

PRESS RELEASE

First malaria medicine for newborn babies and young infants <5 kg receives approval

- *Coartem® (artemether-lumefantrine) Baby becomes first malaria treatment approved for newborn babies and young infants*
- *Rapid approvals in eight African countries now expected under special global health scheme run by Swiss agency for therapeutic products (Swissmedic)*
- *Novartis plans to introduce infant-friendly Coartem Baby on largely not-for-profit basis to increase access in areas where malaria is endemic*

Geneva, 08 July 2025 – Coartem® (artemether-lumefantrine) Baby has been approved by Swissmedic as the first malaria medicine for newborns and young infants. The new treatment, also known as Riamet® Baby in some countries, was developed through a Medicines for Malaria Venture (MMV) and Novartis collaboration to treat the potentially deadly mosquito-borne disease.

Eight African countries also participated in the assessment and are now expected to issue rapid approvals under the Swiss agency's Marketing Authorization for Global Health Products procedure.¹ Novartis plans to introduce the infant-friendly treatment on a largely not-for-profit basis to increase access in areas where malaria is endemic.

"Malaria is one of the world's deadliest diseases, particularly among children. But with the right resources and focus, it can be eliminated," said Martin Fitchet, CEO of MMV. "The approval of *Coartem Baby* provides a necessary medicine with an optimized dose to treat an otherwise neglected group of patients and offers a valuable addition to the antimalarial toolbox."

Until now, there has been no approved malaria treatment for infants weighing less than 4.5 kilograms, leaving a treatment gap. They have instead been treated with formulations intended for use in older children, which may increase the risk of overdose and toxicity. Malaria vaccines are also not approved for the youngest babies.²

Some 30 million babies are born in areas of malaria risk in Africa every year,³ with one large survey across West Africa reporting infections ranging between 3.4% and 18.4% in infants younger than 6 months old.⁴ However, current data on malaria in young babies is extremely limited, as they are rarely included in clinical trials of antimalarial agents.^{5,6}

"The available malaria treatments have only been properly tested in children aged at least 6 months because smaller infants are usually excluded from treatment trials," said Professor Umberto D'Alessandro, Director of the MRC Unit, The Gambia at the London School of Hygiene and Tropical Medicine. "That matters because neonates and young infants have immature liver function and metabolize some medicines differently, so the dose for older children may not be appropriate for small babies."

The new dose strength designed for young infants was developed by Novartis with the scientific and financial support of MMV, and as part of the [PAMAfrica consortium](#), which is co-funded by the [European & Developing Countries Clinical Trials Partnership](#) and the [Swedish International Development Cooperation Agency](#). The treatment is dissolvable, including in breast milk, and has a sweet cherry flavor to make it easier to administer.

“For more than three decades, we have stayed the course in the fight against malaria, working relentlessly to deliver scientific breakthroughs where they are needed most,” said Vas Narasimhan, CEO of Novartis. “Together with our partners, we are proud to have gone further to develop the first clinically proven malaria treatment for newborns and young babies, ensuring even the smallest and most vulnerable can finally receive the care they deserve.”

About the CALINA study

The Swissmedic approval is based on the Phase II/III [CALINA](#) study, which investigated a new ratio and dose of *Coartem* (artemether-lumefantrine) to account for metabolic differences in babies under 5 kilograms. It is indicated for the treatment of infants and neonates weighing between 2 and less than 5 kilograms with acute, uncomplicated infections due to *Plasmodium falciparum* or mixed infections, including *P. falciparum*. *Coartem* is known by the brand name *Riamet* in Switzerland and some other countries.

About malaria

Malaria is a life-threatening disease caused by a parasite and spread to humans by certain types of mosquitoes. According to the most recent WHO data, there were 263 million cases of malaria and 597,000 deaths in 2023, almost all of them in Africa. Children under 5 years old accounted for about three in four malaria deaths in the region.⁷

References

1. Eight African countries participated in [Swissmedic's Marketing Authorization for Global Health Products \(MAGHP\) procedure](#) for Coartem Baby – Burkina Faso, Cote d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Tanzania and Uganda – and are expected to approve the medicine following approval by Swissmedic. These eight countries accounted for 47% of estimated cases in 2023, according to the WHO's Global Health Observatory
2. WHO. [Malaria vaccines \(RTS,S and R21\)](#)
3. Reddy, Valentina et al. Global estimates of the number of pregnancies at risk of malaria from 2007 to 2020: a demographic study. *The Lancet Global Health*, Volume 11, Issue 1, e40 - e47
4. Ceesay SJ et al. Malaria Prevalence among Young Infants in Different Transmission Settings, Africa. *Emerg Infect Dis*. 2015 Jul;21(7):1114-21. doi: 10.3201/eid2107.142036. PMID: 26079062; PMCID: PMC4480393.
5. Alessandro U, et al. Malaria in infants aged less than six months - is it an area of unmet medical need? *Malar J*. 2012 Dec 2;11:400. doi: 10.1186/1475-2875-11-400. PMID: 23198986; PMCID: PMC3529680.
6. Dobbs, et al. *Plasmodium* malaria and antimalarial antibodies in the first year of life. *Parasitology*. 2016;143(2):129-138. doi:10.1017/S0031182015001626
7. WHO. [Malaria](#).

Notes for editors

About MMV

MMV is a Swiss not-for-profit working to deliver a portfolio of accessible medicines with the power to treat, prevent and eliminate malaria. Born in 1999 to drive health equity, we close critical gaps in research, development and access – to expand the use of existing antimalarials and innovate new compounds. This starts with women and children.

It's working. As of 2024, MMV-supported products have effectively treated an estimated 711 million patients. We cannot stop now.

With a quarter of a billion malaria cases and nearly 600,000 deaths reported in 2023, progress towards disease elimination has stalled. MMV is part of an ecosystem of partners determined to change this. We pioneer new solutions that align with local and global health priorities and promote the equitable development of effective and affordable products that work to help end malaria and advance health for all.

For more information, visit www.mmv.org.

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About Novartis in malaria innovation

Novartis finds breakthroughs for diseases neglected by science and brings innovative medicines to communities on the margins of healthcare, building on 85 years of innovation in global health. Novartis has built the industry's largest pipeline of treatments to control or eliminate malaria and neglected tropical diseases, backed by nearly USD 490 million in funding for global health R&D since 2021. This includes four new antimalarial compounds with the potential to combat rising drug resistance, one of which is just completing Phase III trials, and another which is a potential single-dose cure. Since 1999, Novartis has delivered more than 1.1 billion treatment courses of antimalarials, mostly at no profit, including 500 million treatments of a child-friendly formulation for babies weighing at least 5 kilograms.

About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach nearly 300 million people worldwide.

Reimagine medicine with us: Visit us at www.novartis.com and connect with us on [LinkedIn](#), [Facebook](#), [X/Twitter](#) and [Instagram](#).

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