Ivermectin

Section: 6. Anti-infective medicines > 6.1. Anthelminthics > 6.1.2. Antifilarials

EMLc | Codes ATC: P02CF01

Indication	Lymphatic filariasis Code ICD11: 1F66.3
INN	Ivermectin
Type de médicament	Chemical agent
Type de liste	Liste de base
Formulations	**Oral > Solid > tablet:** 3 mg
Historique des statuts LME	Ajouté pour la première fois en 2011 (TRS 965) Modifié en 2013 (TRS 985) Modifié en 2023 (TRS 1049) Modifié en 2025 (TRS 1064)
Sexe	Tous
Âge	Aussi recommandé pour les enfants
Équivalence thérapeutique	moxidectin (Codes ATC: P02CX03) Oral > Solid > tablet: 2 mg
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Ivermectin
DrugBank	Ivermectin

Recommandation du comité d'experts

The Expert Committee recognized the public health importance of effective treatments for the control and elimination onchocerciasis and lymphatic filariasis. These neglected tropical diseases affect millions of people, primarily in sub-Saharan Africa, and result in serious social and economic consequences. The Committee noted with concern the predictions that WHO elimination targets for onchocerciasis and lymphatic filariasis may not be reached by 2030 with existing elimination strategies. Based on the evidence presented, the Committee considered that moxidectin demonstrated superior efficacy and comparable safety to ivermectin for onchocerciasis and has regulatory approval for adults and children from 4 years for this indication. The Committee noted the evidence for moxidectin in lymphatic filariasis (published after the submission deadline) which demonstrated superior efficacy of a single dose of moxidectin plus albendazole over the current standard of care of annual doses of ivermectin plus albendazole, and comparable efficacy to other treatment regimens. Moxidectin was equally well tolerated as other treatment regimens. Overall, the Committee considered that the balance of benefits to harms for moxidectin was favourable. The Committee expressed some concern about the current limited availability of moxidectin, and financial implications of its use, considering that moxidectin would need to be procured whereas ivermectin is currently donated for mass drug elimination programmes. The Committee was encouraged by the support of the technical department for listing of moxidectin, and their advice that moxidectin is being considered for inclusion in the WHO guidelines currently under development. The Committee also noted that moxidectin 2 mg tablets are included on an invitation to manufactures of medicinal products for neglected tropical diseases to submit an expression of interest for WHO prequalification, and the advice of the manufacturer of their intention to consider pursuing prequalification. The Committee considered that moxidectin may offer an advantage over ivermectin for

reducing overall programmatic costs by virtue of a potential to reduce the number of administration cycles needed to achieve disease elimination. Based on these considerations, the Committee recommended the inclusion of moxidectin on the core list of the EML and EMLc as a therapeutic alternative to ivermectin for use in mass drug administration programmes for the control and elimination of onchocerciasis and lymphatic filariasis in adults and children.

Contexte

Moxidectin has not previously been evaluated for inclusion on the Model Lists. The Model Lists currently include ivermectin for the treatment of onchocerciasis and lymphatic filariasis, and albendazole and diethylcarbamazine for the treatment of lymphatic filariasis.

