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

TORHELMIN

1. Generic Name:

Ivermectin Dispersible Tablets 12mg

2. Qualitative and quantitative composition:

Each uncoated dispersible tablet contains:

Ivermectin I.P. ..……..12 mg

Excipients .....q.s.

Colour : Tartrazine

The excipients used are Microcrystalline Cellulose, Starch, Colour Tartrazine, Sodium Metabisulphite, Talcum, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Croscarmellose Sodium, Aspartame, Flavour Vanilla and Magnesium Stearate.

3. Dosage form and strength:

Dosage form: Uncoated dispersible tablet

Strength: 12 mg

4. Clinical particulars:

4.1 Therapeutic indication:

Ivermectin is indicated for the treatment of the following infections in adults:

- Strongyloidiasis of the intestinal tract
- Onchocerciasis

4.2 Posology and method of administration:

Posology

Ivermectin is prescribed as a single dose (12 mg) in adult patients with 'Strongyloidiasis of the intestinal tract' and 'Onchocerciasis'.

Method of administration

Oral

4.3 Contraindications:

Ivermectin tablets are contraindicated in patients who are hypersensitive to any component of this product.

4.4 Special warnings and precautions for use:

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. 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.

Precautions

General

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: pain (including neck and back pain), red eye, conjunctival hemorrhage, dyspnea, urinary and/or fecal incontinence, difficulty in standing/walking, mental status changes, confusion, lethargy, stupor, seizures, or coma. This syndrome has been seen very rarely following the use of ivermectin. In individuals who warrant treatment with ivermectin for any reason and have had significant exposure to Loa loa-endemic areas of West or Central Africa, pretreatment assessment for loiasis and careful posttreatment followup should be implemented.

Ivermectin Tablets should be taken on an empty stomach with water.

Strongyloidiasis

The patient should be reminded of the need for repeated stool examinations to document clearance of infection with Strongyloides stercoralis.

Onchocerciasis

The patient should be reminded that treatment with ivermectin does not kill the adult Onchocerca parasites, and therefore repeated follow-up and retreatment may be required.

4.5 Drug-Interaction:

Post-marketing reports of increased INR (International Normalized Ratio) have been rarely reported when ivermectin was co-administered with warfarin.

4.6 Use in special populations

Pregnancy

Teratogenic Effects

Pregnancy Category C: Ivermectin has been shown to be teratogenic in mice, rats, and rabbits when given in repeated doses of 0.2, 8.1, and 4.5 times the maximum recommended human dose, respectively (on a mg/m2/day basis). Teratogenicity was characterized in the three species tested by cleft palate; clubbed forepaws were additionally observed in rabbits. These developmental effects were found only at or near doses that were maternotoxic to the pregnant female. Therefore, 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 breastfeed 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 has not been established.

Geriatric Use: Reported clinical studies of ivermectin did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, treatment of an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Strongyloidiasis in Immunocompromised Hosts: In immunocompromised (including HIV-infected) patients being treated for intestinal strongyloidiasis, repeated courses of therapy may be required. Adequate and well-controlled clinical studies have not been conducted in such patients to determine the optimal dosing regimen. Several treatments, i.e., at 2 week intervals, may be required, and cure may not be achievable. Control of extra-intestinal strongyloidiasis in these patients is difficult, and suppressive therapy, i.e., once per month, may be helpful.

4.7 Effects on ability to drive and use machines:

Ivermectin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects:

Strongyloidiasis

In reported 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%).

In comparative trials, patients treated with ivermectin experienced more abdominal distention and chest discomfort than patients treated with albendazole. However, ivermectin was better tolerated than thiabendazole in comparative studies involving 37 patients treated with thiabendazole.

The Mazzotti-type and ophthalmologic reactions associated with the treatment of onchocerciasis or the disease itself would not be expected to occur in strongyloidiasis patients treated with ivermectin.

Laboratory Test Findings

In clinical trials involving 109 patients given either one or two doses of 170 to 200 mcg/kg ivermectin, the following laboratory abnormalities were seen regardless of drug relationship:

elevation in ALT and/or AST (2%), decrease in leukocyte count (3%). Leukopenia and anemia were seen in one patient.

