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Update as of 26 November 2024:

The company for Cinainu has requested a re-examination of EMA's November 2024 opinion. Upon receipt of the grounds of this request, the Agency will re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Cinainu (extracts from *Allium cepa* (onion) fresh bulb and *Citrus limon* (lemon) fresh fruit, *Paullinia cupana* (guarana) seed, and *Theobroma cacao* (cocoa) seed)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Cinainu, a herbal medicine intended for the treatment of alopecia areata (hair loss) in children.

The Agency issued its opinion on 14 November 2024. The company that applied for authorisation, Legacy Healthcare, may ask for a re-examination within 15 days of receiving the opinion.

What is Cinainu and what was it intended to be used for?

Cinainu was developed as a herbal medicine for treating moderate-to-severe alopecia areata in children from 2 to 17 years of age.

Alopecia areata is a condition in which the body's immune system attacks hair follicles in skin, causing hair loss on the scalp or other parts of the body.

Cinainu contains as its active substance extracts from onion, lemon, guarana and cocoa and was to be available as a solution to be applied on the skin.

How does Cinainu work?

The way Cinainu works is not clear. It was suggested that the medicine could reduce cell death and inflammation in the scalp and influence different phases of the hair growth cycle.

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What did the company present to support its application?

The company presented results of a main study in 107 children from 2 to 17 years of age who had moderate-to-severe alopecia areata affecting between 25% and 95% of the scalp. The participants had twice daily sprays of Cinainu or a placebo (dummy treatment) for 24 weeks.

The study looked for improvements in the SALT score, a standard rating score for alopecia that ranges from 0, meaning no hair loss, to 100, meaning complete hair loss.

What were the main reasons for refusing the marketing authorisation?

The Agency's human medicines committee (CHMP) noted that the company had not shown conclusively that the medicine used in the main study was comparable to the medicine it intended to place on the market.

In addition, the results of the main study did not show that the medicine was effective in treating moderate-to-severe alopecia areata. There were also others concerns about the study, including the fact that a relatively small proportion of participants were included in the final analysis presented to the Agency.

As the medicine was for long-term use, the Committee was also concerned that the company had not provided sufficient safety data from laboratory studies, such as toxicity studies. Finally, there were problems related to quality control and stability of the medicine and the risk of impurities.

Therefore, the Agency's opinion was that the benefits of Cinainu did not outweigh its risks and it recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no consequences for patients in clinical trials or in compassionate use programmes with Cinainu.