Brosur IVERMECTIN 12

IVERMAX 12
IVERMECTIN
Caplet 12 mg

COMPOSITION:
Each caplet contains :
Ivermectin ..... 12 mg

PHARMACEUTICAL FORM
Caplet.

CLINICAL PHARMACOLOGY
Pharmacokinetics
Following oral administration of Ivermax, plasma concentrations are approximately proportional to the dose. Ivermax is metabolized in the liver, and Ivermax 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 Ivermax in man is approximately 18 hours following oral administration.

Ivermax is primarily metabolized by CYP3A4. CYP2D6 and CYP2E1 were also shown to be involved in the metabolism of Ivermax but to a significantly lower extent compared to CYP3A4. Concentrations of Ivermax do not significantly inhibit the metabolizing activities of CYP3A4, CYP2D6, CYP2C9, CYP1A2, and CYP2E1.

Microbiology
Ivermax 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 glutamate-gated 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 gamma-aminobutyric 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, Ivermax does not readily cross the blood-brain barrier in humans.

INDICATIONS AND USAGE
IVERMAX is indicated for the treatment of the following infections:

Strongyloidiasis of the intestinal tract. IVERMAX is indicated for the treatment of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode *parasite Strongyloides stercoralis*.

Onchocerciasis. IVERMAX is indicated for the treatment of onchocerciasis due to the nematode *parasite Onchocerca volvulus*.

NOTE: IVERMAX 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*.

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

WARNINGS
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 IVERMAX for onchocerciasis may experience these reactions in addition to clinical adverse reactions possibly, probably, or definitely related to the drug itself. (See ADVERSE REACTIONS, Onchocerciasis.)

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 Ivermax.

Information for Patients
IVERMAX should be taken on an empty stomach with water. (See CLINICAL PHARMACOLOGY, Pharmacokinetics)

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 IVERMAX does not kill the adult *Onchocerca parasites*, and therefore repeated follow-up and retreatment is usually required.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Ivermax.

Ivermax 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.

Ivermax 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).

Pregnancy, Teratogenic Effects
Pregnancy Category C
Ivermax 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/m^2/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, Ivermax does not appear to be selectively fetotoxic to the developing fetus. There are, however, no adequate and well-controlled studies in pregnant women. Ivermax should not be used during pregnancy since safety in pregnancy has not been established.

Nursing Mothers
IVERMAX 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 weighing less than 15 kg have not been established.

Geriatric Use
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.

ADVERSE REACTIONS
Strongyloidiasis
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%).

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 IVERMAX. (See ADVERSE REACTIONS, Onchocerciasis.)

Onchocerciasis
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%). (See WARNINGS.)

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

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.

DOSAGE AND ADMINISTRATION
Strongyloidiasis
The recommended dosage of IVERMAX 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 caplets on an empty stomach with water. (See Pharmacokinetics.) In general, additional doses are not necessary. However, follow-up stool examinations should be performed to verify eradication of infection.

Onchocerciasis
The recommended dosage of IVERMAX 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 caplets on an empty stomach with water. (See CLINICAL PHARMACOLOGY, Pharmacokinetics.) 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.

Storage
Store at temperatures below 30°C
Protect from direct sunlight, heat and humidity

Packaging
Box, 1 Strip @ 10 caplet
Box, 2 Strip @ 20 caplet
Box, 10 Strip @ 10 caplet
Bottle @ 20 caplet

Reg. no.: DKL2107926604A1

On Medical prescription Only

Manufactured by :
PT HARSEN LABORATORIES
JAKARTA - INDONESIA

260.00 mm

90.00 mm

DISETUJUI OLEH BPOM : 20/09/2021

ID : EREG100289VR12100102

Brosur Informasi IVERMECTIN 12

IVERMAX 12
IVERMECTIN
Informasi Produk untuk pasien

Apa isi Leaflet ini
Leaflet ini menjawab beberapa pertanyaan umum tentang IVERMAX 12.
Leaflet ini tidak mengandung semua informasi yang tersedia dan bukan sebagai pengganti konsultasi dengan dokter atau apoteker anda.

Semua obat memiliki resiko dan manfaat. Dokter Anda telah mempertimbangkan risiko Anda menggunakan IVERMAX 12 dengan manfaat yang mereka harapkan untuk Anda.

Jika Anda memiliki kekhawatiran dalam penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

Simpan Leaflet ini dengan obatnya.
Anda mungkin perlu membacanya lagi.

IVERMAX 12 digunakan untuk pengobatan infeksi berikut:

Strongyloidiasis pada saluran usus. IVERMAX digunakan untuk pengobatan strongyloidiasis usus karena parasit nematoda *Strongyloides stercoralis*.