Onchocerciasis

In reported clinical trials, involving 963 adult patients treated with 100 to 200 mcg/kg ivermectin, worsening of the following Mazzotti reactions during the first 4 days post-treatment were reported:

Arthralgia/synovitis (9.3%), 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%).

In reported clinical trials, ophthalmological conditions were examined in 963 adult patients before treatment, at day 3, and months 3 and 6 after treatment with 100 to 200 mcg/kg ivermectin. Changes observed were primarily deterioration from baseline 3 days post-treatment. Most changes either returned to baseline condition or improved over baseline severity at the month 3 and 6 visits. The percentages of patients with worsening of the following conditions at day 3, month 3 and 6, respectively, were: limbitis: 5.5%, 4.8%, and 3.5% and punctate opacity: 1.8%, 1.8%, and 1.4%. The corresponding percentages for patients treated with placebo were: limbitis: 6.2%, 9.9%, and 9.4% and punctate opacity: 2.0%, 6.4%, and 7.2%.

In reported clinical trials involving 963 adult patients who received 100 to 200 mcg/kg ivermectin, the following clinical adverse reactions were reported as possibly, probably, or definitely related to the drug in ≥1% of the patients: facial edema (1.2%), peripheral edema (3.2%), orthostatic hypotension (1.1%), and tachycardia (3.5%). Drug-related headache and myalgia occurred in <1% of patients (0.2% and 0.4%, respectively). However, these were the most common adverse experiences reported overall during these trials regardless of causality (22.3% and 19.7%, respectively).

A similar safety profile was observed in an open reported study in pediatric patients ages 6 to 13.

The following ophthalmological side effects do occur due to the disease itself but have also been reported after treatment with ivermectin: 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.

Laboratory Test Findings

In reported controlled clinical trials, the following laboratory adverse experiences were reported as possibly, probably, or definitely related to the drug in ≥1% of the patients: eosinophilia (3%) and hemoglobin increase (1%).

Post-Marketing Experience

The following adverse reactions have been reported since the drug was registered overseas:

- Onchocerciasis
- Conjunctival hemorrhage

All Indications

• Hypotension (mainly orthostatic hypotension), worsening of bronchial asthma, toxic epidermal necrolysis, Stevens-Johnson syndrome, seizures, hepatitis, elevation of liver enzymes, and elevation of bilirubin.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

4.9 Overdose:

Significant lethality was observed in mice and rats after single oral doses of 25 to 50 mg/kg and 40 to 50 mg/kg, respectively. No significant lethality was observed in dogs after single oral doses of up to 10 mg/kg. At these doses, the treatment-related signs that were observed in these animals include ataxia, bradypnea, tremors, ptosis, decreased activity, emesis, and mydriasis.

In accidental intoxication with, or significant exposure to, unknown quantities of veterinary formulations of ivermectin in humans, either by ingestion, inhalation, injection, or exposure to body surfaces, the following adverse effects have been reported most frequently: rash, edema, headache, dizziness, asthenia, nausea, vomiting, and diarrhea. Other adverse effects that have been reported include: seizure, ataxia, dyspnea, abdominal pain, paresthesia, urticaria, and contact dermatitis.

In case of accidental poisoning, supportive therapy, if indicated, should include parenteral fluids and electrolytes, respiratory support (oxygen and mechanical ventilation if necessary) and pressor agents if clinically significant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

5. Pharmacological properties:

5.1 Mechanism of Action:

Ivermectin is a member of the avermectin class. Avermectin has anti-inflammatory effects by inhibiting lipopolysaccharide-induced production of inflammatory cytokines. Anti-inflammatory properties of cutaneous ivermectin have been observed in animal models of skin inflammation. Ivermectin also causes death of parasites, primarily through binding selectively and with high affinity to glutamate-gated chloride channels, which occur in invertebrate nerve and muscle cells. The mechanism of action of Ivermectin in treating the inflammatory lesions of ivermectin is not known but may be linked to anti-inflammatory effects of ivermectin as well as causing the death of Demodex mites that have been reported to be a factor in inflammation of the skin.