Pertinence pour la santé publique

The public health relevance of effective and safe anthelminthic treatment is well established. Latest estimates indicate at least 246 million people require preventive chemotherapy against onchocerciasis (1). The prevalence of onchocerciasis in 2021 was 19.6 million (95% uncertainty interval (UI) 17.8 to 21.7 million), an increase of 17.7% compared with 2010. In 2021, onchocerciasis was responsible for the loss of 1.26 million (95% UI 0.75 to 1.90 million) disability-adjusted life years (DALYs). Key sequelae contributing to DALYs are moderate to severe skin disease and blindness (2). Estimates in 2022 indicate that about 794 million people worldwide require preventive chemotherapy against lymphatic filariasis (3). The prevalence of lymphatic filariasis in 2021 was 56.9 million (95% UI 48.7 to 67.9), a decrease of 39.9% compared with 2010. In 2021, lymphatic filariasis was responsible for the loss of 1.31 million DALYs (95% UI 0.77 to 2.22 million DALYs). Key sequelae contributing to DALYs are lymphoedema and hydrocele (4). Both onchocerciasis and lymphatic filariasis are filarial diseases that have serious social and economic consequences, both to the individual and their communities, such as stigmatization due to their physical manifestations and the compounding of poverty which undermines development in endemic countries. The WHO road map for neglected tropical diseases, 2021–2030, identified onchocerciasis as a disease targeted for elimination (interruption of transmission) and lymphatic filariasis for elimination as a public health problem (5). The targets to be reached by 2030 are: • for onchocerciasis, to have at least 12 countries verified for elimination of transmission, and to have stopped mass drug administration (MDA) in at least one focus in 34 countries, in more than 50% of the population in at least 16 countries and in the entire endemic population in at least 12 countries; • for lymphatic filariasis, implementing post-MDA or post-validation surveillancein all 72 endemic countries and achieve validation of elimination as a public health problem in 58 of 72 endemic countries. Ivermectin, a first-generation macrocyclic lactone of the avermectin class, is presently used in MDA programmes for the treatment of onchocerciasis and lymphatic filariasis in endemic regions, in accordance with the following WHO recommendations. • In areas where onchocerciasis is endemic (in the absence of lymphatic filariasis or loiasis), the current WHO-recommended MDA regimen is ivermectin given annually (or biannually). • In areas where lymphatic filariasis is endemic (in the absence of onchocerciasis or loiasis), the current WHO-recommended MDA combination regimen is annual diethylcarbamazine plus albendazole, or ivermectin, diethylcarbamazine and albendazole. • In areas where lymphatic filariasis and onchocerciasis are co-endemic (in the absence of loiasis), the current WHO-recommended MDA combination regimen is annual ivermectin and albendazole. Ivermectin is currently the only available treatment option for use in onchocerciasis and has been associated with unsustained and suboptimal responses. In studies on treatment for onchocerciasis, ivermectin failed to sustain skin microfilariae clearance for either 6 or 12 months (the two most commonly used ivermectin treatment intervals) in most infected individuals and microfilariae repopulation of the skin was shown to occur within 3 months of treatment (6, 7). Given this situation, elimination in many places may not be achievable and targets may be difficult to reach. Therefore, one of the critical actions listed to achieve elimination targets is to implement alternative MDA strategies or improved interventions for onchocerciasis where appropriate. Despite significant progress by the Global Programme to Eliminate Lymphatic Filariasis to eliminate lymphatic filariasis as a public health problem, infection rates in a variety of settings have remained above elimination targets, even after many rounds of treatment (3). Progress has been particularly poor in communities co-endemic for onchocerciasis, where the so-called gold standard diethylcarbamazine combinations cannot be

used due to safety concerns. An alternative treatment with comparable efficacy to diethylcarbamazine combinations but without the safety risks is urgently needed to ensure these areas are not left behind. In 2023, the WHO-hosted Global Accelerator for Paediatric formulations (GAP-f) network released the first list of priority paediatric formulations for five neglected tropical diseases to target research and development, and to address the specific needs of infants and children (8). Moxidectin for onchocerciasis and scabies was included as a priority in this list, reinforcing the public health need for this population.

