitinib (as phosphate).

Butylated hydroxytoluene (E321), cetyl alcohol, dimeticone (E900), disodium edetate (E385), glyceryl stearate, paraffin (E905), macrogol, medium chain triglycerides, methyl parahydroxybenzoate (E218), phenoxyethanol, polysorbate 20 (E432), propylene glycol (E1520), propyl parahydroxybenzoate, purified water, stearyl alcohol and xanthan gum (E415).

LOT:

EXP:

Do not store above 30 °C.
Read the package leaflet before use.
Keep out of the sight and reach of children.

Ruxolitinib
Cream
15 mg/g

Manufacturer: Tiofarma B.V.
Address:
Hermanus Boerhaavestraat 1
Oud Beijerland, 3261 ME
Netherlands

Origin Reg. No.:
EU/1/23/1726/002

Ruxolitinib
Cream
15 mg/g

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附件：說明書

Package leaflet: Information for the patient

Ruxolitinib cream 15 mg/g

Read all of this leaflet carefully before you start 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ruxolitinib cream is and what it is used for

Ruxolitinib cream contains the active substance ruxolitinib. It belongs to a group of medicines called Janus kinase inhibitors.

Ruxolitinib cream is used on the skin to treat vitiligo with facial involvement in adults and adolescents from 12 years. Vitiligo is an autoimmune disease, where the body's immune system attacks the cells that produce the skin pigment melanin. This causes a loss of melanin, leading to patches of pale pink or white skin. In vitiligo, ruxolitinib reduces the immune system's activity against the melanin-producing cells, allowing the skin to produce pigment and regain its normal colour.

2. What you need to know before you use Ruxolitinib cream

Do not use Ruxolitinib cream

- if you are allergic to ruxolitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Ruxolitinib cream.

Ruxolitinib cream is not for use on the lips, in the eyes, mouth or vagina. If cream accidentally gets into these areas, thoroughly wipe off and/or rinse off the cream with water.

Children under 12 years

Do not give Ruxolitinib cream to children younger than 12 years because it has not been studied in this age group.

Other medicines and Ruxolitinib cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Using Ruxolitinib cream at the same time as other medicines on the affected skin is not recommended, as it has not been studied.

After applying Ruxolitinib cream, wait at least 2 hours before applying other medicines, sunscreen or body creams/oils to the same skin area.

Pregnancy and breast-feeding

Ruxolitinib cream should not be used by pregnant or breast-feeding women as this has not been investigated. If you are a woman of childbearing age, you should use an effective contraception during treatment and during 4 weeks after applying Ruxolitinib cream for the last time.

It is not known if ruxolitinib passes into breast milk after applying it to the skin. The effects of this medicine in breastfed infants are unknown; therefore, Ruxolitinib cream should not be used if you are breast-feeding or planning to breastfeed. You may start breast-feeding approximately four weeks after applying Ruxolitinib cream for the last time.

Driving and using machines

Ruxolitinib cream is unlikely to have an effect on your ability to drive and use machines.

Ruxolitinib cream contains propylene glycol, cetyl alcohol, stearyl alcohol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and butylated hydroxytoluene

- This medicine contains 150 mg propylene glycol (E1520) in each gram of cream, which may cause skin irritation.
- Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).
- Butylated hydroxytoluene (E321) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use Ruxolitinib cream

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

Recommended dose

- Apply a thin layer of cream twice daily to affected areas of your skin. Wait at least 8 hours between applications.
- The cream should not be used on more than 10% (one tenth) of your body. This surface area represents the equivalent to ten times the palm of one hand with the five fingers.

Method of administration

- This medicine is for use on the skin only.

附件：說明書

- Do not apply to skin surfaces other than the ones instructed by your doctor. The medicine should be used at the smallest skin area necessary.
- Wash your hands after applying this medicine, unless you are treating your hands. If someone applies this medicine to you, they should wash their hands after application.
- Avoid washing treated skin for at least 2 hours after application of Ruxolitinib cream.

Duration of use

Your doctor will decide how long you should use the cream for.
A minimum duration of 6 months is recommended but satisfactory treatment may require over 12 months. If you achieve satisfactory repigmentation of treated areas, consult your doctor to discuss if treatment of those areas could be stopped. Consult your doctor if you experience loss of repigmentation after stopping treatment.
Do not use more than two 100 gram tubes a month.

If you use more Ruxolitinib cream than you should

Wipe off the excess cream if this occurs.

If you forget to use Ruxolitinib cream

If you forget to apply the cream at the scheduled time, do it as soon as you remember, then continue your normal dosing schedule. However, if the next scheduled dose is due within 8 hours, skip the missed dose.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. The following side effects have been reported with Ruxolitinib cream:
Common (may affect up to 1 in 10 people)
- acne at application site

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Ruxolitinib cream

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 30 °C.
Once the tube has been opened, use the cream within 6 months but not after the expiry date.
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. Contents of the pack and other information

What Ruxolitinib cream contains

- The active substance is ruxolitinib.
  One gram of cream contains 15 mg of ruxolitinib.
- The other ingredients are butylated hydroxytoluene (E321), cetyl alcohol, dimeticone (E900), disodium edetate (E385), glyceryl stearate, paraffin (E905), macrogol, medium chain triglycerides, methyl parahydroxybenzoate (E218), phenoxyethanol, polysorbate 20 (E432), propylene glycol (E1520), propyl parahydroxybenzoate, purified water, stearyl alcohol, xanthan gum (E415).

See section 2 "Ruxolitinib cream contains propylene glycol, cetyl alcohol, stearyl alcohol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and butylated hydroxytoluene".

What Ruxolitinib cream looks like and contents of the pack

Ruxolitinib cream is coloured white to off-white, supplied in a tube containing 100 g cream.
There is one tube per carton.

Manufacturer

Tiofarma B.V.
Hermanus Boerhaavestraat 1
Oud-Beijerland, 3261 ME
Netherlands