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Ranbaxy receives CDSCO approval to market Synriam in India

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Ranbaxy today announced that it has received approval from Central Drugs Standard Control Organisation (CDSCO) to manufacture and market Synriam (arterolane maleate and piperaquine phosphate tablet 150+750 mg) in India, for treating uncomplicated malaria in adults caused by Plasmodium vivax parasite.

The company said that Phase III clinical trials for this drug conducted in India successfully demonstrated its efficacy and tolerability as comparable to chloroquine. Now further, the company has also received permission to conduct Phase III clinical trials for the pediatric formulation in pediatric patients of uncomplicated Plasmodium falciparum malaria.

Commenting on the approval, Arun Sawhney, CEO & MD, Ranbaxy, said, "Synriam is a new age cure for malaria, and is fast emerging as the preferred option in the hands of doctors. This approval makes Synriam one of the few therapies in the world that successfully treats both, Plasmodium vivax and Plasmodium falciparum malaria. Ranbaxy remains committed in its fight against malaria and we are making all efforts to make this new therapy accessible to patients around the world."

Traditional drugs are proving to be ineffective against the deadly malarial parasite because it has progressively acquired marked resistance to available drugs. Last year, Ranbaxy launched India's first new drug, Synriam, for the treatment of uncomplicated Plasmodium falciparum malaria in India. Since its launch, Synriam has successfully treated around one million patients said the press release.

The company is also making efforts to make Synriam available in African, Asian and South American markets where malaria is rampant. The company said that it has also filed New Drug Applications (NDAs) for marketing Synriam in a few African countries.

Synriam provides quick relief from most malaria-related symptoms, including fever, and has a cure rate of over 95%. The drug is also said to be conforming to the recommendations of the World Health Organization (WHO) for using combination therapy in malaria.

The dosage regimen for Synriam remains as one tablet per day for three days. The drug is also claimed to be independent of dietary restrictions for fatty foods or milk, as is the case with older anti-malarial therapies.

According to the WHO's World Malaria Report 2012, India has about 1.3 million confirmed cases of malaria each year. About 50% of them are caused by Plasmodium vivax, the second most important species after Plasmodium falciparum. Globally, 40% of total malaria burden is due to Plasmodium vivax.