Bénéfices

Onchocerciasis The application presented findings from a 2022 systematic review and meta-analysis of two randomized controlled trials that compared the efficacy and safety evidence of moxidectin and ivermectin for the control and elimination of onchocerciasis in adults and adolescents aged 12 years and older (9). Primary efficacy outcomes included: complete microfilariae clearance, defined as the proportion (%) of people with undetectable skin microfilariae at 6 or 12 months after treatment; duration of microfilariae clearance, assessed as the follow-up time at which the maximum proportion of individuals with undetectable skin microfilariae is achieved after treatment; and mean microfilariae densities and range before and at 6 or 12 months after treatment. Pooled analysis showed increased odds of skin microfilariae clearance 12 months post-treatment in the moxidectin 8 mg group compared to the ivermectin 150 µg/kg group (1495 participants, log odds ratio (OR): 2.81, 95% confidence interval (CI) 0.95 to 4.68; moderate-certainty of evidence), corresponding to 48 more moxidectin treated patients per 1000 (95% CI 1 fewer to 93 more) achieving skin microfilariae clearance in absolute terms. Given that treatment with moxidectin will be given to populations co-infected with other neglected tropical diseases, a secondary objective of this systematic review was to assess the efficacy of moxidectin for the control and elimination of other filarial and helminth infections. The authors identified no added effect of moxidectin for the treatment and control of Strongyloides stercoralis, Trichuris trichiura, Schistosoma haematobium and Schistosoma mansoni. The available evidence showed that outcomes in these diseases would be similar to those with ivermectin. The evidence at the time of the review for lymphatic filariasis was insufficient to determine whether moxidectin could be used for annual MDA to eliminate lymphatic filariasis in implementation units co-endemic for onchocerciasis (9). The systematic search used for the above-mentioned systematic review was repeated by the applicants in August 2024. No new publications of relevance to the efficacy of moxidectin for the control and elimination of onchocerciasis were identified. However, three additional publications were identified as contributing to the evidence on the efficacy of moxidectin in other filarial and helminth infections. A 2024 study reported efficacy findings of a double-blind, randomized, ivermectin-controlled trial comparing a 2 mg moxidectin dose and the standard 150 µg/kg ivermectin dose for onchocerciasis in individuals with low loa loa microfilarial densities (10). The study was conducted in Cameroon and enrolled 72 adult men with loa loa microfilarial density between 5 and 1000 microfilariae/mL. A key outcome was the loa loa microfilarial density reduction rate in the first month after treatment. Median microfilarial density reduction rates were significantly higher after ivermectin than moxidectin at day 3 (70.2% versus 48.5%), day 7 (76.4% versus 50.0%) and day 30 (79.8% versus 48.1%). The authors concluded that further studies with higher doses of moxidectin (up to the standard dose of 8 mg used for treatment of onchocerciasis) and in patients with higher loa loa microfilarial densities are warranted. A 2023 study reported efficacy findings from a community-based, randomized, placebo-controlled, parallel-group superiority trial of moxidectin 8 mg plus albendazole 400 mg and ivermectin 200 µg/kg plus albendazole 400 mg combination therapy compared with albendazole monotherapy in adolescents and adults infected with T. trichiura in Côte D'Ivoire (11). The primary outcome was proportion cured (cure rate) assessed 2–3 weeks post-treatment. For the 210 participants with primary outcome data, cure rates were 15.3% in the moxidectin–albendazole arm and 22.5% in the ivermectin–albendazole arm, which did not differ significantly from the cure rate of 13.4% in the albendazole arm (differences: 1.8 percentage points (95% CI –10.1 to 13.6) and 9.1 percentage points (95% CI –3.9 to 21.8), respectively). The authors concluded that all therapies showed similar low efficacy in treating trichuriasis in Côte d'Ivoire. Efficacy findings were reported from a randomized, double-blind, parallel-group, non-inferiority, phase IIb/III trial of a single oral dose of either moxidectin (8 mg) or ivermectin (200 µg/kg bodyweight) for S. stercoralis infection in adults in Cambodia and Lao People's Democratic Republic (12). In total, 726 participants were enrolled and randomly assigned to moxidectin (n = 363) or ivermectin (n = 363). The primary

