

Package leaflet: Information for the user
Molevac Suspension
50 mg/5 ml oral suspension
Active substance: Pyrvinium

Read the entire package leaflet carefully before you start taking this medicine, because it contains important information.

Always take this medicine exactly as described in this package leaflet or as your doctor or pharmacist has told you.

- Keep the package leaflet. You may want to read it again later. read again.
 - If you notice any side effects, contact your doctor require.
- package leaflet. See section 4. • If your symptoms worsen or do not improve, you must see a doctor.

What is in this package leaflet What is Molevac and what is it used for?

What is in this package leaflet

1. What is Molevac and what is it used for?
2. What should you consider before taking Molevac?
3. How should Molevac be taken?
4. What side effects are possible?
5. How should Molevac be stored?
6. Contents of the package and further information

1. What is Molevac and what is it used for?

Molevac is a treatment for pinworm infestation (oxyuriasis), and can be used in children from 1 year, adolescents, and adults.

The active ingredient in Molevac, pyrvinium, is specifically effective against pinworms (oxyurids), and its worm-killing effect is based on disrupting the metabolism of the pinworms by Molevac.

2. What should you consider before taking Molevac?

Molevac must not be taken if you are allergic to pyrvinium or any of the other ingredients of this medicine listed in section 6, in case of liver damage, inflammatory bowel diseases, or kidney dysfunction.

Warnings and precautions

Please talk to your doctor or pharmacist before taking Molevac.

Molevac colors the stool bright red, this has no pathological significance, but merely indicates that the active ingredient has properly passed through the gastrointestinal tract.

The active ingredient of Molevac, pyrvinium, can lead to discoloration of textiles, for example, through vomiting or red coloring of the stool, this discoloration is not washable.

In case of a worm infestation, family members or other close contacts are often also affected, ask your doctor or pharmacist whether these contacts should also be treated, and pay attention to personal hygiene and thorough cleaning of living areas (home, workplace) and clothing.

Children

The safety and efficacy of Molevac in children under 1 year have not been established, therefore Molevac is not suitable for this age group.

Taking Molevac with other medicines

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines.

No interactions with other medicines have been observed so far.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

During pregnancy, you should only take Molevac if it is absolutely necessary considering the risk to mother and child, e.g., because other active substances must not be taken. When using Molevac during pregnancy, the amount of medicine should be related to the body weight before pregnancy (see also section 3. 'How to take Molevac').

Breastfeeding

Breastfeeding mothers should pump and discard milk during the use of Molevac for safety reasons.

Women of childbearing age

Women of childbearing age should use a reliable contraceptive method during treatment with Molevac, as the potential risk of using Molevac during pregnancy is unknown.

Driving and using machines

No special precautions are necessary.

Molevac contains sucrose (sugar), benzoic acid, benzyl alcohol, propylene glycol, and sodium.

Sucrose (sugar)

Please only take Molevac after consulting your doctor if you know you have an intolerance to certain sugars. 5 ml of suspension contains 1.15 g of sucrose (sugar). If you need to follow a diabetic diet, you should take this into account.

Benzoic acid

This medicine contains 5 mg of benzoic acid per 5 ml of suspension.

Benzyl alcohol

This medicine contains 0.2 mg of benzyl alcohol per 5 ml of suspension. Benzyl alcohol can cause allergic reactions.

Propylene glycol

This medicine contains 662 mg of propylene glycol per 5 ml of suspension.

If your child is under 5 years old, talk to your doctor or pharmacist before giving them this medicine, especially if your child is also receiving other medicines that contain propylene glycol or alcohol.

Do not take this medicine if you are pregnant or breastfeeding, unless your doctor has recommended it, your doctor may conduct additional tests while you are taking this medicine.

Do not take this medicine if you have liver or kidney disease, unless your doctor has recommended it, your doctor may conduct additional tests while you are taking this medicine.

Sodium

This medicine contains approximately 98 mg of sodium (main component of table salt) per 40 ml suspension (maximum single dose), which corresponds to about 5% of the recommended maximum daily sodium intake for an adult with food.

