

TO ERR IS HUMAN: A LABEL ERROR THAT COULD HAVE BEEN FATAL

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Recently there was a report of a possible medication error caused by wrong label which occurred in a private clinic in Pasir Mas, Kelantan. On 7th April 2016, Adam Bukhari Mohd Jazal, 6 years old, was rushed to Hospital Raja Perempuan Zainab (HRPZ) II after he experienced muscle cramps and up rolling of both eyeballs after consuming what was thought to be an antibiotic syrup. Further investigation revealed that the clinic staff wrongly attached the label for Lindane Lotion onto the CO-AMOXICLAV 228mg/5mL suspension and vice versa.

Lindane lotion (red bottle cap in the picture) is an **external application** for the treatment of head lice and scabies. Mother of Adam Bukhari followed the instructions on the label and administered 5mL of Lindane lotion at 12am on 4th April and applied the CO-AMOXICLAV suspension on the site affected. After 2 hours, Adam started to feel dizzy and complaint of stomach ache, which his mother administered paracetamol syrup to ease the pain. On 5th April at 12pm, a second dose of Lindane lotion was given orally. After 2 hours, Adam experienced worsening symptoms was admitted to the hospital for further treatment. A root-cause analysis to analyse the potential factors contributing to the error should be carried out to avoid this medication error from occurring in the future.



WHAT IS SCABIES?

Scabies is a contagious skin condition caused by tiny mites *Sarcoptes scabiei* that burrow into the skin. The main symptom of scabies are **intense itching** and a **skin rash** on areas where the mites have burrowed. The intense itching associated with scabies is thought to be caused by the immune system reacting to the mites and their saliva, eggs and faeces. Without effective treatment, the life cycle of the scabies mite can continue indefinitely. Scabies mites are resistant to soap and hot water and can't be scrubbed out of the skin.

HOW SCABIES IS SPREAD?

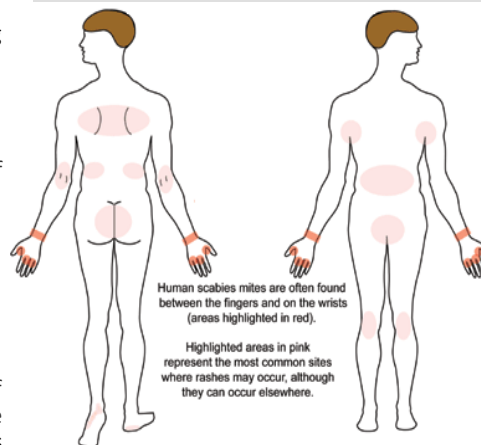
Scabies mites can be transmitted by:

- prolonged direct skin contact (>10min, often through hand holding)
- having sex with an infected person
- rarely transmitted by contact with contaminated clothes, towels and bedding.
- increased risk of catching scabies in confined environments (schools and nursing homes), where people are in close proximity to one another.

SYMPTOMS OF SCABIES

It may take **2 - 6 weeks** to develop sign of scabies. Symptoms will start within **1 to 5 days** if you've had a scabies infection in the past.

- **Burrow marks** - a small red blotches and silvery lines (2 - 10mm long) with a black dot at one end that can be seen with a magnifying glass. Commonly occur in the loose skin between the fingers (the web spaces), the inner surface of the wrists, elbow, and the hands or the soles and sides of the feet.
- **Intense itching** which is often worse at night, or after a hot bath or shower.
- **Pimple-like rash** - commonly found in the underarm area around the waist, inside of the elbow, the lower buttocks, the lower legs, the soles of the feet. the knees, the shoulder blades, the female genital area, the groin and around the ankles. In infants and young children, burrow marks tend to appear in different places on their body, including on the face, head, neck, scalp, palms of the hands and soles of the feet.
- **Scales or blisters**—may develop on the soles of the feet and palms of the hands infants with scabies.
- **Sores** caused by scratching . An infection can develop in the sores.



Example of crusted scabies

CRUSTED (NORWEGIAN) SCABIES

It is an uncommon form of scabies. It is highly contagious with huge numbers of mites and more common in immunocompromised and neurologically impaired individuals. Pruritus may be minimal or absent. Characterized by diffuse hyperkeratosis, associated with variable degree of underlying erythroderma. Hyperkeratosis and crusting are particularly severe on the hands, including the palms and soles, under the fingernails, on the ears, trunk and extremities.

TREATMENT FOR SCABIES (REF: GUIDELINE FOR MANAGEMENT OF SCABIES IN ADULTS AND CHILDREN February 2015 BY MINISTRY OF HEALTH MALAYSIA)