Onchocerciasis. IVERMAX digunakan untuk pengobatan onchocerciasis akibat nematoda parasit *Onchocerca volvulus*.

Sebelum Anda meminum IVERMAX 12
Anda tidak boleh meminum ini ketika

- Anda memiliki alergi terhadap IVERMAX 12 atau salah satu bahan yang tercantum di akhir brosur ini
- Anda sedang hamil, atau berniat untuk hamil
- Telah melewati tanggal kedaluwarsa (EXP) yang dicetak pada kemasan.
  Jika Anda minum obat ini setelah melewati tanggal kedaluwarsa, pengobatan mungkin tidak akan bekerja.

Jika Anda tidak yakin apakah Anda harus meminum IVERMAX 12, konsultasikan dengan dokter Anda.

Penggunaan pada anak
Efektivitas dan keamanan pada pasien anak dengan berat badan kurang dari 15 kg belum ditetapkan.

Penggunaan pada usia lanjut
Secara umum, pengobatan pada pasien usia lanjut harus hati-hati.

Sebelum Anda mulai meminumnya
Beritahu dokter Anda jika :

1. **jika Anda sedang menyusui atau berencana untuk menyusui.**
   Dokter Anda akan mendiskusikan kemungkinan risiko pada bayi Anda jika Anda menggunakan IVERMAX 12 saat Anda menyusui.
2. **Anda pernah atau sedang mengalami kondisi medis apapun, terutama:**
   penyakit hati
3. **Anda pernah dirawat karena *Onchocerciasis* sebelumnya.**
   Anda lebih mungkin mengalami efek samping yang serius dibandingkan dengan orang lain.
4. **jika Anda memiliki alergi terhadap obat lain atau zat lain, seperti makanan, pengawet, atau pewarna.**

Jika Anda belum memberi tahu dokter Anda tentang semua hal di atas, beri tahu mereka sebelum Anda meminum IVERMAX 12.

Minum obat lain
Beritahu dokter Anda jika Anda sedang mengonsumsi obat lain, termasuk yang Anda beli tanpa resep dari dokter, supermarket atau toko obat.

Beberapa obat dan IVERMAX 12 dapat saling mengganggu. Ini termasuk warfarin, yang digunakan untuk mencegah penggumpalan darah.

Dokter atau apoteker Anda memiliki lebih banyak informasi tentang obat-obatan yang harus diperhatikan atau dihindari saat mengonsumsi IVERMAX 12.

Cara meminum IVERMAX 12
Berapa banyak yang harus diminum
Dokter Anda akan memberi tahu Anda berapa banyak kaplet yang perlu Anda minum.
Dosisnya tergantung pada infeksi Anda dan berat badan Anda. Dosis untuk pengobatan Strongyloidiasis adalah dosis oral tunggal sekitar 200 mcg ivermectin per kg berat badan.

Dosis untuk pengobatan Onchocerciasis adalah dosis oral tunggal sekitar 150 mcg Ivermectin per kg berat badan. Interval dosis yang paling umum digunakan adalah 12 bulan. Untuk pengobatan individual pasien, pengobatan ulang dapat dipertimbangkan dengan interval singkat 3 bulan.

Bagaimana cara meminumnya

Ambil IVERMAX 12 sebagai dosis tunggal dengan segelas air saat perut kosong.

Jika Anda meminum terlalu banyak (overdosis)
Segera hubungi dokter Anda atau fasilitas kesehatan jika Anda mengira Anda pernah atau orang lain mungkin telah meminum terlalu banyak IVERMAX 12. Lakukan ini bahkan jika tidak ada tanda-tanda ketidaknyamanan atau keracunan. Anda mungkin membutuhkan tindakan medis secepatnya.

Jika Anda mengonsumsi terlalu banyak kaplet, Anda mungkin mengalami beberapa hal berikut:

- ruam kulit, gatal-gatal;
- pembengkakan pada tungkai, pergelangan kaki atau kaki;
- sakit kepala, pusing, merasa mengantuk
- mual, muntah, diare; sakit perut
- pupil mata Anda membesar
- sesak napas;
- berjalan limbung; aktivitas menurun; gemetar (atau tremor); kelemahan yang tidak biasa; kesemutan atau mati rasa pada tangan atau kaki; kejang.

Saat Anda menggunakan IVERMAX 12
Hal yang harus Anda lakukan

Kunjungi dokter Anda jika dijadwalkan, untuk memeriksa perkembangan infeksi Anda.
Ini untuk membantu memastikan bahwa infeksi telah sembuh sepenuhnya.

