

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ILADEK 3 (tablets)

Each tablet contains ivermectin

Read all of this leaflet carefully before you start taking ILADEK 3

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ILADEK 3** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **ILADEK 3** is and what it is used for
2. What you need to know before you take **ILADEK 3**
3. How to take **ILADEK 3**
4. Possible side effects
5. How to store **ILADEK 3**
6. Contents of the pack and other information

1. What **ILADEK 3** is and what it is used for

ILADEK 3 tablet contains ivermectin. This is a type of medicine which is used for infections caused by some parasites.

It is used to treat:

- an infestation of the intestine called intestinal strongyloidosis (anguillulose). It is caused by a type of roundworm called *Strongyloides stercoralis*;
- an infestation of blood called microfilaraemia due to lymphatic filariasis. It is caused by an immature worm called *Wuchereria bancrofti*;
- onchocerciasis, a disease caused by infestation with a parasite: the *Onchocerca volvulus* filariae;
- skin mites (scabies). This is when tiny mites burrow under your skin. This can cause you severe itching.
- the safety and effectiveness of ivermectin for the treatment of COVID-19 has not been established.

2. What you need to know before you take ILADEK 3

Do not take:

- If you are hypersensitive (allergic) to ivermectin or any of the other ingredients of **ILADEK 3** (listed in section 6). Symptoms of an allergic reaction to a medicine may include skin rash, difficulty breathing or fever.

Warnings and precautions

Tell your doctor or health care provider before taking **ILADEK 3**.

Take special care with ILADEK 3

- If you have a deficient immune system,
- If you live or have lived in parts of Africa where there are cases of human parasitic infestation with the *Loa loa* filarial worm also called eye-worm,
- If you currently live or have lived in parts of Africa. The use of diethylcarbamazine citrate (DEC) to treat *Onchocerca volvulus* infestation may increase the risk of adverse effects that can sometimes be serious.

Children

The safety of using ivermectin in children weighing less than 15 kg has not been evaluated.

Other medicines and ILADEK 3

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- If you are pregnant, do not take **ILADEK 3** tablet. The decision will be made in agreement with your doctor.
- If you are breastfeeding or intend to breastfeed, as **ILADEK 3** passes into breast milk. Your doctor may decide to start your treatment one week after the birth of your child.

Driving and using machines

You may feel side effects such as dizziness, drowsiness, or feeling shaky or like you are spinning after taking **ILADEK 3**. If you experience such symptoms, avoid driving vehicles or operating machinery.

3. How to take ILADEK 3

Do not share medicines prescribed for you with any other person.

Always take **ILADEK 3** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take **ILADEK 3** orally
- In children less than 6 years, tablets should be crushed before swallowing.
- Take the number of tablets prescribed by your doctor at one time, with water and on an empty stomach. No food should be taken 2 hours before or after administration because the influence of diet on the absorption of the medicine by your body is not known.

The treatment consists of a single dose.

- The dose depends on your illness as well as your weight or height.
- Your doctor will tell you how many tablets to take.

Treatment of intestinal strongyloidiasis (*anguillulosis*)

The usual dose is:

BODY WEIGHT (kg)	DOSE (number of 3 mg tablets)
15 to 24	one
25 to 35	two
36 to 50	three
51 to 65	four
66 to 79	five
≥ 80	six

Treatment of microfilaraemia caused by *Wuchereria bancrofti*

The usual dose is:

BODY WEIGHT (kg)	DOSE when given once every 6 months (number of 3 mg tablets)	DOSE when given once every 12 months (number of 3 mg tablets)
15 to 25	one	two
26 to 44	two	four
45 to 64	three	six
65 to 84	four	eight

The dose will be repeated every 6 months or every 12 months. Alternatively, and in the absence of a set of weighing scales, the ivermectin dosage for administration in mass treatment campaigns can be determined by the patient's height, as follows:

HEIGHT (cm)	DOSE when given once every 6 months (number of 3 mg tablets)	DOSE when given once every 12 months (number of 3 mg tablets)
90 to 119	one	two
120 to 140	two	four
141 to 158	three	six
> 158	four	eight

Treatment of human scabies:

Ivermectin should only be taken when your doctor is certain or thinks you have scabies.

Take a dose of 200 micrograms of ivermectin per kilogram of body weight.

You will not know, for 4 weeks, if the treatment was totally effective. Your doctor may prescribe a second single dose within 8 to 15 days.