endpoint was the cure rate assessed 14–21 days after treatment. For the participants with primary outcome data, cure rates were 93.6% (95% CI90.5 to 96.0; 324 of 346 participants) in the moxidectin group and 95.7% (95% CI 93.0 to 97.6; 335 of 350 participants) in the ivermectin group, in a between-group difference of –2.1 percentage points (95% CI –5.5 to 1.3). The authors concluded that moxidectin was non-inferior to ivermectin in terms of efficacy in the treatment of strongyloidiasis. The application presented unpublished data from Study MDGH-MOX-1006, a pharmacokinetic and safety study of moxidectin to identify the optimal treatment dose for children aged 4 to 11 years (13). Thirty-six participants in Ghana aged 4 to 17 years with or at risk of onchocerciasis were enrolled in three cohorts. A single dose of moxidectin was administered: 8 mg (cohort I; 12 to 17 years), 6 or 8 mg (cohort II; 8 to 11 years) or 4 mg (cohort III; 4 to 7 years). The data indicated that moxidectin doses of 6 mg in children aged 8 to 11 years and 4 mg in children aged 4 to 7 years provide comparable exposures to those achieved with a moxidectin dose of 8 mg in adolescents 12 years and older and adults. A simplified dosing regimen to support ease of operationalization in field treatment programmes has been proposed and was investigated using the moxidectin population pharmacokinetic model and relevant weight-for-age growth charts. Simulations identified that an age-based regimen consisting of a 4 mg dose for children 4 to < 8 years and an 8 mg dose for children and adolescents ≥ 8 to 17 years provides a pharmacokinetically-optimized and simplified age-based alternative to three different doses across ages from 4 years to adults. Based on these data, regulatory approval applications have been submitted to the United States Food and Drug Administration and the Ghana Food and Drugs Authority. The safety of this dose regimen is currently being further examined in a clinical study in the Democratic Republic of the Congo and Côte d'Ivoire which is assessing the safety of single dose moxidectin compared with single dose ivermectin in participants 4 years and older (14). Lymphatic filariasis A phase III, randomized, open-label study evaluated the safety and efficacy of moxidectin combination treatments versus ivermectin combination treatments for lymphatic filariasis in adults in Côte d'Ivoire (15). Participants (n = 164) were randomly assigned to receive ivermectin 200 micrograms/kg plus albendazole 400 mg (IA), given annually; moxidectin 8 mg plus albendazole 400 mg (MoxA), given once; ivermectin 200 micrograms/kg plus diethylcarbamazine 6 mg/kg plus albendazole 400 mg (IDA), given once, or moxidectin 8 mg plus diethylcarbamazine 6 mg/kg plus albendazole 400 mg (MoxDA), given once. The primary outcome was the proportion of individuals in each group with clearance of W. bancrofti microfilariae at 12 months post-treatment. At 12 months post-treatment, the proportion of participants with microfilaria clearance 8/25 (32%) for IA versus 18/19 (95%) for MoxA (adjusted risk ratio (RR) 2.79, 95% CI 1.59 to 4.90), and 24/28 (86%) for IDA versus 27/28 (96%) for MoxDA (adjusted RR 1.07, 95% CI 0.90 to 1.27). Differences were diminished 24 months post-treatment: 13/25 (52%) for IA versus 14/16 (88%) for MoxA (adjusted RR 1.49, 95% CI 1.02 to 2.19), and 20/22 (91%) for IDA versus 21/23 (91%) for MoxDA (adjusted RR 0.98, 95% CI 0.83 to 1.15). The authors concluded that a single dose of MoxA was superior to IA for microfilaria clearance at 12 months and compared favourably to two annual doses of IA at 24 months. There was no difference between MoxA and IDA or MoxDA for microfilaria clearance at 24 months.

Torts

From the 2022 systematic review of moxidectin and ivermectin for the control and elimination of onchocerciasis, pooled analysis of two randomized controlled trials (1555 participants) showed moderate-certainty evidence of no significant difference between moxidectin and ivermectin in the occurrence of all adverse events after treatment (log OR 0.43, 95% CI –1.64 to 2.50) and serious adverse events (log OR 0.15, 95% CI –0.42 to 0.73). In absolute terms, 37 fewer persons per 1000 experienced any adverse event after treatment with moxidectin compared with ivermectin (9). At the time of publication of the systematic review, the data available were insufficient to evaluate whether moxidectin was safe to use in implementation areas co-endemic for onchocerciasis and lymphatic filariasis or loiasis. The systematic search used for the above-mentioned systematic review was repeated by the applicants in August 2024 and six additional studies relevant to the safety of moxidectin were identified. A 2023 paper reported findings from a pharmacokinetic sub-study in 58 participants (ages 18 to 63 years) of the NCT04410406 trial on the pharmacokinetics and drug interactions of moxidectin 8 mg plus albendazole 400 mg with or without diethylcarbamazine 6 mg/kg compared to ivermectin 0.2 mg/kg plus albendazole 400 mg with or without diethylcarbamazine 6 mg/kg (16). The addition of moxidectin to albendazole with or without diethylcarbamazine for lymphatic filariasis therapy did not alter the drug exposure of co-administered drugs