5.2 Pharmacodynamic properties:

Absorption and Distribution:

Ivermectin is well absorbed orally, widely distributed in the body, but does not enter CNS, sequestrated in liver and fat, and has a long terminal t½ of 48–60 hours.

Metabolism and Excretion:

It is metabolized by CYP3A4 in liver, and is excreted almost exclusively in the feces over an estimated 12 days, with less than 1% of the administered dose excreted in the urine.

5.3 Pharmacokinetic properties:

Following oral administration of ivermectin, plasma concentrations are approximately proportional to the dose. In two studies, after single 12-mg doses of ivermectin in fasting healthy volunteers (representing a mean dose of 165 mcg/kg), the mean peak plasma concentrations of the major component (H2B1a) were 46.6 (±21.9) (range: 16.4 to 101.1) and 30.6 (±15.6) (range: 13.9 to 68.4) ng/mL, respectively, at approximately 4 hours after dosing. Ivermectin is metabolized in the liver, and ivermectin and/or its metabolites are excreted almost exclusively in the feces over an estimated 12 days, with less than 1% of the administered dose excreted in the urine. The plasma half-life of ivermectin in man is approximately 18 hours following oral administration.

The safety and pharmacokinetic properties of ivermectin were further assessed in a reported multiple-dose clinical pharmacokinetic study involving healthy volunteers. Subjects received oral doses of 30 to 120 mg (333 to 2000 mcg/kg) ivermectin in a fasted state or 30 mg (333 to 600 mcg/kg) ivermectin following a standard high-fat (48.6 g of fat) meal. Administration of 30 mg ivermectin following a highfat meal resulted in an approximate 2.5-fold increase in bioavailability relative to administration of 30 mg ivermectin in the fasted state.

In vitro studies using human liver microsomes and recombinant CYP450 enzymes have shown that ivermectin is primarily metabolized by CYP3A4. Depending on the in vitro method used, CYP2D6 and CYP2E1 were also shown to be involved in the metabolism of ivermectin but to a significantly lower extent compared to CYP3A4. The findings of in vitro studies using human liver microsomes suggest that clinically relevant concentrations of ivermectin do not significantly inhibit the metabolizing activities of CYP3A4, CYP2D6, CYP2C9, CYP1A2, and CYP2E1.

Microbiology

Ivermectin is a member of the avermectin class of broad-spectrum antiparasitic agents which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamategated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gammaaminobutyric acid (GABA).

The selective activity of compounds of this class is attributable to the facts that some mammals do not have glutamate-gated chloride channels and that the avermectins have a low affinity for mammalian ligand-gated chloride channels. In addition, ivermectin does not readily cross the blood-brain barrier in humans.

Ivermectin is active against various life-cycle stages of many but not all nematodes. It is active against the tissue microfilariae of Onchocerca volvulus but not against the adult form. Its activity against Strongyloides stercoralis is limited to the intestinal stages.

Clinical Studies

Stongyloidiasis: Two reported controlled clinical studies using albendazole as the comparative agent were carried out in international sites where albendazole is approved for the treatment of

strongyloidiasis of the gastrointestinal tract, and three controlled studies were carried out in the U.S. and internationally using thiabendazole as the comparative agent. Efficacy, as measured by cure rate, was defined as the absence of larvae in at least two follow-up stool examinations 3 to 4 weeks post-therapy. Based on this criterion, efficacy was significantly greater for ivermectin (a single dose of 170 to 200 mcg/kg) than for albendazole (200 mg b.i.d. for 3 days). Ivermectin administered as a single dose of 200 mcg/kg for 1 day was as efficacious as thiabendazole administered at 25 mg/kg b.i.d. for 3 days.

In reported study conducted in France, a non-endemic area where there was no possibility of reinfection, several patients were observed to have recrudescence of Strongyloides larvae in their stool as long as 106 days following ivermectin therapy. Therefore, at least three stool examinations should be conducted over the three months following treatment to ensure eradication. If recrudescence of larvae is observed, retreatment with ivermectin is indicated. Concentration techniques (such as using a Baermann apparatus) should be employed when performing these stool examinations, as the number of Strongyloides larvae per gram of feces may be very low.

