

TORHELMIN

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TORHELMIN (Ivermectin Dispersible Tablets
12mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Ivermectin is a member of the avermectin class. Avermectin has anti-inflammatory effects by inhibiting lipopolysaccharide-induced production of inflammatory cytokines. Ivermectin also causes death of parasites, primarily through binding selectively and with high affinity to glutamate-gated chloride channels.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Ivermectin Tablets are contraindicated in patients who are hypersensitive to any component of this product.

WARNINGS & PRECAUTIONS: **Warnings:** 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. **Precautions:** 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.

DRUG INTERACTION: Post-marketing reports of increased INR (International Normalized Ratio) have been rarely reported when ivermectin was coadministered with warfarin and Ivermectin was not genotoxic in vitro.

ADVERSE REACTIONS: asthenia/fatigue, abdominal pain **Gastrointestinal:** anorexia, constipation, diarrhea, nausea, vomiting **Nervous System/Psychiatric:** dizziness, somnolence, vertigo, tremor **Skin:** pruritus, rash, urticaria **Onchocerciasis:** arthralgia/synovitis, axillary lymph node enlargement and tenderness, cervical lymph node enlargement and tenderness, inguinal lymph node enlargement and tenderness, other lymph node enlargement and tenderness, pruritus, skin involvement including edema, papular and pustular or frank urticarial rash, fever, facial edema, peripheral edema, orthostatic hypotension, tachycardia.

Manufactured by:

Innova Captab Ltd.

1281/1, Hilltop Industrial Estate, Near EPIP Phase-I,

Jharmajri, Baddi, Distt. Solan [H.P.], India.

IN/ TORHELMIN 12 mg/MAY-21/01/ABPI

(Additional information is available on request)