

Approval of Covid-19 related medicines under Ayush

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Government of India has released “National Clinical Management Protocol based on Ayurveda and Yoga for management of COVID-19” prepared by the National Task force in consensus from various expert committees.

The Ministry of AYUSH has formed an Inter-disciplinary AYUSH R&D Task Force having representation from Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR), All India Institute of Medical Sciences (AIIMS) and AYUSH Institutions. The Inter-disciplinary AYUSH R&D Task Force has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases for studying four different interventions viz. Ashwagandha, Yashtimadhu, Guduchi + Pippali and a poly herbal formulation (AYUSH-64).

AYUSH-64 and Kabasur Kudineer has been identified for Covid-19 treatment. The research outcomes of the clinical trials has demonstrated efficacy of AYUSH- 64 in the treatment of asymptomatic & mild cases as standalone and for the management of mild and moderate COVID-19 as an adjunct to standard care. It was observed that AYUSH-64 as adjunct treatment to Standard Care resulted in significant improvement in clinical recovery. AYUSH 64 is also recommended in “National Clinical Management Protocol based on Ayurveda and Yoga for management of COVID-19” prepared by National Task Force in consensus from various expert committees. Further, Kabasur Kudineer, a siddha preparation was also subjected to clinical trials for studying the efficacy in Covid-19 patients by Central Council for Research in Siddha (CCRS) under Ministry of Ayush and is also found useful in the treatment of mild to moderate covid-19 infection.

In order to provide maximum benefit of AYUSH systems of medicine, a nationwide campaign has been undertaken for distribution of AYUSH-64 and Kabasura Kudineer through the Research Councils and the National Institutes under the Ministry of Ayush across the country.

Ministry has issued Orders to all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees there under to allow the licensed manufacturers for AYUSH-64 under their jurisdiction to include new indication of AYUSH-64 for repurposing as an intervention for the management of asymptomatic, mild to moderate COVID-19 in addition to existing indication(s) and to expedite the process of the licensing/approval of such applications for the manufacturing of AYUSH-64 medicine, provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, are fulfilled. So far, 37 manufacturing units of 11 states have been transferred AYUSH-64 technology by CCRAS through National Research Development Corporation (NRDC).

The Ministry of AYUSH has constituted an Interdisciplinary Technical Review Committee (ITRC) for COVID-19 for the examination of the applications/claims on patent & proprietary (P&P) ASU&H medicines/classical ASU& H medicines with new indication or re-purposing of licensed P&P, ASU&H medicines for COVID-19, forwarded by the State Licensing Authorities/Individuals referred by the Drug Policy Section of Ministry of Ayush. So far, the following applications have been approved in the ITRC with respect to COVID-19 claims:-

- a. Divya Coronil tablet of Patanjali Research Foundation Trust, Haridwar, Uttarakhand- recommended as supporting measure in the management of COVID-19 without claiming cure.
- b. Clevira Tablet of M/s Apex Laboratories Private Ltd., Tamilnadu has been recommended as a supporting measure for mild to moderate condition of COVID-19.
- c. Kabasura Kudineer of Sri Sri Tattva, Sriveda Sattva Pvt. Ltd., Bangalore has been recommended as an intervention for prevention and mild to moderate symptoms of COVID-19.

As per the requests received from State/UT Governments regarding utilization of National AYUSH Mission (NAM) funds for purchase of medicines including AYUSH-64 medicine in the context of COVID-19 pandemic, an amount of Rs. 2271.551 Lakh has been approved by Ministry of Ayush till date.

This information was given by Minister of State for Ayush Shri Sarbananda Sonowal in a written reply in Rajya Sabha today.

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