Clinical condition	Recommended therapy	Alternative therapy	Additional measures	Comments
Classical scabies i. Infants < 2 months	6% Sulphur in Calamine Lotion. Rinse off after 24 hours and then reapply every 24 hours for the next 3 days.	-	Treat whole body including the face (avoid eyes and mouth)	Treat all family members/ close contacts simultaneously
ii. Children < 2 years	2 applications of Permethrin 5% (A-SCABS) lotion for 8-12 hours at one week apart.	6% Sulphur in Calamine Lotion. Rinse off after 24 hours and then reapply every 24 hours for 3 days	Treat whole body including the face (avoid eyes and mouth)	Crotamiton 10% cream TDS for 5-7days for nodular scabies.
iii. Children < 12 years	2 applications of Permethrin 5% (A-SCABS) lotion for 8-12 hours at one week apart.	Benzyl Benzoate 12.5% lotion Whole body neck and below. Rinse off after 24 hours then reapply for 3 consecutive days.		Crotamiton 10% cream TDS for 7-14 days for nodular scabies.
iv. Adults	2 applications of Permethrin 5% (A-SCABS) lotion for 8-12 hours at one week apart.	Benzyl Benzoate 25% lotion whole body; neck and below. Rinse off after 24 hours then reapply for 3 consecutive days.		People in close physical contact, even without symptoms, should receive treatment at the same time.
v. Pregnancy/ lactating women	2 applications of Permethrin 5% (A-SCABS) lotion for 8-12 hours at one week apart.	-		
Crusted scabies	Apply Permethrin 5% (A-SCABS) lotion every 2-3 days for 1-2weeks PLUS Ivermectin* (200ug/kg/dose) should be taken with food. Depending on the infection severity, ivermectin should be taken in 3 doses (days 1,2,8), 5 doses (days 1,2,8,9,15) or 7 doses (days1,2,8,9,15,22,29).	Oral Ivermectin* (200ug/kg single dose and repeat after 2 weeks) alone or in combination with permethrin OR several applications of Benzyl Benzoate 25%(with or without tea tree oil) lotion*. Benzyl benzoate may cause immediate skin irritation. Lower concentrations may be used in children (10% or 12.5%).	Apply keratolytic agents (salicylic acid in vaseline) to hyperkeratotic areas to help reduce crusting of the skin and aid in the absorption of the topical permethrin or benzyl benzoate. Keep nails short and apply medication to subungual areas.	Patients may need admission. Strict control to prevent spread of infection.

*Product not available in PPUKM.

NOTE: Oral ivermectin should be considered for patients who have failed treatment with or who cannot tolerate FDA-approved topical medications for the treatment of scabies. If used for classic scabies, 2 doses of oral ivermectin (200µg/kg/dose) should be taken with food, each approximately 1 week apart. The safety of ivermectin in children weighing less than 15 kg and in pregnant women has not been established. Note that although ivermectin guidelines recommend taking on an empty stomach, scabies experts recommend taking with a meal to increase bioavailability.

IMPORTANT: Scabicide should be applied to all areas of the body from the neck down to the feet and toes. When treating infants & young children, it should be applied to their entire head & neck because scabies can affect their face, scalp, and neck, as well as the rest of their body. The scabicide should be applied to a clean body & left on for the recommended time before washing it off. Clean clothing should be worn after treatment. Since the symptoms of scabies are due to a hypersensitivity reaction (allergy) to mites and their feces (scybala), itching may still continue for several weeks after treatment even if all the mites and eggs are killed. If itching is still present more than 2 to 4 weeks after treatment or if new burrows or pimple-like rash lesions continue to appear, retreatment may be necessary.

TREATMENT FOR FOMITES:

- Underwear, clothing, towels, bed linen and slippers used by the affected person in the **72 hours prior** to treatment should be laundered using a hot wash cycle (>50°C) or hot tumble dried to kill the mites.
- If items are unable to be laundered or hot tumble dried, place them in a plastic bag for 72 hours before airing and reusing.
- Mattresses should be thoroughly vacuumed, ironed or steam cleaned, paying particular attention to the seams.
- Where possible, amenities such as toilets and chairs should not be shared (until 24 hours after the first treatment).

CAN LINDANE BE USED TO TREAT SCABIES?

Lindane 1% Lotion/cream (Gamma benzene hexachloride) is an organochloride. Although FDA-approved for the treatment of scabies, lindane is **not recommended as a first-line therapy**. Overuse, misuse, or accidentally swallowing lindane can be toxic to the brain and other parts of the nervous system, hence its usage should be restricted to patients who failed treatment/intolerant to other medications with less risk.

Direction of use: Apply a thin layer of 1% topical preparation onto all skin areas from the neck to toes. Completely wash off from the body with warm water after 8-12 hr.

Contraindications: Pregnant & breast feeding women, premature infants, children <10 years, patients with seizure disorders, persons who have very irritated skin or sores where the lindane will be applied, infants, children, the elderly, and persons who weigh less than 110 pounds. Avoid applying after a hot bath to prevent/reduce percutaneous absorption.

Precautions:

- Do not use Lindane Lotion more than once to treat an attack of scabies or to treat a second attack of scabies that comes soon after the first episode. Using it more than once can cause seizures and death. Even if you still itch after using Lindane Lotion, do not apply more or reapply. Scabies (bugs) can make your skin itch for a few weeks even after all of the bugs are dead.
- If you are applying Lindane Lotion for another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves as more lindane can go through that type of glove. Wash your hands well and thoroughly when you are done.
- Make sure your skin is clean and does not have any other lotion, cream, or oil on it. Oils can make Lindane Lotion go through your skin faster and may increase the risk of seizures.
- Wait for at least **1 hour after bathing** before you apply Lindane Lotion on your skin. Wet or warm skin can make Lindane Lotion penetrate your skin faster and may increase the risk of seizures.
- The drug should be applied from the neck downwards all over the body. The most common mistake is that the drug is applied only to the affected areas, which leads to a relapse of the disease. The drug dispensed should not be diluted.

NOTE: Members of the affected household and all close contacts should be treated, even in the absence of symptoms, at the same time. Mostly only 1 treatment is needed, only symptomatic contacts require two treatments (with permethrin 5%).