

The Head Louse and its Treatment with GOLDGEIST® FORTE.

Pattern of Life and Feeding Habit

The head louse is a wingless insect, which lives only as parasite on man. There it almost exclusively lives on the scalp, preferably in the temple, ear and neck region, but also in beard and eyebrows.

The head louse has developed legs that have hook-like claws for climbing in the hair. The body is very pressure-resistant: it resists a load of up to 1 kg. They use their feeding tube to suck blood from the scalp 2 to 3 times a day, a few millilitres altogether. When sucked full with blood, the head louse appears red brown to red, otherwise it is grey.

Without human blood they survive only for a few days: at 35°C one day, at 25-20°C two days, but at 10-20°C 7 days.

The head louse can lay viable eggs even after 5 days without feeding.

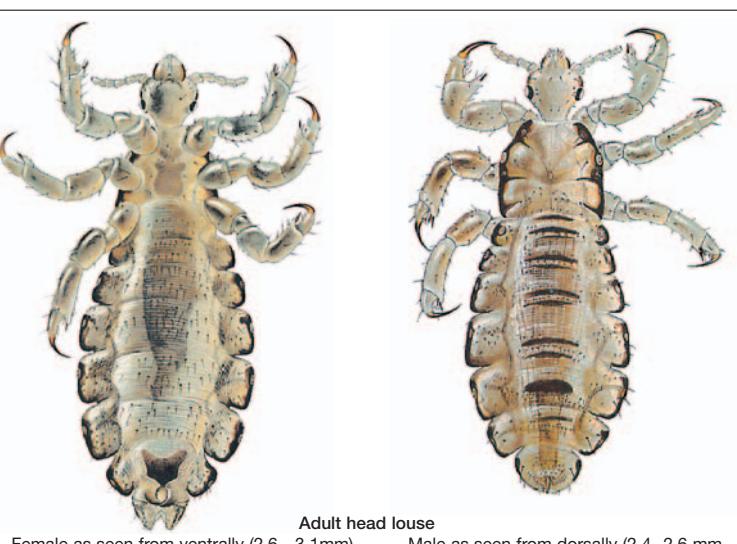
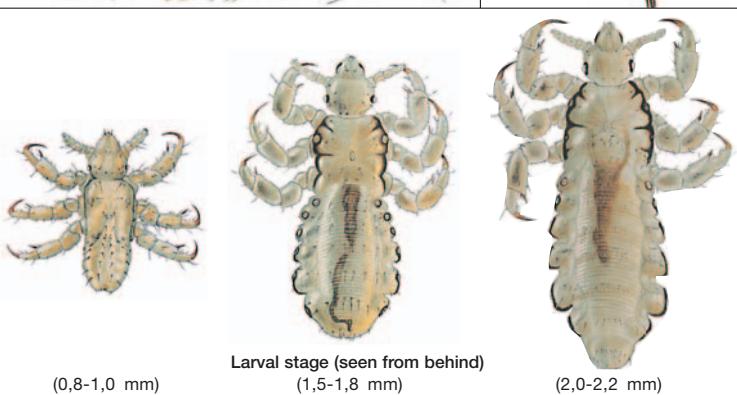
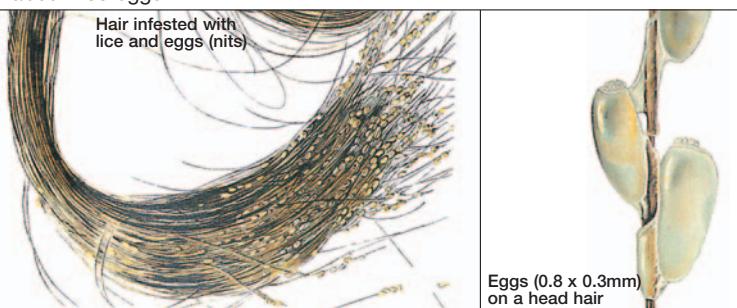
Development

The head louse prefers a temperature of approx. 28°C, which is the temperature in the human hair. The development slows down at 22°C, and stops almost completely at 10°C. Eggs are no longer deposited at temperatures below 12°C. The female head louse sticks the eggs (nits) usually to the base of the hair like beads on a string, using a very robust adhesive secretion.

The nits cannot be wiped off or washed away with water.

8.5 days after the egg has been laid, the larva hatches. During another 8.5 days, it passes through 3 developmental stages. 1-2 days after the 3rd moult, male and female head lice have reached sexual maturity, so that approximately 3 weeks after the egg deposition a new generation can develop.

Males live approximately 15 days, females approximately 30-35 days. During this time, the fertilised female lays up to 4 eggs per day, altogether about 100 eggs.