Onchocerciasis: The evaluation of ivermectin in the treatment of onchocerciasis is based on the results of clinical studies involving 1278 patients. In a reported double-blind, placebo-controlled study involving adult patients with moderate to severe onchocercal infection, patients who received a single dose of 150 mcg/kg ivermectin experienced an 83.2% and 99.5% decrease in skin microfilariae count (geometric mean) 3 days and 3 months after the dose, respectively. A marked reduction of >90% was maintained for up to 12 months after the single dose. As with other microfilaricidal drugs, there was an increase in the microfilariae count in the anterior chamber of the eye at day 3 after treatment in some patients. However, at 3 and 6 months after the dose, a significantly greater percentage of patients treated with ivermectin had decreases in microfilariae count in the anterior chamber than patients treated with placebo.

In a separate reported open study involving pediatric patients ages 6 to 13 (n=103; weight range: 17 to 41 kg), similar decreases in skin microfilariae counts were observed for up to 12 months after dosing.

6. Nonclinical properties:

Carcinogenesis, Mutagenesis, Impairment of Fertility

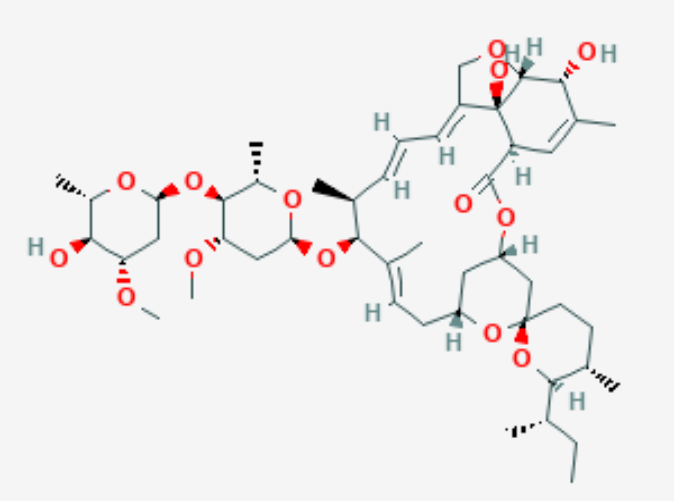
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ivermectin.

Ivermectin was not genotoxic in vitro in the Ames microbial mutagenicity assay of Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100 with and without rat liver enzyme activation, the Mouse Lymphoma Cell Line L5178Y (cytotoxicity and mutagenicity) assays, or the unscheduled DNA synthesis assay in human fibroblasts.

Ivermectin had no adverse effects on the fertility in rats in studies at repeated doses of up to 3 times the maximum recommended human dose of 200 mcg/kg (on a mg/m^2/day basis).

7. Description:

Ivermectin is (1R,4S,5'S,6R,6'R,8R,10E,12S,13S,14E,16E,20R,21R,24S)-6'-[(2S)-butan-2-yl]-21,24-dihydroxy-12-[(2R,4S,5S,6S)-5-[(2S,4S,5S,6S)-5-hydroxy-4-methoxy-6-methyloxan-2-yl]oxy-4-methoxy-6-methyloxan-2-yl]oxy-5',11,13,22-tetramethylspiro[3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene-6,2'-oxane]-2-one. The empirical formula is $C_{48}H_{74}O_{14}$ and its molecular weight is 875.1 g/mol. The chemical structure is:



Ivermectin Dispersible Tablets 12mg are light yellow coloured, round shaped, biconvex, uncoated dispersible tablet, plain on both sides. The excipients u.sed are Microcrystalline Cellulose, Starch, Colour Tartrazine, Sodium Metabisulphite, Talcum, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Croscarmellose Sodium, Aspartame, Flavour Vanilla and Magnesium Stearate.

8. Pharmaceutical particulars:

8.1 Incompatibilities:

Not applicable.

8.2 Shelf-life:

Do not use later than the date of expiry.

