

## Package leaflet: Information for users

Molevac® Dragees  
50 mg coated tablets Active ingredient: Pyrvinium  
For children from 3 years, adolescents and adults

Read the entire package leaflet carefully through, before you with the intake this medication begin, because it contains important information.

Take this medication always exactly as in this Package leaflet described or. exactly according to instructions your doctor or pharmacist one.

Keep the package leaflet on. Maybe you want these later again read.  
Questions you your pharmacist, if you further information or a advice need.  
If you side effects notice, contact your doctor or pharmacist . This also applies to side effects. This applies also to side effects, which are not listed in this package leaflet stated .. See Section 4  
If your symptoms worsen or there is no improvement ,you must see a doctor in any case consult a physician.

What is in this package leaflet contains

1. What is Molevac and what is it usedfor?
2. What should you know before taking from Molevac note?
3. How is Molevac to take?
4. What side effects are possible?
5. How is Molevac to store?
6. Contents of the Package and further information

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

is a medication for the treatment Treatment in pinworm infestation (oxyuriasis). Molevac can be used in children from 3 years, adolescents and adults Adults.

Molevac contained active ingredient pyrvinium is is specifically against pinworms (oxyurids) effective. The vermifuge effect is based on a disruption of metabolism of the pinworms by Molevac.

2. What should you before taking Molevac consider ? Molevacmust

not be taken if you become,

- if You allergic to the active ingredient pyrvinium, methyl- or. propyl-4-hydroxybenzoate or any of the section 6. mentioned other components of this medication are.
- in Liver damage
- in inflammatory bowel diseases
- in renal impairment

Warnings and precautions

Please consult your with your doctor or pharmacist before you take Molevac ..

Molevac colors the stool bright red. This has no clinical significance, but indicates only that the active ingredient has passed through the gastrointestinal tract properly.

The active ingredient of Molevac, pyrvinium, can for example through vomiting or through reddish discoloration of the stool lead to a discoloration of textiles. This discoloration is not washable.

In a worm infestation are often also the family members or other close contacts affected. Questions You your doctor or pharmacist, if in these contacts also a treatment carried out should . Pay attention also additionally on body hygiene and a thorough cleaning of the living areas (apartment, workplace) as well as the clothing.

#### Children

Molevac Dragees are for the treatment of children under 3 years not suitable. For children from an age of 1 year is available Molevac as suspension available ..

of from Molevac together with other medicines

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

So far have been no interactions with other Medicines observed.

#### Pregnancy, Lactation and Fertility-Reproductive ability

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

#### Pregnancy

During pregnancy you may Molevac only take, if this considering the risk to mother and child is absolutely necessary required is, e.g. because other active substances not taken may be.

During the application of Molevac in pregnancy should the amount of medication to the Body weight before the pregnancy referenced be (see also section 3. "How is Molevac to take?").

#### Lactation

Breastfeeding mothers should from safety reasons during the application of Molevac the milk pump and discard.

#### Women of childbearing age

Women of childbearing age should during the treatment with Molevac a reliable contraceptive method use, as the possible risk with use of Molevac in pregnancy not known is.

#### Driving ability and ability to operate machinery

It are no special precautions necessary.

#### Molevac contains sucrose (sugar)

Please take you Molevac only after consultation with your doctor if, when you know is, that you suffer from a Intolerance towards certain sugars suffer.

### 3. How is Molevac to be taken?

Take this medicine always exactly as in this package leaflet described or, exactly according to the with your doctor or pharmacist agreement arrangement a. Ask your with your doctor or pharmacist after, if you are not sure ..

Molevac

is administered as a rule as a single dose administered . If.

Cases by doctor not otherwise prescribed, is the usual dose:

Children from 3 years, Adolescents and Adults receive 1 coated tablet Molevac (corresponding 50 mg pyrvinium) per 10 kg body weight. The maximum dose is for children, adolescents and adults (also for a body weight of more than 80 kg) 8 coated tablets Molevac (corresponding 400 mg pyrvinium), see dosage table.

In case of insufficient efficacy should not the amount of medication increased, but the Treatment repeated be.

#### Dosage table

Age approx. (years)	Body weight approx. (kg)	Number Molevac Dragees
Children or. Adolescents		
3-5	12-19	1-2
6-9	20-29	2-3
10-12	30-39	3-4
13-14	40-49	4-5
15-16	50-59	5-6
Adults		
	60-69	6-7
	70-79	7-8
	80 (or more)	8

#### Application in children and adolescents

The dosage in children from 3 years and adolescents can be found in the dosage table ..

