Imec

Prescription Only

Ivermectin 6 mg

Presentation

Imec 6 tablet: Each tablets contains 6 mg Ivermectin BP.

Description

Ivermectin is very effective in onchocerciasis and it is now the drug of choice. A single dose of 150 mcg/kg by mouth produces a prolonged reduction in microfilarial levels. Retreatment at intervals of 6 to 12 months depending on symptoms must be given until the adult worms die out. Reactions are usually slight and most commonly take the form of temporary aggravation of itching and rash. Diethylcarbamazine or suramin should no longer be used for onchocerciasis because of their toxicity.

Indications

Strongyloidiasis of the intestinal tract: Ivermectin is indicated for the treatment of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. This indication is based on clinical studies of both comparative and open-label designs, in which from 64-100% of infected patients were cured following a single 200 mcg/kg dose of Ivermectin.

Onchocerciasis: Ivermectin is indicated for the treatment of onchocerciasis due to the nematode parasite Onchocerca volvulus. This indication is based on randomized, double-blind, placebo-controlled and comparative studies conducted in 1427 patients in onchocerciasis-endemic areas of West Africa. The comparative studies used diethylcarbamazine citrate (DEC-C).

Dosage and Administrations

Strongyloidiasis: The recommended dosage of Ivermectin for the treatment of strongyloidiasis is a single oral dose designed to provide approximately 200 mcg of Ivermectin per kg of body weight. Patients should take tablets on an empty stomach with water. In general, additional doses are not necessary. However, follow-up stool examinations should be performed to verify eradication of infection.

Dosage Guidelines for Ivermectin for Strongyloidiasis:

Body Weight (kg)	*Dose*
15-24	3 mg
25-35	6 mg
36-50	9 mg
51-65	12 mg
66-79	15 mg
>80	200 mcg/kg

Onchocerciasis: The recommended dosage of Ivermectin for the treatment of onchocerciasis is a single oral dose designed to provide approximately 150 mcg of Ivermectin per kg of body weight. Patients should take tablets on an empty stomach with water. In mass distribution campaigns in international treatment programs, the most commonly used dose interval is 12 months. For the treatment of individual patients, retreatment may be considered at intervals as short as 3 months.

Dosage Guidelines for Ivermectin for Onchocerciasis:

Body Weight (kg)	*Dose*
15-25	3 mg
26-44	6 mg
45-64	9 mg
65-84	12 mg
>85	150 mcg/kg

Side Effects

Strongyloidiasis: In four clinical studies involving a total of 109 patients given either one or two doses of 170 to 200 mcg/kg of Ivermectin, the following adverse reactions were reported as possibly, probably, or definitely related to Ivermectin. Body as a whole: asthenia/fatigue (0.9%), abdominal pain (0.9%) *Gastrointestinal*: anorexia (0.9%), constipation (0.9%), diarrhea (1.8%), nausea (1.8%), vomiting (0.9%) *Nervous System/Psychiatric:* dizziness (2.8%), somnolence (0.9%), vertigo (0.9%), tremor (0.9%) Skin: pruritus (2.8%), rash (0.9%), and urticaria (0.9%). *Onchocerciasis*: arthralgia/synovitis (19.3%), axillary lymph node enlargement and tenderness (11.0% and 4.4%, respectively), cervical lymph node enlargement and tenderness (5.3% and 1.2%, respectively), inguinal lymph node enlargement and tenderness (12.6% and 13.9%, respectively), other lymph node enlargement and tenderness (3.0% and 1.9%, respectively), pruritus (27.5%), skin involvement including edema, papular and pustular or frank urticarial rash (22.7%), and fever (22.6%), abnormal sensation in the eyes, eyelid edema, anterior uveitis, conjunctivitis, limbitis, keratitis, and chorioretinitis or choroiditis. These have rarely been severe or associated with loss of vision and have generally resolved without corticosteroid treatment. The following adverse reactions have been reported since the drug was registered overseas: hypotension (mainly orthostatic hypotension), worsening of bronchial asthma, toxic epidermal necrolysis, and Stevens-Johnson syndrome.

Contraindications

It is contraindicated in patients who are hypersensitive to any component of this product.

Warning and Precautions

Historical data have shown that microfilaricidal drugs, such as diethylcarbamazine citrate (DEC-C), might cause cutaneous and/or systemic reactions of varying severity (the Mazzotti reaction) and ophthalmological reactions in patients with onchocerciasis. These reactions are probably due to allergic and inflammatory responses to the death of microfilariae. Patients treated with Ivermectin for onchocerciasis may experience these reactions in addition to clinical adverse reactions possibly, probably, or definitely related to the drug itself. The treatment of severe Mazzotti reactions has not been subjected to controlled clinical trials. Oral hydration, recumbency, intravenous normal saline, and/or parenteral corticosteroids have been used to treat postural hypotension. Antihistamines and/or aspirin have been used for most mild to moderate cases. After treatment with microfilaricidal drugs, patients with hyperreactive onchodermatitis (sowda) may be more likely than others to experience severe adverse reactions, especially edema and aggravation of onchodermatitis. Rarely, patients with onchocerciasis who are also heavily infected with Loa loa may develop a serious or even fatal encephalopathy either spontaneously or following treatment with an effective microfilaricide. In these patients, the following adverse experiences have also been reported: back pain, conjunctival hemorrhage, dyspnea, urinary and/or fecal incontinence, difficulty in standing/walking, mental status changes, confusion, lethargy, stupor, or coma.

Use in Special Populations

Pregnant Women: Pregnancy Category C. Ivermectin does not appear to be selectively fetotoxic to the developing fetus. There are, however, no adequate and well-controlled studies in pregnant women. Ivermectin should not be used during pregnancy since safety in pregnancy has not been established.

Nursing Mothers: Ivermectin is excreted in human milk in low concentrations. Treatment of mothers who intend to breast feed should only be undertaken when the risk of delayed treatment to the mother outweighs the possible risk to the newborn.

Pediatric Use: Safety and effectiveness in pediatric patients weighing less than 15 kg have not been established.

Geriatric Use: Clinical studies of Ivermectin did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Drug Interactions

No information provided.

Pharmaceutical Precautions

Store below 30°C in a dry place protected from light. Keep out of reach of Children.

Commercial Pack

Imec 6 tablet: Each box contains 1X10 tablets in Alu-PVC blister pack.

Manufactured by:

POPULAR

POPULAR PHARMACEUTICALS LTD
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