8.3 Packaging information:

TORHELMIN is available in Blister pack of 10 tablets

8.4 Storage and handing instructions:

Store at a temperature not exceeding 30°C, Protect from light and moisture.

Keep out of reach of children.

9. Patient Counselling Information

Package leaflet: Information for the user

TORHELMIN

Ivermectin Dispersible Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

9.1. What TORHELMIN is and what it is used for

TORHELMIN contains the active substance ivermectin that belongs to a group of medicines called avermectins. The drug is used in Strongyloidiasis of the intestinal tract and Onchocerciasis.

9.2. What you need to know before you take TORHELMIN

Do not use TORHELMIN

- If you are allergic to ivermectin or any of the other ingredients of this medicine.

If this applies to you, do not take TORHELMIN and tell your doctor immediately.

Warnings and precautions

- Talk to your doctor or pharmacist before using TORHELMIN. At the start of treatment, some patients may experience worsening of the symptoms of ivermectin, however this is uncommon and usually resolves within 1 week of the treatment. Talk to your doctor if this happens.

If any of these apply to you, talk to your doctor before taking TORHELMIN.

Other medicines and TORHELMIN

Other medicines may have an effect on TORHELMIN, you should therefore tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

- TORHELMIN is not recommended during pregnancy. If you are breast-feeding, you should not use this medicine, alternatively, you should stop breast-feeding before starting treatment with TORHELMIN.
- You should consult your doctor to help you decide between using TORHELMIN and breast-feeding, taking into account the benefit of the treatment and the benefit of breast-feeding.

Driving and using machines

TORHELMIN has no or negligible influence on the ability to drive and use machines.

TORHELMIN contains:

- The active substance is ivermectin. One gram of drug contains 12 mg of ivermectin.
- The other ingredients are Microcrystalline Cellulose, Starch, Colour Tartrazine, Sodium Metabisulphite, Talcum, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Croscarmellose Sodium, Aspartame, Flavour Vanilla and Magnesium Stearate.

9.3. How to take TORHELMIN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should use TORHELMIN daily over the treatment course and the treatment course may be repeated. Your doctor will tell you how long you will need to use TORHELMIN. The duration of treatment can vary from person to person and depends on the severity of the disorder. You may notice an improvement after 4 weeks of treatment. In case of no improvement after 3 months, you should discontinue TORHELMIN and consult your doctor.

The recommended dose for Ivermectin is as a single dose (12 mg) in adult patients with 'Strongyloidiasis of the intestinal tract' and 'Onchocerciasis'. Treatment should continue for as long as your doctor tells you.

Method of administration: Oral

Hepatic impairment

If you have liver problems, please consult your doctor before using TORHELMIN.

Use in children and adolescents

TORHELMIN should not be used by children and adolescents.

If you use more TORHELMIN than you should

If you use more than the daily recommended dose, please contact your doctor, who will advise you on what action to take.

If you forget to use TORHELMIN

Do not use a double dose to make up for a forgotten dose.

If you stop using TORHELMIN

The effect will be observe only after several doses of this medicine. It is important that you continue using TORHELMIN as long as prescribed by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4.Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

TORHELMIN may cause the following 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%), diarrhoea (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 (9.3%), 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%), facial edema (1.2%), peripheral edema (3.2%), orthostatic hypotension (1.1%), tachycardia (3.5%).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

9.5. How to store TORHELMIN

Store at a temperature not exceeding 30°C, Protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and on each blister or bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

9.6. Contents of the pack and other information

What TORHELMIN contains

The active substance is *ivermectin.* Each uncoated dispersible tablet contains 12 mg of ivermectin.

The other ingredients are

Microcrystalline Cellulose, Starch, Colour Tartrazine, Sodium Metabisulphite, Talcum, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Croscarmellose Sodium, Aspartame, Flavour Vanilla and Magnesium Stearate.

Colours: Tartrazine

TORHELMIN is available in Blister pack of 10 tablets.

10. Details of manufacturer

Manufactured by:

Innova Captab Ltd

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

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

11. Details of permission or licence number with date

Mfg Lic No. MNB/16/970 issued on 25.08.2020

12. Date of revision

Not applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

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