Hal-hal yang tidak boleh Anda lakukan
Jangan berikan IVERMAX 12 kepada orang lain, meskipun mereka memiliki kondisi yang sama dengan Anda.

Hal-hal yang harus diperhatikan
Berhati-hatilah saat mengemudi atau mengoperasikan mesin sampai Anda tahu bagaimana IVERMAX 12 memengaruhi Anda.

IVERMAX 12 dapat menyebabkan pusing, sakit kepala ringan, sensasi berputar (vertigo), tremor, kelelahan atau mengantuk pada beberapa orang. Pastikan Anda tahu bagaimana Anda bereaksi terhadap IVERMAX 12 sebelum Anda mengemudikan mobil, mengoperasikan mesin atau melakukan tugas lain yang mengharuskan Anda waspada.

Efek samping
Beri tahu dokter atau apoteker Anda sesegera mungkin jika Anda merasa tidak enak badan saat menggunakan IVERMAX 12.

Seperti pada obat-obatan lainnya, IVERMAX 12 mungkin memiliki efek samping meskipun tidak setiap orang mengalaminya.
Terkadang efeknya serius, seringkali tidak. Anda mungkin memerlukan perawatan medis jika mengalami beberapa efek samping.

Tanyakan pada dokter atau apoteker Anda jika Anda memiliki pertanyaan lebih lanjut.

Untuk *Onchocerciasis*:
Beritahu dokter Anda jika Anda mengalami efek samping berikut:

- nyeri otot atau sendi
- pembesaran kelenjar getah bening
- ruam kulit, gatal atau bengkak
- demam
- pusing, terutama saat beranjak dari duduk atau berbaring
- memburuknya asma
- sakit kepala
- stevens-Johnson syndrome
- kejang
- hepatitis
- peningkatan enzim di hati
- peningkatan bilirubin
- pembengkakan kelopak mata, konjungtivitis, mata berpasir atau nyeri, mata kemerahan, gangguan penglihatan

Untuk Strongyloidiasis :
Beritahu dokter Anda jika Anda mengalami efek samping berikut:

- kelelahan yang tidak biasa
- Ketidaknyamanan perut
- Gangguan pencernaan: kehilangan nafsu makan, sembelit, diare, mual, muntah
- Gangguan system saraf/psikiatrik: pusing, mudah mengantuk, sensasi berputar, gemetar atau tremor
- Kulit: ruam kulit dan gatal-gatal
- Pusing, terutama saat beranjak dari duduk atau berbaring
- Memburuknya asma
- Sakit kepala
- Stevens-Johnson syndrome
- Kejang
- Hepatitis
- Peningkatan enzim di hati
- Peningkatan bilirubin

Setelah menggunakan IVERMAX 12

Penyimpanan
Simpan kaplet Anda dalam kemasan sampai tiba waktunya untuk diminum.

Jika Anda mengeluarkan kaplet dari kotak atau kemasan, kaplet mungkin tidak dapat disimpan dengan baik.

Simpan di bawah 30°C. Lindungi dari sinar matahari langsung. Panas dan lembab.

Jangan simpan dengan obat lain di kamar mandi atau dekat wastafel.

Jangan tinggalkan di dalam mobil atau di kusen jendela.

Panas dan kelembaban dapat merusak beberapa obat-obatan.

Simpan dimana anak anak tidak dapat meraihnya.

Lemari yang terkunci setidaknya satu setengah meter di atas tanah adalah tempat yang baik untuk menyimpan obat-obatan.

Pembuangan

Jika kaplet telah melewati tanggal kadaluwarsa tanyakan apoteker Anda apa yang harus dilakukan dengan yang tersisa.

Deskripsi Produk
Seperti apa bentuknya
IVERMAX 12 adalah kaplet dengan permukaan cembung, berwarna putih, satu sisi tulisan HARSEN dengan breaking line dan sisi lain breaking line.

Bahan
Bahan aktif :
IVERMAX 12 mengandung ivermectin.
12 mg per kaplet.

Bahan tambahan :

- Microcrystalline cellulose
- BHA
- Pregelatinized Starch
- Povidone K-30
- asam sitrat anhidrat
- Polysorbate 80
- Alkohol
- Magnesium stearate
- Croscarmellose sodium
- Colloidal silicon dioxide
- Purified Water

Kemasan

Dus, 1 Strip @ 10 kaplet	No. Reg.: DKL2107926604A1
Dus, 2 Strip @ 10 kaplet	No. Reg.:
Dus, 10 Strip @ 10 kaplet	No. Reg.:
Botol @ 20 kaplet	No. Reg.:

Harus dengan resep dokter

Diproduksi oleh :
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