



FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
24 JUNE 2013

HSA ALERTS PUBLIC TO TWO ILLEGAL PRODUCTS CLAIMING TO TREAT PAIN AND MULTIPLE MEDICAL CONDITIONS

Products are found to contain a potent steroid and other undeclared Western medicines

The Health Sciences Authority (HSA) is alerting members of the public to two products found to contain undeclared medicinal ingredients:

- i) "MONTALIN" Jamu Pegal Linu Dan Asam Urat
- ii) Orange capsules accompanied with Chinese leaflet titled "百合保健素" (Bai He Bao Jian Su)

2 Members of the public who are taking "MONTALIN" capsules are advised to stop using it immediately. However, for those who have bought "百合保健素" (Bai He Bao Jian Su) found to contain a potent steroid and other undeclared ingredients, they are advised to consult a doctor immediately, particularly so if they have been taking the product for more than one week. These consumers should not stop taking the product on their own without seeking proper medical advice, as sudden discontinuation of the product can cause serious withdrawal symptoms, such as confusion and low blood pressure. For photos and more information on the potential dangers of these products, please refer to **Annexes A & B**.

"MONTALIN" Jamu Pegal Linu Dan Asam Urat

3 An astute doctor had reported that two of her patients suffered from adverse effects after taking "MONTALIN", sold under the guise of traditional Jamu medicine for pain relief. One of the patients, in her 70s, who had taken the product for 2 weeks, was admitted to hospital for sudden lower limb and facial swelling. The product was purchased by her relative from overseas. Another patient in her 60s experienced sudden weight gain and high blood sugar after 3 months of taking the product given by her friend.

4 Investigations and testing by HSA detected undeclared medicines such as piroxicam and paracetamol in the product samples.

Unlabelled orange capsules accompanied with a leaflet titled "百合保健素"

5 HSA received feedback from a member of public who was concerned about the safety of some orange capsules sold by a local Chinese female. The product, to be taken orally or applied on the skin, purported to treat more than 40 medical conditions such as rheumatism, pneumonia and infections of the skin.

6 The product would be sold in a small zip-lock bag of 30 capsules and usually accompanied with a leaflet titled “百合保健素”, describing the indications and ingredients in Chinese, and a name card bearing the seller’s contact details. A total of 6 different western medicinal ingredients, which should only be used under medical supervision were found in the capsules. The 6 undeclared ingredients were bethamethasone valerate (steroid), chlormethiazole, chlorpheniramine, famotidine, frusemide, and piroxicam.

Warning and advice to sellers

7 HSA warns sellers to stop the sales and distribution of these illegal products. Complementary health products are not allowed to contain western medicinal ingredients or substances controlled under the Poisons Act or Health Products Act. Anyone found convicted of selling these illegal products will face a penalty fine of up to \$10,000 and/or imprisonment for a period of up to two years under the Poisons Act, and a penalty fine of up to \$100,000 and/or imprisonment for a period of up to three years under the Health Products Act.

8 Sellers should be cautious when sourcing for health products to sell and are reminded of their responsibility in ensuring the safety of the products and adherence to local legislations prior to introducing them to the market, including selling them online.

Public advisory

9 HSA advises members of the public to stop the use of “MONTALIN”. For those consuming the steroid-containing “百合保健素”, they should consult a doctor as soon as possible **before stopping the product**. Sudden discontinuation of steroids without proper medical supervision can cause serious withdrawal symptoms such as weakness, fatigue, confusion, low blood pressure and bowel obstruction, especially when these products are taken for more than a week.

10 Consumers with medical conditions are also advised not to self-medicate and to seek proper medical advice for their conditions. In general, consumers should exercise discretion when buying health products, especially those with exaggerated claims or which offer “quick-fix” solutions. Unlike other commodities, consumption of poor quality and falsely labelled health products can cause serious health effects.

11 Members of the public who have any information on the sale of these two products or other illegal products may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: hsa_is@hsa.gov.sg. Additionally, members of public are encouraged to visit www.healthdangers.sg to learn more about the dangers of buying illegal health products from dubious sources.

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▪ 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.

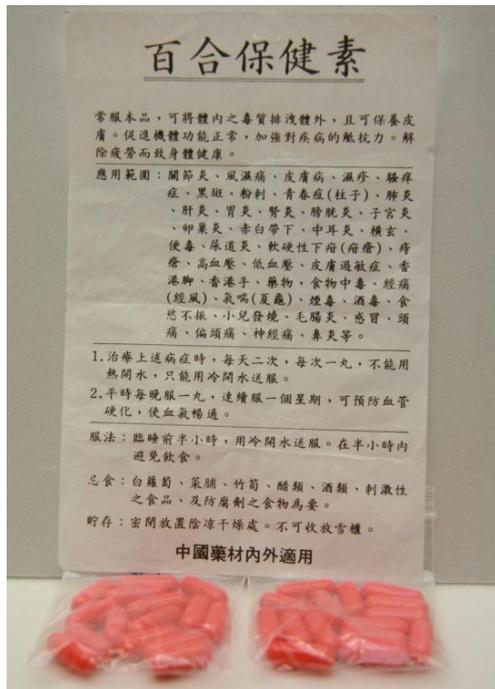
1. “MONTALIN” Jamu Pegal Linu Dan Asam Urat