compared with ivermectin combinations. The safety and tolerability of moxidectin and ivermectin combination treatments for lymphatic filariasis were assessed in the NCT04410406 trial in which 164 participants were treated and monitored for treatment-emergent adverse events (17). Eighty-seven participants (53.0%) experienced one or more grade 1 or grade 2 treatment-emergent adverse event. Grade 3 haematuria was reported in four participants (three after treatment with ivermectin plus diethylcarbamazine plus albendazole, and one after treatment with ivermectin plus albendazole). No serious adverse events were reported and no significant differences in frequency or types of treatment-emergent adverse events between treatment groups were reported. Grade 2 treatment-emergent adverse events were more frequent after triple drug treatments (ivermectin plus diethylcarbamazine plus albendazole, 14.6%; moxidectin plus albendazole, 9.5%) than after two-drug treatments (ivermectin plus albendazole, 7.3%; moxidectin plus albendazole, 2.5%). No difference in treatment-emergent adverse events based on baseline microfilariae counts was seen (OR 0.69, 95% CI 0.33 to 1.43; P = 0.319). The authors concluded that all treatment regimens were well tolerated and no difference in safety parameters between regimens that contained ivermectin or moxidectin were observed. Another study reported safety findings from a double-blind, randomized, controlled trial comparing a single 2 mg moxidectin dose and 150 µg/kg ivermectin dose in 72 participants with low loa loa microfilarial density (between 5 and 1000 microfilariae/mL) (10). The safety outcome was occurrence of adverse events in the first month of treatment. A total of 49 and 59 adverse events were reported in the moxidectin and ivermectin groups, respectively. No serious or severe adverse events occurred in either treatment group. The incidence of grade 2 adverse events was higher among participants treated with ivermectin than moxidectin (38.5% and 14.3%, respectively; P = 0.043). The most frequently reported clinical adverse events with moxidectin were headache, fatigue, pruritus and fever. The most frequent laboratory abnormality was grade 1 creatinine increase, occurring in 25.7% and 18.2% of participants in the moxidectin and ivermectin groups, respectively. Neutropenia occurred in 8.6% and 18.2% of the participants in the moxidectin and ivermectin groups, respectively. The authors concluded that a single 2 mg moxidectin dose had a similar safety profile to 150 µg/kg ivermectin in patients with low loa loa microfilariae density. Data were analysed from a randomized, double-blind phase III trial comparing the efficacy and safety of a single oral dose of 8 mg moxidectin and 150 µg/kg ivermectin in 1463 participants with Onchocerca volvulus infection (18). The outcomes were ocular adverse events observed within 6 months of treatment. Ocular Mazzotti reactions occurred in 12.4% and 10.2% of moxidectin- and ivermectin-treated participants, respectively, without differences in type or severity. The risk for at least 1 ocular Mazzotti reaction was higher in women (OR 1.54, 95% CI 1.10 to 2.16) and in participants with microfilariae levels in the anterior chamber > 10 at screening (OR 2.70, 95% CI 1.27 to 5.75) and 4 days post-treatment (OR 1.619, 95% CI 0.80 to 3.28). Safety findings were reported from a community-based, randomized, placebo-controlled, parallel-group superiority trial of moxidectin 8 mg plus albendazole 400 mg and ivermectin 200 µg/kg plus albendazole 400 mg combination therapy compared with albendazole monotherapy in adolescents and adults infected with T. trichiura in Côte D'Ivoire (11). Safety endpoints were assessed pre-treatment and at 3 and 24 hours post-treatment. In total, 102/255 (40.0%) participants experienced an adverse event: 37/86 (43.0%) who received ivermectin plus albendazole; 34/85 (40.0%) who received moxidectin plus albendazole; and 31/84 (36.9%) who received albendazole monotherapy. The most common adverse events were abdominal pain, headache and itching, and were predominantly mild and transient. Safety findings were also reported from a randomized, double-blind, parallel-group, non-inferiority, phase IIb/III trial of single oral doses of moxidectin 8 mg (n = 363) or ivermectin 200 µg/kg (n = 363) for S. stercoralis in 726 adults in Laos and Cambodia (12). Safety endpoints were assessed before treatment, and 2–3 hours, 24 hours, and 14–21 days after treatment. Following treatment, 153 (21.1%) participants experienced an adverse event: 74 (20.4%) who received moxidectin and 79 (21.8%) who received ivermectin. The most common adverse events were abdominal pain and headache and were predominantly mild and transient.

Preuves supplémentaires

The application also presented details of other ongoing trials of moxidectin, for which results are not yet available. These include a randomized phase IIIb trial comparing efficacy and safety of annual and biannual doses of moxidectin or ivermectin for treatment of onchocerciasis, and a randomized phase II dose-finding study of moxidectin for the treatment of scabies.