3. How to take Molevac?

Always take this medicine exactly as described in this leaflet or as agreed with your doctor or pharmacist, ask your doctor or pharmacist if you are not sure.

Dosage

Molevac is usually administered as a single dose.

Unless otherwise prescribed by the doctor, the usual dose is:

Children from 1 year, adolescents, and adults receive 5 ml Molevac (equivalent to 50 mg pyrvinium) per 10 kg body weight, the maximum dose for children, adolescents, and adults (even with a body weight of more than 80 kg) is 40 ml Molevac (equivalent to 400 mg pyrvinium), see dosage table.

If the effectiveness is insufficient, the amount of medicine should not be increased, but the treatment should be repeated.

Dosage table

Age approx. (Years)	Body weight approx. (kg)	Amount of medicine (Single dose) in ml
Children or adolescents		
1-3	10-14	5-7.5
4-5	15-19	7.5-10
6-9	20-29	10-15
10-12	30-39	15-20
13-14	40-49	20-25
15-16	50-59	25-30

Adults

	60-69	30-35
	70-79	35-40
	80 (or more)	40

Use in children and adolescents

The dosage for children from 1 year and adolescents can be found in the dosage table.

Method of administration

Molevac can be taken with a meal or on an empty stomach. If you need to take a larger amount of suspension, it is best to divide the intake into three portions: before, during, and after the meal.

In children, Molevac suspension can be diluted with water or other liquids (fruit juice).

Shake the suspension before use.

Pregnant women

When using Molevac during pregnancy, the dosage should be based on the body weight before pregnancy, regarding possible risks in Use of Molevac during pregnancy, see section 2 under "Pregnancy, lactation, and fertility".

Patients with impaired renal function

Molevac must not be used in patients with impaired renal function (see section 2 under "Molevac must not be taken").

Patients with impaired liver function

Molevac must not be used in patients with liver damage (see section 2 under "Molevac must not be taken").

Elderly patients (over 65 years)

Unless there is an impairment of liver or kidney function, no special precautions are necessary.

Duration of use

Repeat the treatment with Molevac after 2 to 4 weeks in the same way.

If you have taken a larger amount of Molevac than you should, an increase in the undesirable effects (see also section 4. "What side effects are possible?") of Molevac may occur. If signs of poisoning appear after taking Molevac, please seek medical attention immediately, as they can initiate gastric lavage or the administration of activated charcoal.

If you forget to take Molevac, you can take the missed dose on the same day without any issues. In any case, you should take the total amount of Molevac mentioned in this package leaflet.

If you have further questions about taking this medicine, please contact your doctor or pharmacist.

4. What side effects are possible?

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

The following frequency categories are used to evaluate side effects:

Very common: more than 1 in 10 treated

Common: 1 to 10 treated out of 100

Occasional: 1 to 10 treated out of 1,000

Rare: 1 to 10 treated out of 10,000

Very rare: less than 1 treated out of 10,000

Gastrointestinal disorders

Common: abdominal pain, nausea, vomiting

Occasional: diarrhea

Rare: stomach cramps, flatulence, constipation

Very rare: inflammation of the oral mucosa (stomatitis)

Nervous system disorders

Occasional: headache

Very rare: seizures, dizziness

Diseases of the respiratory system, thoracic cavity, and mediastinum

Very rare: temporary internal laryngeal swelling (laryngeal edema)

Diseases of the skin and subcutaneous tissue

Very rare: allergic skin reactions with and without itching, such as hives with blister and wheal formation (urticaria), photosensitivity, rashes, skin bleeding (purpura), as well as swelling of the skin and mucous membranes (angioedema).

Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist, this also applies to side effects not listed in this package leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: <http://www.bfarm.de>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Molevac?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the label and outer carton after 'Use by:'.

The expiry date refers to the last day of that month.

Never dispose of medicines via wastewater (e.g., do not dispose of via the toilet or sink). Ask your pharmacist how to dispose of medicines you no longer use. You will help protect the environment. Further information can be found at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Molevac contains

The active substance is pyrvinium, 5 ml suspension contains 50 mg pyrvinium (as embonate).

