

Montalin® and adulteration

Introduction

Montalin® ("MONTALIN" Jamu Pegal Linu Dan Asam Urat) is a supplement and comes from Indonesia and has been promoted as a natural powerful composition of herbs. It is claimed to relieve discomfort and pain in rheumatism (neutralizes uric acid), painful joints, stiff muscles, muscle cramps and tired legs / feet, high cholesterol, inflammation in the body, moisture build-up, hay fever, stress, headaches and menstrual cramps, immune system (keep your body fit and vital) (1). This product is not authorized for sale in Netherlands, but it is possible to purchase it over the Internet.

In 2013, the Singapore Health Sciences Authority warned consumers not to use this product after it was found to contain ingredients that were not declared on the label, such as piroxicam and paracetamol (2).

Product information

The declared ingredients in Montalin® (1) are extracts from the following ingredients:

- *Centella Asiatica* : 35 %
- *Glaziosa Superbal* : 25 %
- *Minosa Pudical* : 15 %
- *Phyllanthus Urinalialinn* : 10 %
- *Sonchus Arvesisi* : 10 %

Online product information mentions: '*The advised dosage in case of serious or chronic complaints: 14 days 1 time per day 2 capsules in the morning with breakfast (when taken in the evening it can hinder sleep). Then possibly reduce to 1 capsule per day / every other day. Mild complaints: 14 days 1 time per day 1 capsule in the morning with breakfast. Then possibly reduce to 1 capsule every other day. Combination with other drugs: Montalin® is a powerful composition of herbs and does not always go together with "Western" medication, so try it carefully! Combining Montalin® with other medicines is at your own risk. It has been found not to interact well with blood thinners and beta blockers. Consult your doctor if you are also taking other medication (3).*'

Reports

Pharmacovigilance centre Lareb received four reports in January 2021 of unexpected beneficial effect in combination with adverse reactions after use of the herbal supplement Montalin®. All reports were sent by a doctor's assistant who became suspicious due to this combination*.

Table 1. Reports on Montalin®

Patient number, ID sex, age primary source	Drug Dosage Indication	Concomitant medication	Reported ADRs*	Latency after start Action taken Outcome
1-NL-LRB-00430484 M, 51-60 years Other health professional	Montalin® Unknown Arthrosis		Stomach pain	- Unknown Unknown
2-NL-LRB-00430487 M, 51-60 Years Other health professional	Montalin® Unknown Arthralgia	Paracetamol	Palpitations	1 Week Dose reduced Recovering
3-NL-LRB-00430489 F, 51-60 years Other health professional	Montalin® Unknown Joint stiffness	Diclofenac-Na Simvastatin Amlodipine Temazepam Acenocoumarol	Palpitations Blood pressure increased Energy increased	4 Months Drug withdrawn Unknown
4-NL-LRB-00430490 F, 61-70 years Other health professional	Montalin® Unknown Arthropathy	Paracetamol Ibuprofen	Palpitations Heartbeats irregular Feeling jittery Hypertension	2 Weeks Dose not Changed Not recovered

*All four patients reported quick relieve of the pain after use of Montalin®.

Sample Analysis

Sample of the used supplement Montalin® by one of the patients was collected and sent to the National Institute for Public Health and the Environment (RIVM) for analysis.

The sample was examined for the presence of pharmacologically active substances using UPLC-QTOF-MS / MS and magnetic resonance spectroscopy. The results of the investigation are shown in Table 2.

Table 2 Products received with (in gray) found pharmacologically active substances.

Product description	Identity of the found compounds	Content
capsule with beige powder	Meloxicam ¹	13mg/g ²
	Acetaminophen 1	924mg/g ²

1 The presence of the reported compound has been confirmed with a reference standard.

2 The contents have been determined with an accuracy of $\pm 20\%$.

The presence of meloxicam and acetaminophen has been confirmed with a reference standard. The capsule arrived at RIVM in damaged condition, therefore the analysis results has been given as mg/g capsule powder content. An attempt was made to determine the weight of the capsule contents; and this was 389,45 mg. In this case the assumed amount of meloxicam per capsule is thus 5.20 mg and the amount of acetaminophen is 359.85 mg.