Treatment of *Onchocerciasis*

The recommended dosage for the treatment of onchocerciasis is 150 µg / kg in a single oral dose.

In individual treatment, a renewal of the cure can be considered after a time interval of 3 months.

In onchocerciasis mass treatment campaigns, the time interval between each distribution is usually 12 months. However, in some areas it may be better to repeat every 6 months depending on the importance of the parasite infestation.

As an indication, the dose based on weight is:

BODY WEIGHT (kg)	DOSE (number of 3 mg tablets)
15 to 25	one
26 to 44	two
45 to 64	three
65 to 84	four
≥ 85	150 mcg/kg

Ivermectin will not prevent you from having one of these infestations. It is not effective on adult worms. **ILADEK 3** tablet should only be taken with the advice of your doctor when the parasite infestation is certain or is strongly suspected.

Your doctor will tell you how long your treatment with **ILADEK 3** will last. Do not stop treatment early. If you have the impression that the effect of **ILADEK 3** is too strong or too weak, tell your doctor or pharmacist.

If you take more ILADEK 3 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ILADEK 3

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ILADEK 3 can have side effects.

Not all side effects reported for **ILADEK 3** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ILADEK 3**, please consult your health care provider for advice.

Side effects are usually not serious and do not last long. They may be more likely to happen in people infected with several parasites.

This is particularly true if they have the worm *Loa loa*.

If any of the following happens, stop taking **ILADEK 3** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden fever
- Sudden skin reactions (such as skin rash or itching) or other serious skin reactions
- Difficulty breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to **ILADEK 3**. You may need urgent medical attention or hospitalisation.

Other side effects

- liver disease (acute hepatitis),
- modification of some laboratory tests (increase of liver enzymes,
- increase of bilirubin on blood, increase of eosinophil levels),
- presence of blood in urine.

These are all serious side effects. You may need urgent medical attention.

The side effects listed below depend on what you are taking **ILADEK 3** for. They also depend on the presence or absence of other infections:

People with intestinal strongyloidiasis (*anguillulosis*) may have the following side effects:

- feeling unusually weak,
- loss of appetite, stomach pain, constipation, or diarrhoea,
- nausea or vomiting,
- feeling sleepy or dizzy,
- shaking or tremors.

In case of intestinal strongyloidiasis (*anguillulosis*), adult roundworms can also be found in your stool.

People with microfilaraemia caused by *Wuchereria bancrofti* may have the following side effects:

- sweats or fever,
- headache,
- feeling unusually weak,
- muscle, joint and whole-body pain,
- loss of appetite, nausea,
- stomach pain (abdominal and epigastric pain),
- painful cough or throat,
- difficulty breathing,
- low blood pressure when standing up - you may feel dizzy or light-headed,
- chills,
- dizziness,
- pain or discomfort in the testicles.

People with scabies may have the following side effects:

- itching (pruritus) may get worse at the start of treatment. This does not usually last long.

Highly infested individuals with *Loa loa* worm may have the following side effects:

- disorders of the brain function,
- neck pain or back pain,
- bleeding in the white of the eye (also called red eye),
- shortness of breath,
- loss of control of the bladder or intestines,
- difficulty standing or walking,
- disorders of the mental state,
- feeling drowsy or confused,
- unable to respond to other people or coma.

Infected individuals with the worm (*Onchocerca volvulus*) responsible for river blindness may have the following side effects:

- itching or rash,
- joint or muscle pain,
- fever,
- nausea or vomiting,
- swelling of the lymph nodes,
- swelling, especially in the hands, ankles or feet,
- diarrhoea,
- dizziness,
- low blood pressure (hypotension). You may feel dizzy or lightheaded when

standing up,

- fast heart rate,
- headache or feeling tired,
- vision problems and other eye problems such as infection, redness or unusual sensations,
- bleeding in the white of the eye or swelling of the eyelids,
- worsening of asthma.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **ILADEK 3**.

5. How to store ILADEK 3

Store all medicines out of reach of children.

Store at or below 25 °C

Do not use after the expiry date stated on the blister and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ILADEK 3 contains

- The active substance is ivermectin.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, butylhydroxyanisole and magnesium stearate.

What ILADEK 3 looks like and contents of the pack

The tablets are round, white or almost white, flat chamfered and 5,5 mm in diameter.

The tablets are packed in Polyamide/Aluminium/PVC – Aluminium blister.

The blister strips will be packed in cartons with 1, 4, 10 or 20 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd

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This leaflet was last revised in

Registration/Application number

Access to the corresponding Professional Information