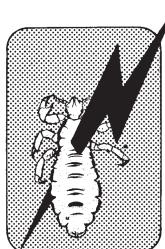
Transmission

Head lice can migrate from one head to another upon close physical contact. However, they can also be transmitted by sharing hats, pillows, bedding, combs and hairbrushes. Likewise, lice can migrate from infested caps, hats and other pieces of clothing to others hanging close to them, e.g. in schools and shared accommodations.

Head louse infestation (*Pediculosis capitis*)

At the beginning of the disease, head lice can be barely seen. They are only recognised by their bites. The secretions from the salivary glands enter the skin during bloodsucking and cause violent itching. Sores on the head, especially in the temple, ear and neck region, indicate an infestation with head lice.

Bacteria and dirt may enter the sores, which causes skin rashes and swellings of the lymph nodes. If neglected, hair, skin secretions and pus can entangle to a foul smelling braid, in which the lice nest massively.



Treatment with GOLDGEIST® FORTE

Our research and development has brought up a very fast and effective treatment.

For the treatment it is important that not only the lice and lice larvae are killed, but also the very resistant nits, so that hatching of new larvae is prevented. Otherwise follow-up treatment would be necessary. Likewise, reinfections must be prevented. Therefore all contact persons that come into question (family, friends) should be examined and also treated, if necessary. **GOLDGEIST® FORTE** kills the lice quickly. Eradication is straightforward and comfortable. A single application kills lice, larvae and notably the nits.

GOLDGEIST® FORTE combines the reliability of a fast-acting contact insecticide with the soothing properties of a cosmetic hair shampoo. Thoroughly saturate the hair with the pleasantly fragrant liquid. **GOLDGEIST® FORTE** immediately immobilizes lice and larvae on contact. After 30-45 minutes everything is generally killed or irreversibly damaged, including the nits. Afterwards, thoroughly rinse the hair just if you were normally washing your hair, and then comb it with a nit removal comb. In order to prevent reinfections, thorough cleaning of combs and hairbrushes is recommended. Always use your own comb. Towels, clothing including underwear and bedding should be changed and washed at 60°C. Lice that are in clothing that cannot be washed can be starved out by sealing the clothes into a plastic bag and storing it at a warm place for 2 weeks. Lice on clothes, wigs and other small items can also be killed by exposing to hot air (45°C) for 60 minutes. Alternatively, tightly seal the items (clothing, sheets, toys) in a bag and store in the deep-freezer for two days at -10°C to -15°C. Thoroughly vacuum clean carpets, upholstery, car seats, head rests etc. to remove loose hairs.

This medication has been tested and authorised for use as agent against head lice and for officially ordered disinfestations measures, according to §18 of the Infektionsschutzgesetz (a German legislation relating to protection against infection)
Only to be sold in pharmacies.

GOLDGEIST® FORTE for fast and thorough removal of head lice, pubic lice, body lice and their nits. For topical use only. Keep away from eyes or mucous membranes. Small children must be observed during treatment.



contains Pyrethrum

EDUARD GERLACH GmbH
D-32292 Lübbecke

GOLDGEIST® FORTE, active substance: pyrethrum extract. Regarding risks and side effects, please read the package insert and consult your physician or pharmacist.

Instructions for use

Dear Patient

Please read these instructions for use carefully because they contain important information on the use of this medicinal product. If you have any further questions, please ask your doctor or your pharmacist.

GOLDGEIST® FORTE solution Extract of pyrethrum

Qualitative and quantitative composition:

100 g solution contains:

Pharmaceutically active substance:

Extract of pyrethrum 0.3 g
Extract of flowers of Chrysanthemum cinerariaefolium (1 : 2.5), adjusted to 25%
pyrethrin with isoparaffin, extraction medium: 1) n-hexane, 2) methanol/isoparaffin

Other ingredients:

5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxol
(piperonyl butoxide) 0.7 g
chlorocresol 0.9 g
diethylene glycol 40.0 g

sodium lauryl ether sulfate solution 27 %, purified water, 2-propanol, macrogol-
6-glycerol-caprylocaprate, isoparaffin (C13-C14), odorant, chinoline yellow E
104, phosphoric acid (for pH-adjustment).

Pharmaceutical form and content

Solution for use on the hair and skin

Pack sizes: Bottles of 75 ml (N1), 250 ml (N2), 2 x 250 ml (N3)

Substance group: Antiparasitic

Name and address of pharmaceutical company

EDUARD GERLACH GmbH, Bäckerstraße 4 - 8, 32312 Lübbecke

Therapeutic indications

For fast and thorough destruction of lice and nits. Head lice, crab lice and clothing lice.

Contraindications

When should GOLDGEIST FORTE not be used?

Please ask your doctor whether you should use GOLDGEIST FORTE if the following information applies to you: Known sensitivity (allergy) to pyrethrum extract or synthetic pyrethrins of the allethrin type, piperonyl butoxide, chlorocresol or one of the other ingredients of GOLDGEIST FORTE.

