

23 February 2011

HSA WARNS AGAINST TAKING THREE HEALTH PRODUCTS FOUND TO CONTAIN UNDECLARED POTENT WESTERN MEDICINES

The Health Sciences Authority (HSA) alerts members of the public not to take three health products sold under the disguise of traditional medicines, labelled with the following names:

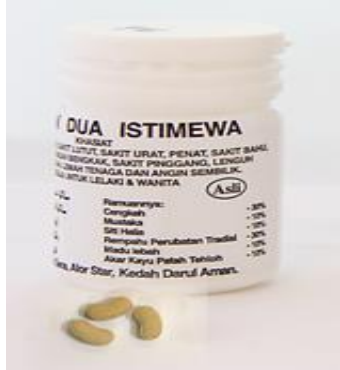
- i) “Majun Dua Istimewa”,
- ii) “Raja Maajun-Jerat Dan Seret Angin” and
- iii) “Horkut Chooi Foong Hor Lok Tan [虎骨追风活络丹]

2 These three products were sent for analytical tests at HSA's Pharmaceutical Laboratory and found to contain various undeclared potent western medicines. Members of the public who have the above-mentioned products in their possession should not consume them as they can cause serious side effects.

About the Products and Serious Adverse Effects

3 HSA conducted in-depth investigations after receiving reports of side effects in consumers taking these products, which were found to contain undeclared potent western medicinal ingredients. These products were of dubious origin and were obtained from overseas or local sources. Please refer to Annex A for details of the product labelling.

i) Majun Dua Istimewa

| Majun Dua Istimewa | Presentation |
|---|---|
|  | <p>Malay traditional medicine packaged in small white plastic containers containing bean-shaped tablets.</p> <p>The product label claims that it can be used to treat general weakness, numbness of the leg and pain.</p> |
| | Western Medicines Detected |
| | Dexamethasone |


4 Two consumers, one middle-aged and one elderly who were otherwise healthy, consumed “Majun Dua Istimewa” for about three months and subsequently suffered from fluid retention and significant weight gain. Some of these symptoms are similar to the serious adverse effects caused by the prolonged unsupervised use of the corticosteroid, dexamethasone. They have since stopped taking the product and sought medical attention.

ii) Raja Maajun-Jerat Dan Seret Angin

| Raja Maajun-Jerat Dan Seret Angin | Presentation |
|--|--|
|  | <p>Malay traditional medicine packaged in clear plastic containers containing black pills.</p> <p>The product label claims that it can treat pains, body weakness, tension, cramps and rheumatism.</p> |
| | <p>Western Medicines detected</p> <p>Dexamethasone, Chlorpheniramine</p> |

5 A middle-aged female consumer reportedly developed jaundice and fever after taking “Raja Maajun-Jerat Dan Seret Angin” for about 7 months. She is currently hospitalised for the treatment of her medical condition.

iii) Horkut Chooi Foong Hor Lok Tan [虎骨追风活络丹]

| Horkut Chooi Foong Hor Lok Tan | Presentation |
|---|---|
|  | <p>Chinese traditional medicine packaged in brown glass bottle containing black pills.</p> <p>The label claims to treat general weakness, sprain, backache, and pain.</p> |
| | <p>Western Medicines detected</p> <p>Indomethacin, Paracetamol, Dexamethasone and Dextromethorphan</p> |

6 An elderly male consumer had been taking “Horkut Chooi Foong Hor Lok Tan [虎骨追风活络丹]” for more than 5 years and was subsequently diagnosed by his

doctor to suffer from adrenal insufficiency (a hormonal disorder that occurs when the adrenal glands do not produce enough hormones) characterised by severe weight loss over time after stopping the product. This may be an adverse effect caused by the withdrawal of prolonged consumption of a steroid like dexamethasone. The patient's condition has since improved with medical treatment and dietary supplementation.

About the Undeclared Western Ingredients when used without medical supervision

7 Both dexamethasone and indomethacin, are used for anti-inflammatory purposes (i.e. reduce swelling and inflammation). Unsupervised long-term use of dexamethasone can cause increased blood glucose level, high blood pressure, muscle damage, mental disorders and weak bones. Sudden withdrawal after prolonged use of dexamethasone can lead to serious outcomes such as muscle weakness and kidney failure. Unsupervised use of indomethacin may cause stomach bleeding and kidney failure especially in susceptible individuals, which can lead to life-threatening outcomes.

8 Dextromethorphan can cause rapid heartbeat and dizziness while chlorpheniramine can cause drowsiness and urinary retention. Although paracetamol rarely causes serious side effects when taken as directed, large doses may also lead to adverse outcomes such as liver damage.

Public Advisory

9 Health products that contain undeclared western medicines are considered as illegal products. They are dangerous and harmful to health as they are made under poor manufacturing conditions with no proper quality controls or professional oversight.