To establish a more reliable weight we have purchased a package of 40 capsules Montalin® (via bol.com; delivered by montalinshop.nl). The package contained 10 separately sealed pouches with 4 capsules in each. The average weight of 1 capsules was 0,6g and of the content 0,485g. Based on this the estimated amount of meloxicam per capsule is 6,30mg and the amount of paracetamol is 448,14mg. This means that when the consumers follow the advice to take daily two capsules, they consume about 12mg of meloxicam and almost 1g of paracetamol each day. It is however not clear whether this newly purchased package also contains undeclared ingredients. And in addition, with these illegal products the content may vary between batches.

Other sources of information

In June 2013 The Health Sciences Authority (HSA) in Singapore have issued a warning for the product "MONTALIN" Jamu Pegal Linu Dan Asam Urat. Investigations and testing by HSA detected undeclared medicines such as piroxicam and paracetamol in the product samples. HSA advises members of the public to stop the use of "MONTALIN".

A 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 (2).

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID). It has anti-inflammatory, analgesic and antipyretic properties. The recommended dose for long-term treatment of rheumatoid arthritis and ankylosing spondylitis in elderly patients is 7.5 mg per day. In patients with an increased risk of adverse drug reactions, the starting dose of treatment should be 7.5 mg per day. If the effect is insufficient, a dosage increasing to a maximum of 15 mg / day is recommended.

The risk of gastrointestinal bleeding, ulceration or perforation is greater with increasing doses of NSAID, in patients with an ulcer, especially if complicated by an ulcer bleeding or perforation and in the elderly. These patients should receive treatment starting with the lowest possible dose. Patients with uncontrolled hypertension, congestive heart failure, established ischemic heart disease, peripheral arterial disease and / or cerebrovascular disease only be treated with meloxicam after careful consideration. The same consideration should be made before starting long-term treatment in patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) (4).

Long-term use of high doses of paracetamol (acetaminophen) may cause serious liver damage. Liver damage is possible in adults who take 10 g or more paracetamol once taken. Ingestion of 5 g of paracetamol or more can cause liver damage in patients with risk factors. The anticoagulant effect of warfarin and other coumarins may increase with prolonged, regular use of paracetamol (5).

Discussion and conclusion

An attentive doctor's assistant found it suspicious that some of the patients with osteoarthritis reported an unexpected rapid improvement in their symptoms. Upon inquiry, it turned out that they all used the herbal supplement Montalin®. The product could only be ordered through a web-shop. After consultation and permission of the patients, she reported data from four patients to Lareb. All of them used Montalin® to relieve osteoarthritis, three of them in addition to regular medicines. They were convinced that they were taking a safe supplement and that the rapid reduction in pain was due to the natural herbal ingredients. However, the analysis of the sample by the RIVM shows that in addition to the declared herbs, Montalin® also contains registered medicines. Based on the analysis results and weight of the capsules from the ordered sample each capsule contains about 12 mg meloxicam and almost 1 gram paracetamol. These are not mentioned on the label and are therefore illegal. Patient 2 was already using paracetamol, patient 3 used diclofenac in addition to acenocoumarol, simvastatin, amlodipine and temazepam. Patient 4 was using paracetamol and ibuprofen. This means that their dose of the pain medication unintentionally was increased. The use of a high dosage of NSAIDs could be supportive for the occurrence of palpitations and an increase in blood pressure. Patient 1, not reporting co-medication, experienced stomach upset, which is a known adverse drug reaction of meloxicam (NSAIDs). Consumption of falsely labelled health products can cause serious health effects. This also applies to Montalin®. The illegally added meloxicam and paracetamol pose additional health risks if taken without medical supervision. Consumers must be warned about the contaminated product Montalin® and its distribution should be forestalled.

References

1. Bijsluiter Montalin. p. <https://www.montalin.nl/bijsluiter>.
2. HSA Alerts Public to Two Illegal Products Claiming to Treat Pain and Multiple Medical Conditions. 2013. p. <https://www.hsa.gov.sg/announcements/press-release/hsa-alerts-public-to-two-illegal-products-claiming-to-treat-pain-and-multiple-medical-conditions>.
3. Algemene informatie Montalin.shop: Montalin kruidencapsules p. <https://media.s-bol.com/g297PgEAZ6Bk/original.pdf>.
4. Product information meloxicam. p. https://www.geneesmiddeleninformatiebank.nl/smpc/h107068_smpc.pdf.
5. Foreign Product Alert: MONTALIN Jamu Pegal Linu Dan Asam Urat. 2014. p. <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/37715a-eng.php>.

This signal has been raised on April 30, 2021. It is possible that in the meantime other information became available.