The other ingredients are:

Benzoic acid, cherry flavor (contains benzyl alcohol), methylcellulose, sodium hydroxide, sodium phosphate 12 H₂O, poloxamer 188, propylene glycol, saccharin sodium 2 H₂O, sucrose, hydrochloric acid 10%, sorbitan monolaurate (Ph. Eur.), purified water.

What Molevac looks like and contents of the pack

Red viscous suspension with cherry odor, 25 ml suspension with measuring cup, Molevac is available in the following pack sizes: 25 ml, 2 x 25 ml, not all pack sizes may be marketed.

Pharmaceutical entrepreneur and manufacturer

INFECTOPHARM Arzneimittel und Consilium GmbH, Von-Humboldt-Str. 1, 64646 Heppenheim, www.infectopharm.com.

This package leaflet was last revised in November 2023.

Dear patients, dear parents.

You or your child have been diagnosed with a worm infestation and have been prescribed Molevac by your doctor or purchased it over-the-counter at the pharmacy. Naturally, you are concerned about how to get rid of the pests, so we have compiled some information to help you understand the background of this condition and assist you in carrying out the treatment properly.

Pinworm infestation – the most common worm disease

Pinworms are parasites, i.e., organisms that live in a foreign organism, the so-called host, and feed at its expense.

Pinworms are by far the most common type of worm that affects people in temperate climates. In many countries, it is estimated that one-third of all children harbor these parasites. Transmission from person to person is very easy through smear and dirt infection and can occur even through simple handshaking.

How does a pinworm infection occur?

If you or your child are infested with pinworms, it is not necessarily the result of poor personal hygiene. Transmission can easily occur within community facilities, such as kindergartens, through shared use of toilets, toys, or clothing. Infection is also possible when playing in public playgrounds through contaminated sand.

Pinworm eggs are very stable; they can remain infectious in a dry environment for up to 3 weeks and can be stirred up with room dust. Therefore, the pinworm can be transmitted not only through direct contact but also through inhalation. Once in the body, the eggs mature into adult worms within 14 days, which can grow up to 11 mm long.

A female located in the large intestine crawls out of the anus at night when the affected patient is asleep and lays up to 10,000 eggs at once in the area of the anal opening. This leads to intense itching, and the patient begins to scratch themselves partially unnoticed in their sleep. In this

way, thousands of worm eggs get under the fingernails, especially children then put their fingers in their mouths, and the cycle begins anew.

How do I recognize a pinworm infection?

There are many people who are infested with pinworms but do not notice it. Often, the worm infestation causes only minor or no symptoms. However, if you notice that your child often scratches their anus, you should always consider a worm infection. Other signs can include fatigue and therefore lack of concentration, sleep disturbances, irritability during the day, loss of appetite, paleness, weight loss, general malaise.

After a female has laid its eggs, it dies. You may then be able to see the worms, up to 11 mm long, with the naked eye in pajamas or bed linen.

How is a pinworm infestation treated?

If a pinworm infection is confirmed by a doctor, it should definitely be treated with a medication against worms, a so-called anthelmintic.

The active ingredient pyrvinium, which is contained in both Molevac Suspension and Molevac Dragees, has been used for several decades in many countries to treat worm infections. Pyrvinium is practically not absorbed into the human bloodstream.

Therefore, Molevac is generally very well tolerated. It works only where it is supposed to: in the intestine, where the worms are located.

What else can I do?

The use of Molevac is very simple. In addition to the intake prescribed by your doctor, you should also definitely observe some hygiene measures: make sure that your child washes their hands thoroughly after playing outside and after each visit to the toilet, keep your child's fingernails as short and clean as possible, ensure adequate hygiene in the anal area, wash all clothes and bed linen that your child has been in contact with (60 °C wash is sufficient), avoid stirring up dust as much as possible (e.g., when making beds).

From time to time, we hear that even with the correct use of Molevac and careful adherence to all hygiene measures, the worm infection seemingly does not disappear. In such cases, it is often a family member who harbors worms without noticing, responsible for reinfection. In this case, be sure to speak with your doctor. In persistent cases, simultaneous treatment of all family members may be necessary.

Wishing you a speedy recovery,

Arzneimittel und Consilium GmbH
8231.82.00/03
581200111G11
581200111G11