10 Ms Chan Cheng Leng, Division Director of the Enforcement Branch of HSA says, "Consumers should be wary of complementary medicines that provide quick relief of symptoms such as pain and swelling associated with chronic disease conditions. There is a likelihood that they may contain undeclared potent Western medicines that can cause serious adverse effects when consumed."

11 HSA strongly advises anyone who has these products in their possession to stop consuming them. They should seek medical advice if they feel unwell or are concerned about their health.

12 Traditional medicines are not allowed to contain western medicinal ingredients or substances controlled under the Poisons Act. If convicted, the penalty is a fine of

up to \$10,000 and/or imprisonment for a period not exceeding two years under the Poisons Act.

13 HSA has an active post-market vigilance and surveillance system to detect safety issues with health products and will take the necessary actions to safeguard public health. Members of the public, who have encountered these three illegal products or any other suspicious products, are encouraged to report their sales to the Enforcement Branch of HSA at **Tel: 6866 3485** or **Email: hsa_is@hsa.gov.sg**.

HEALTH SCIENCES AUTHORITY

23 February 2011

▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

▪ About HSA's Health Products Regulation Group

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

HSA WARNS AGAINST TAKING THREE HEALTH PRODUCTS FOUND TO CONTAIN POTENT WESTERN MEDICINES

Health Products detected with potent western medicines



(left to right)

Majun Dua Istimewa, Horkut Chooi Foong Hor Lok Tan [虎骨追风活络丹], Raja Maajun-Jerat Dan Seret Angin

1. Product Labelling of “Majun Dua Istimewa”

Label information in Malay:

| | |
|-------------------------------|---|
| Product Description | Majun Dua Istimewa |
| Ingredients | Cengkeh - 30%; Mustaka – 10%; Siti Halia – 10%; Rempah2 Perubatan Tradisi – 30%; Madu lebah – 10%; Akar Kayu Patah Tehloh – 10% |
| Indications | Sakit Sendi Tulang, Sakit Lutut, Sakit Urat, Penat, Sakit Bahu, Lumpuh Kaki, Tangan Bengkak, Sakit Pinggang, Lenguh Seluruh Badan, Lemah Tenaga dan Angin Sembilik. Sesuai untuk Lelaki & Wanita |
| Instruction for dosage | Dewasa: 2 Biji Sekali Makan. 1 Hari 2 Kali Makan. |

English Translation of label information

| | |
|--------------------------------|--|
| Product name | Majun Dua Istimewa |
| Ingredients | Cloves – 30%, Nut Grass – 10%, Ginger – 10%, Traditional Medicinal Spices – 30%, Honey – 10%, Patah Tehloh Roots – 10% |
| Indications as on label | Joint pain, Knee pain, Nerve pain, Tiredness, Shoulder pain, Numbness of the legs, Swollen hands, Lower back pain, Whole body weakness, Low energy, Trapped Wind Suitable for men & women |
| Instruction for dosage | Take 2 tablets each time. Take 2 times a day. |

2. Product Labelling of “Raja Maajun-Jerat Dan Seret Angin”

Label information in Malay:

| | |
|----------------------------|--|
| Product Description | Raja Maajun-Jerat Dan Seret Angin |
| Indications as | Sesuai untuk lelaki/wanita. Dirumus dari ramuan herba. Mujarab |

| | |
|-----------------|--|
| on label | merawat sakit pinggang, urat, tulang, sendi, lutut. Tumit kaki, lengoh/sengal, sakit kepala, tengkok, tegang urat/otot, kebas, krem, sakit dalam tubuh, letih, lesu. |
|-----------------|--|

English Translation of label information

| | |
|--------------------------------|--|
| Product name | Raja Maajun-(Black Pill) Remove Wind |
| Indications as on label | Suitable for men/women. Extracted from herbs. Efficient in healing pain in the waist, veins, bones, joints, knee, feet, soles, weakness of the body, rheumatism, muscle tension/joint tension, numbness, cramp, pain inside the body, tiredness. |

3. Product Labelling of “Horkut Chooi Foong Hor Lok Tan” [虎骨追风活络丹]

Labelling in Chinese

| | |
|-------|--|
| 名称 | 虎骨追风活络丹 |
| 工能与主治 | 普通体能衰弱， 关节扭伤， 背痛，神经痛，关节肿痛，关节酸痛， 风湿痛及关节僵直等 |
| 服法 | 成人每次一至二粒， 每日三次， 以温开水服送。 |

Labelling in English

| | |
|--------------------------------|---|
| Product name | Horkut Chooi Foong Hor Lok Tan |
| Indications as on label | For general weakness, sprain, backache, body pain, neuralgia, gout, arthralgia, rheumatism and stiff joints |
| Dose | Adults: 1-2 pills 2-3 times a day, with warm water. |