

**Consumer Update**

**Jan 2022**

## **Ivermectin 3 mg and 6 mg Scored tablets: Risk of Disturbance of consciousness**

EDA performs label update to include the following:

### **Side effects**

Disturbance of consciousness from serious (Incidence: unknown)

### **Post marketing adverse reactions**

Neurological toxicity including depressed level of consciousness and coma from post marketing

Experience

### **Overdose**

Cases of depressed level of consciousness and coma have been reported with overdosage of Ivermectin

### Background:

Ivermectin 3 mg and 6 mg is indicated for the treatment of the following:

o infections: Strongyloidiasis of the intestinal tract Ivermectin 3 mg and 6 mg 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 64-100% of infected patients were cured following a single 200-mcg/kg dose of ivermectin.

o Onchocerciasis. Ivermectin 3 mg and 6 mg is indicated for the treatment of onchocerciasis due to the nematode parasite *Onchocerca volvulus*. This indication is based on randomized,

double-blind, placebocontrolled and comparative studies conducted in 1427 patients in onchocerciasis-endemic areas of West Africa. The comparative studies used diethylcarbamazine citrate (DEC-C). Ivermectin has no activity against adult *Onchocerca*

*volvulus* parasites. The adult parasites reside in subcutaneous nodules which are infrequently

palpable. Surgical excision of these nodules (nodulectomy) may be considered in the management of patients with onchocerciasis, since this procedure will eliminate the microfilariae-producing adult parasites

**References:** *PMDA* ([Click here](#))