Information on the product label of “MONTALIN” Jamu Pegal Linu Dan Asam Urat (translated):

Name of the product	“MONTALIN” Jamu Pegal Linu Dan Asam Urat
Composition	<p><i>Extract from the following ingredients:</i></p> <ul style="list-style-type: none"> • Centella Asiatica : 35 % • Glaziosa Superbal : 25 % • Minosa Pudical : 15 % • Phyllantnus Urinalialinn : 10 % • Sonchus Arvesisi : 10 % • Dan lain – lain sampai : 100 %
Indication/ For	Gout, stress, rheumatism, swelling of the legs, lowering cholesterol, stiff muscles, fever, bronchitis, dizziness, stabilising the body’s hormones, eliminates blood clots, maintains stamina and lengthens a person’s lifespan
Dosage	2 capsules once daily
Precautions	Avoid nut based foods or nuts (soya beans, melindjo, coffee beans), innards, chayote
Produced/manufactured by	PJ. AIR MADU MAGELANG – INDONESIA POM TR. NO. 053348358

2. Unlabelled orange capsules with its accompanying product leaflet “百合保健素” (Bai He Bao Jian Su)



Information on the leaflet that accompanied the unlabelled orange capsules (translated)

Indications	Arthritis, rheumatism, skin diseases, eczema, pruritus, dark spots, facial comedones, chronic acne, pneumonia, hepatitis, gastritis, nephritis, cystitis (inflammation of the urinary bladder), pelvic inflammatory disease, white or blood-lined vaginal discharge, otitis media (middle ear infection), sexual transmitted diseases, urethritis, haemorrhoids, hypertension, hypotension, skin allergies, tinea pedis, tinea manuum (fungal infections of the foot or hand), drugs and food poisoning, menstrual pain, asthma, nicotine and alcohol poisoning, loss of appetite, feverish conditions in children, typhlenteritis (inflammation of the caecum- part of the large intestine), common cold, headache, migraine, neuralgia, rhinitis.
Claims	Constant consumption of the product will aid in the excretion of toxic substances out of the body, as well as help in the maintenance of the skin.
Usage	<p>1. During treatment of the above-mentioned conditions, take 1 capsule twice a day.</p> <p>2. For maintenance purpose, continue consumption of 1 capsule every evening for one week.</p> <p>To be taken half an hour before sleep with water. Avoid food within the next half an hour.</p> <p>Ideal for oral and topical applications.</p>

I. Information on the potent medicinal ingredients found in the adulterated health products that should only be prescribed by a doctor

Betamethasone valerate

Betamethasone is a corticosteroid that is used to reduce inflammation and is usually applied on the skin. The systemic absorption and adverse effects of betamethasone valerate when taken orally are not well documented in literature. Generally, long term unsupervised use of oral corticosteroids can cause increased blood glucose levels leading to diabetes, high blood pressure, cataracts, muscular and bone disorders, an increased risk of infections and Cushing's syndrome, which is characterised by a round face or 'moon face', and upper body obesity with thin limbs.

Chlormethiazole

Chlormethiazole is a sedative agent that may cause nasal congestion and irritation, conjunctival irritation and headache.

Frusemide

Frusemide is a potent diuretic drug that is used to eliminate water and salt from the body. Excessive 'water-eliminating' effect of frusemide can cause the depletion of sodium, chloride, body water and other minerals in the body.

Piroxicam

Piroxicam, is a non-steroidal anti-inflammatory drug (NSAID) used to treat pain and inflammation in the body. It can cause gastrointestinal adverse effects such as nausea and vomiting and gastric bleeding. Other adverse effects on prolonged usage may include increased risk of heart problems and fluid retention.

II. Other medicinal ingredients:

Chlorpheniramine and famotidine

Both chlorpheniramine and famotidine are available as Pharmacy Only Medicines that should be dispensed by a pharmacist.

Chlorpheniramine is a type of antihistamine used to relieve allergic reactions, such as hay fever, rhinitis, urticaria and asthma. Adverse effects from unsupervised use include drowsiness, nausea, vomiting, diarrhoea and constipation.

Famotidine is used to treat gastrointestinal ulcers and relieve heartburn and indigestion. Possible adverse effects include diarrhoea and other gastrointestinal disturbances, headache, dizziness.

Paracetamol

Paracetamol is available over the counter for the relief of fever and pain. Rare adverse effects include hypersensitivity reactions such as rash.