



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
1 JULY 2019**

HSA ALERT: UNDECLARED POTENT INGREDIENTS FOUND IN FOUR SKIN CREAMS; INFANT HOSPITALISED WITH SERIOUS ADVERSE REACTION

The Health Sciences Authority (HSA) is alerting members of the public not to purchase and use the following creams:

- a) An unlabelled diaper cream supplied by a traditional practitioner in Malaysia
- b) ‘D’Splendid Kidzema Cream’
- c) ‘CLAÍR DE LUNE P. Tuberosa Day Cream’
- d) ‘CLAÍR DE LUNE S. Involcurata Night Cream’

2 An infant (less than one-year-old) developed Cushing’s syndrome following the use of an unlabelled cream for diaper rash. The other three creams were used by consumers to treat their eczema. Users of these creams became concerned about the products when they experienced rapid relief of their condition which worsened when they stopped using them. HSA has tested the creams and found that they contained potent medicinal ingredients including steroids, antibiotics and antifungals:

Name of product	Undeclared potent medicinal ingredients
‘Unlabelled diaper cream’	Steroid: Betamethasone valerate Antifungal: Clotrimazole
‘D’Splendid Kidzema Cream’	Antibiotic: Ciprofloxacin Antifungal: Terbinafine
‘CLAÍR DE LUNE P. Tuberosa Day Cream’	Steroid: Clobetasol propionate Antibiotic: Chloramphenicol, Metronidazole, Sulfamethoxazole, Trimethoprim Antifungal: Ketoconazole
‘CLAÍR DE LUNE S. Involcurata Night	Antihistamine: Chlorpheniramine, Antibiotic:

Cream'	Metronidazole, Sulfamethoxazole, Trimethoprim Antifungal: Griseofulvin
--------	------------------------------------------------------------------------------

Please refer to **Annex A** for photos of some of the products and **Annex B** for more information on the medicinal ingredients found in the products.

UNDECLARED POTENT INGREDIENTS FOUND IN CREAMS USED IN CHILDREN

3 An infant developed Cushing’s syndrome following the use of an unlabelled ‘diaper cream’ for diaper rash. The product was purchased from a traditional practitioner in Malaysia and tested to contain betamethasone valerate (a potent steroid) and clotrimazole (an antifungal medicine). Her symptoms, caused by the steroid, included ‘moon-face’, ‘buffalo hump’ on the back (due to fat accumulation), excessive hair growth on the body and thinning of the skin. The steroid also led to recurrent infections as it suppressed her immune system and caused poor developmental growth. The infant was hospitalised although she has since been discharged and is currently undergoing outpatient treatment.

4 A mother who purchased ‘D’Splendid Kidzema Cream’ for her child’s eczema observed that it cleared up after only two applications of the cream. However, the eczema worsened three days after she stopped the use of the cream. The cream was sold by D’Splendid on its website, at sales booths and other retail outlets. It was labelled to relieve skin rashes, eczema, haemorrhoids and mosquito bites for babies and children up to 14 years old. However, HSA tested and found that it contained ciprofloxacin (an antibiotic) and terbinafine (an antifungal medicine). Creams containing terbinafine are not recommended for use in children under the age of 12, while ciprofloxacin is a prescription only medicine that should only be used under medical supervision. Inappropriate use of antibiotics and antifungals can lead to decreased effectiveness for future infections. HSA has directed the company to stop the sale of ‘D’Splendid Kidzema Cream’ and to recall the affected product from retail outlets.

MULTIPLE UNDECLARED POTENT INGREDIENTS FOUND IN COSMETIC PRODUCTS

5 'CLAÍR DE LUNE P. Tuberosa Day Cream' and 'CLAÍR DE LUNE S. Involucrata Night Cream' are cosmetic products that were sold on various e-commerce and social media platforms. 'CLAÍR DE LUNE P. Tuberosa Day Cream' claimed to be '*anti-allergic*' and can '*reduce acne and eczema*' and '*stimulate metabolism of skin*', while 'CLAÍR DE LUNE S. Involucrata Night Cream' claimed to have '*anti-bacterial*' and '*anti-inflammatory*' properties.

6 A consumer who used the products reported that her eczema flared when she stopped using them. The creams were tainted with multiple potent ingredients including a steroid (in the day cream), an antihistamine (in the night cream), antibiotics, and antifungal medicines in both. Use of creams with these potent ingredients can lead to adverse effects, such as thinning of the skin (from prolonged steroid use), skin rash and skin irritation. The products also carried false and misleading claims of '*all-natural plant-based ingredients*' and '*zero chemical*'. Website administrators of the local e-commerce platforms have been directed to remove the postings for these creams.

