Generic Name:
Moxidectin
Trade Name:
No trade name
Company:
Medicines Development for Global Health
Notes:

FDA has approved moxidectin 8-mg tablets to treat river blindness (onchocerciasis) in patients aged 12 years and older. FDA has also awarded a priority review voucher (PRV) to the manufacturer, Medicines Development for Global Health (MDGH).

River blindness is caused by a parasitic worm, *Onchocerca volvulus.* The disease manifests as severe itching, disfiguring skin conditions, and visual impairment, including permanent blindness, caused by the worm?s larvae (microfilariae).

Approval of moxidectin was based on data from two randomized, double-blind, active controlled clinical studies. Each study met its respective primary endpoints, showing a statistically significant superiority of moxidectin over the current standard of care, ivermectin, in suppressing the presence of the microfilariae in skin. Full results from the Phase III study were published in the *Lancet* in January 2018.

Moxidectin is supplied as 2-mg tablets for administration as an 8-mg dose per oral to patients at least 12 years of age with *O. volvulus* infection.

Medication Monitor Categories:
New Drug Approvals