Do not use GOLDGEIST FORTE on infected or damaged skin, the mucous membranes or around the eyes (if perhaps the eyelashes are affected, for example). Infants should only be treated under the supervision of a doctor.

What should you watch out for during pregnancy or whilst breast feeding?

Pregnancy: There is no evidence from animal studies that GOLDGEIST FORTE will harm the fetus. Even though there has not been any evidence so far that GOLDGEIST FORTE will harm the fetus when used to treat head lice, GOLDGEIST FORTE should only be used after discussion with a doctor. GOLDGEIST FORTE should not be used to treat clothing lice or crab lice in pregnancy because there is insufficient experience of the effects of its use on large surfaces or of possible localised effects.

Breast-feeding: GOLDGEIST FORTE should only be used whilst breast-feeding after discussion with your doctor.

Precautions and warnings

What precautionary measures should be taken into account?

Chlorocresol can cause allergic reactions.

Avoid contact with the eyes as irritation of the mucous membranes can occur.

Interactions with other products

It is possible that the effect of Malathion will be weakened if it is used at the same time.

Posology and Method of Administration

(if not otherwise directed by your doctor)

How much GOLDGEIST FORTE should be used and how often should it be applied?

Head lice: For GOLDGEIST FORTE to work properly, it is important that the whole scalp and hair should be moistened. GOLDGEIST FORTE should therefore be applied to dry hair until it is thoroughly soaked and then rubbed into the scalp. It will be necessary to use the full contents of a 75 ml bottle for long hair or approximately half a bottle for short hair. Leave the fluid to take effect for at least 30 minutes to a maximum of 45 minutes. The hair should then be thoroughly washed with hot water and shampoo and then rinsed. It can then be combed with a fine tooth comb to remove the dead nits. To make sure the treatment has worked, the head should be examined after 8-12 days to check that the use of GOLDGEIST FORTE has dealt with all the lice and nits. If any more living lice or nits are found, the treatment must be repeated.

Because it is so easy for lice to be transferred, it is recommended that all members of the family are treated with GOLDGEIST FORTE, even if lice are only found on one person. Do not use more than 25 ml on small children and take particular care during treatment.

Crab lice: Apply plenty of GOLDGEIST FORTE to the affected sites and wash off the product thoroughly after 30 to 45 minutes using hot water. It is also recommended here that the treatment should be repeated after 8-12 days.

Clothing lice: Contaminated clothing must be disinfested using suitable measures. To aid these measures, hairy parts of the body should be treated with GOLDGEIST FORTE for half an hour as described and then thoroughly washed with hot water.

All indications: Small children should be treated with a maximum of one third (=25 ml) of a bottle and treatment should be supervised. With the 250 ml pack sizes please use the enclosed measuring cup.

Push



Turn

Special instructions

The 75 ml and 250 ml bottles have been provided with a child-proof cap. To open them, press down on the cap and at the same time turn it anti-clockwise. To ensure the safety of children, make sure the cap is tightly closed after use.

Errors and overdose

What are the errors to avoid?

Do not use the product in the area of the eyes, nose or mouth.

After several applications on the same day or after daily use for several days, dryness of the skin, itching, reddening or increased dandruff can occur on the scalp.

What should I do if GOLDGEIST FORTE is taken internally or swallowed?

Rinse out the mouth immediately with plenty of water. Inform your doctor or pharmacist straight away and show him/her the package, or go to the nearest advice centre for cases of poisoning.

Side Effects

Which side effects may occur as a result of the use of GOLDGEIST FORTE?

In rare cases, local skin irritation, occasional itching or temporary reddening of the sites treated can occur. Contact sensitisation can occur very occasionally.

Chlorocresol can provoke allergic reactions.

If you notice any side effects, especially any that are not listed in the package insert, please let your doctor or pharmacist know.

Advice and instructions on shelf life

The expiry date of this medicinal product is printed on the packaging. Do not use this package after this date!

Keep this medicinal product in a dark place and store below 25°C.

After the package has been opened, it may still be used for up to a maximum of three months.

Keep medicinal products out of the reach and sight of children.

For sale from pharmacies only

Approval no: 6495154.00.00

This leaflet was last approved on 2nd March 2007

Further information on GOLDGEIST FORTE:

In accordance with § 18 of the law on protection from infection, this product has been tested for its efficacy against head lice and recognised for disinfections ordered by the authorities.

Properties

GOLDGEIST FORTE is a simple-to-use product for the extermination of lice and nits (eggs from lice).

GOLDGEIST FORTE contains the highly effective contact insecticide pyrethrum in a wetting agent solution that protects the hair and the skin. The plant-based active substances of the pyrethrum extract work very quickly and effectively on lice, but if used correctly are harmless to human beings and are quickly broken down.

GOLDGEIST FORTE contains moisturising substances for special skin compatibility and to add a silky shine to the hair. If necessary, the hair may be washed after treatment with a mild shampoo.