Rapport coût/efficacité

The application reported that at the current production capacity of 1.9 million treatments per year, a proposed price of moxidectin per 8 mg dose is US$ 1.56. The applicant anticipates that with production scaled to about 30.6 million 8 mg treatments, the ex-manufacturer cost per treatment will decrease by more than half (excluding the cost of tooling and manufacturing upgrade that would be required). Shipping and transportation costs are not included in these estimates. In 1987, Merck committed to donating ivermectin to help eliminate onchocerciasis. This commitment expanded in 1998 to include the treatment of lymphatic filariasis. Over 35 years, the Mectizan® Donation Program has grown from 0.3 million treatments to 376.4 million treatments in 2023, corresponding to about 1.355 billion tablets of ivermectin a year. While the actual cost of this ivermectin treatment is not publicly known, the declared market value of the donated treatment is US$ 4.50 per treatment, and Merck benefits from a tax exemption from the United States government for this donation (22). The impact of moxidectin has been studied in mathematical models. A 2015 modelling study based on data from a phase II onchocerciasis clinical trial and using the population based deterministic EPIONCHO epidemiological model reported that both annual moxidectin and biannual ivermectin mass drug administration would achieve similar reductions in programme duration relative to annual ivermectin treatment (23). A 2024 study investigated annual and biannual community-directed treatment with ivermectin (aCDTI, bCDTI) and moxidectin (aCDTM, bCDTM) under various scenarios of the percentage of the total population receiving treatment and microfilarial baseline prevalence, comparing programmatic delivery costs (excluding drug costs) for the number of treatments achieving a 90% probability of elimination of parasite transmission (24). The assumed economic cost of aCDTI or aCDTM) was US$ 50 535 per 100 000 individuals. The results suggested that aCDTM and bCDTM could achieve a 90% probability of elimination of parasite transmission in a shorter programme duration and at lower programmatic delivery costs than aCDTI under all scenarios within 40 years. The sole exception was aCDTM with minimal population coverage in settings with hyperendemic baseline prevalence. For example, assuming minimal coverage in areas with 50% baseline disease prevalence, aCDTM would, with 90% probability, reduce the time to achieving elimination of transmission by 20 years compared with aCDTI, which in turn would translate into a reduction of programmatic costs by 36%. Projections were sensitive to assumptions about the relative permanent adult worm sterilizing effects of moxidectin compared with ivermectin, and the change in total delivery costs when treatment frequency changes.

Directives de l'OMS

WHO guidelines for the treatment of onchocerciasis are not currently available. Treatment recommendations for onchocerciasis on the WHO website currently recommend treating onchocerciasis with ivermectin at least once yearly for 10 to 15 years (19). This is reiterated in the WHO guidelines for stopping mass drug administration and verifying elimination of human onchocerciasis where the current intervention strategy for onchocerciasis is based on mass drug administration with ivermectin (20). This treatment regimen may need to be adjusted in regions where onchocerciasis is co-endemic with loiasis, another filarial disease caused by the loa loa parasite, as treating individuals with high levels of the loa loa parasite with ivermectin may cause serious adverse events (3). The 2017 WHO guideline for alternative mass drug administration regimens to eliminate lymphatic filariasis recommends various preventive chemotherapy strategies, depending on the co-endemicity of lymphatic filariasis with other filarial diseases (21). The recommendations include: • biannual albendazole 400 mg for areas co-endemic with loiasis; • annual ivermectin 200 µg/kg plus albendazole 400 mg in countries co-endemic with onchocerciasis; • annual diethylcarbamazine 6 mg/kg plus albendazole 400 mg in countries without onchocerciasis; and • annual ivermectin 200 µg/kg plus diethylcarbamazine 6 mg/kg plus albendazole 400 mg in communities without onchocerciasis and where other programmatic conditions are met.

Disponibilité

Moxidectin has been approved by the United States Food and Drug Administration and the Ghana Food and Drugs Authority for the treatment of onchocerciasis due to O. volvulus in patients aged 4 years and older. Moxidectin is currently produced with lead time and as required in bottles of 500 tablets. As the use cases for moxidectin become more defined, and in collaboration with its funding partners, MDGH will scale up production capacity to

meet the growing demand from endemic countries. This may require prioritization of use cases and/or working with specific priority countries to balance demand and supply capacity ramp up in the near term. Moxidectin is not currently included on any national essential medicines lists. Moxidectin 2 mg tablets were included in the ninth invitation for expressions of interest for finished pharmaceutical products for neglected tropical diseases for WHO prequalification in October 2024. It is the intention of the applicant to engage with the WHO prequalification unit to support registration of moxidectin for the treatment of onchocerciasis and lymphatic filariasis.

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