ADVISORY TO CONSUMERS

7 Consumers are advised to:

- See a doctor as soon as possible if you or your child are using these products for eczema as sudden stopping of the cream may result in worsening of the condition, or if you or your child have experienced any adverse effects.
- Exercise caution when purchasing health products for use in babies and children, including those that are applied on the skin such as creams. Potent ingredients added into the creams can be absorbed into the body and cause adverse effects.
- Do not use unlabelled products or purchase from unfamiliar overseas sources, unknown or dubious websites or from persons posting offers on online platforms. You cannot be certain what these products contain and where or how

they were made. Babies and children are more vulnerable to serious adverse effects, especially if exposed to potent controlled ingredients.

- Be wary that not all products that claim to be “all natural plant-based product” or “zero chemical” actually are what they claim to be. They could potentially contain undeclared controlled ingredients, which were illegally added to boost the efficacy of these products.

8 HSA has produced a short video on the risks associated with buying health products online. This video can be viewed at https://youtu.be/dmjl_bSqJgA.

ADVISORY TO SELLERS AND SUPPLIERS

9 Sellers and suppliers are warned that:

- It is illegal to sell and supply adulterated products which contain undeclared potent medicinal ingredients.
- Anyone who supplies such adulterated products is liable to prosecution and if convicted, may be imprisoned for up to 3 years and/or fined up to \$100,000.

10 Members of the public who have any information on the sale and supply of these adulterated products may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: hsa_is@hsa.gov.sg.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
1 JULY 2019**

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and

adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

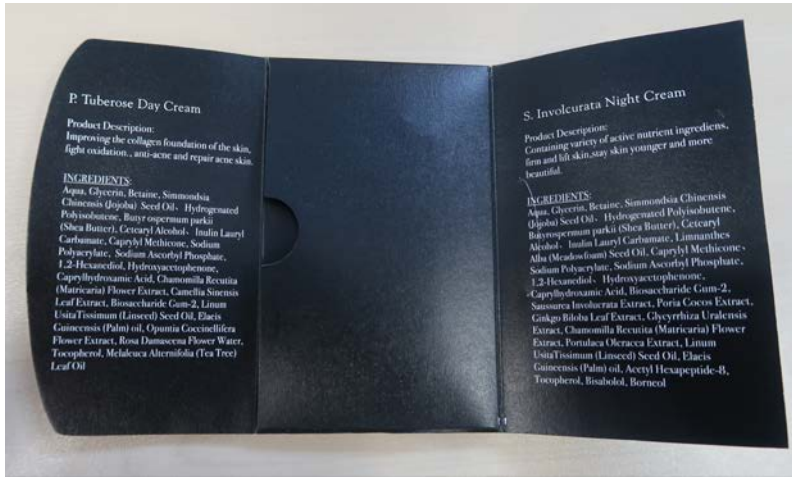
**HSA ALERT: UNDECLARED CONTROLLED INGREDIENTS FOUND
IN FOUR SKIN CREAMS; INFANT HOSPITALISED WITH SERIOUS
ADVERSE REACTION**

1. D'Splendid Kidzema Cream



2. 'CLAÍR DE LUNE P. Tuberosa Day Cream' and 'CLAÍR DE LUNE S. Involcurata Night Cream'





INFORMATION OF UNDECLARED POTENT MEDICINAL INGREDIENTS FOUND IN THE PRODUCTS

Clobetasol propionate and betamethasone valerate

Clobetasol propionate and betamethasone valerate are potent steroids that are usually prescribed for inflammatory conditions and should only be used under strict medical supervision. Adverse effects associated with the topical use of steroids include hypersensitivity reactions and thinning of the skin. They may also be absorbed into the body to cause serious adverse effects such as Cushing's syndrome (characterised by a round face or 'moon face' and upper body obesity with thin limbs) and high blood pressure, when applied to large areas of the skin or used over a prolonged period.

Ciprofloxacin, chloramphenicol, metronidazole, sulfamethoxazole and trimethoprim

Ciprofloxacin, chloramphenicol, metronidazole, sulfamethoxazole and trimethoprim are antibiotics used to treat bacterial infections. Antibiotics (including in creams) should only be used under medical supervision and are prohibited in skincare cosmetic products. Inappropriate use of antibiotics without medical supervision can lead to its decreased effectiveness. Other possible adverse effects associated with the use of topical antibiotics include skin irritation, skin rash, itching of the skin and hypersensitivity reactions.

Terbinafine, clotrimazole, ketoconazole and griseofulvin

Terbinafine, clotrimazole, ketoconazole and griseofulvin are medicines used to treat fungal infections. These ingredients are prohibited in skincare cosmetic products. The possible adverse effects associated with the inappropriate use of creams containing terbinafine, clotrimazole, ketoconazole or griseofulvin may include skin irritation, itching of the skin and skin rash.

Chlorpheniramine

Chlorpheniramine is an antihistamine used to relieve allergic reactions such as hives, asthma and rhinitis. The possible adverse effects of topical chlorpheniramine include skin irritation, skin rash and itching of the skin.