Dragees are for the for the Treatment of children under 3 years not suitable. For children from the age of 1 year is Molevac available as a suspension for oral administration.

#### Method of administration

Take Molevac dragees please unchewed with sufficient liquid in. Molevac can both with a meal and also on an empty Stomach taken be. If you a larger amount dragees take must, distribute the intake best on three portions :: before, during and after the meal.

#### Pregnant women

During the use of Molevac in pregnancy should the dosage be adjusted to the body weight before the pregnancy obtained be. Regarding possible risks during use of Molevac during pregnancy see section 2 under "Pregnancy, lactation and fertility-/reproductive ability".

#### Patients with impaired renal function

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

with impaired liver function Molevac

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

Elderly patients (over 65 years)

If no impairment of liver or of kidney function is present, there are no special considerations to.

Duration of application

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

If you have taken a larger amount of Molevac have, as you should,

can an intensification of the undesirable effects (see also section 4: "What side effects are possible"?) of Molevac occur. Should you after the intake of Molevac signs of poisoning appear, please seek immediately immediately a Doctor on. He can a gastric lavage or the intake of activated charcoal arrange.

If you forget to take from Molevac forgotten have,

can you the missing amount without further still on the same day take. In any case should you however the in this package leaflet mentioned Total amount Molevac take.

If you further questions about taking this medication have, contact your doctor at your doctor or Pharmacist.

#### 4. What side effects are possible?

Like all medicines can also this medicine have side effects , whichhowever do not occur in everyone must must.

In the evaluation of side effects the following frequency categories are used:

Very common: more than 1 treated out of 10

Common: 1 to 10 Treated out of 100

Occasionally: 1 to 10 Treated out of 1,000

Rare: 1 to 10 Treated out of 10,000

Very rare: less than 1 Treated of 10,000

Diseases of the nervous system

Occasionally: Headaches

Very rare: Convulsions

Diseases of the ear and the labyrinth

Very rare: Dizziness

Diseases of the respiratory tract, of the thoracic cavity and mediastinum

Very rare: transient internal laryngeal swelling (laryngeal edema)

#### Diseases of the gastrointestinal tract

Common: Abdominal pain, nausea, vomiting

Occasionally: diarrhea

Rarely: stomach cramps, flatulence, constipation

Very rarely: inflammation of the oral mucosa (Stomatitis)

#### Diseases of the skin and subcutaneous tissue

Very rare: allergic skin reactions with and without itching, such as e.g. urticaria with vesicles- and Wheal formation (Urticaria), Photosensitivity, Rashes (Rash), Skin bleeding (Purpura) as well as Swelling of the skin and mucous membrane (Angioedema)

#### Other possible side effects

Methyl- and propyl-4-hydroxybenzoate can cause hypersensitivity reactions, including delayed reactions provoke.

of side effects If you

notice side effects Side effects contact your doctor or pharmacist for advice Doctor or pharmacist. This also applies to for side effects, which are not listed in this package leaflet specified are. You can side effects also directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg Kiesinger Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de), report. By reporting side effects ,you can contribute to ensuring that more that more Information about the safety of this medication available provided will be ..

5. should Molevac be stored to store Keep

Store inaccessible to. They

You may the medicinal product after the on the blister pack and on the outer carton after "Use by date: " stated expiry date no longer use. The expiry date refers to on the last day of the specified month.

6. Contents of the package and further information

#### What Molevac contains

The active ingredient is Pyrvinium.

1 coated tablet contains 75.25 mg pyrvinium embonate (equivalent to 50 mg pyrvinium base).

The other ingredients are:

mannitol (Ph. Eur.), corn starch, talc, povidone K 25, Magnesium stearate (Ph. Eur.), Polysorbate 80, Carboxymethyl starch-Sodium (Type A) (Ph. Eur.), Sucrose, Gelatin, Shellac, Calcium carbonate, Iron oxides and hydroxides, Sodium benzoate, Methyl-4-hydroxybenzoate (Ph. Eur.), Propyl-4-hydroxybenzoate (Ph. Eur.), bleached wax.

How Molevac looks and Contents of the package

8 coated red-brownish tablets

Pharmaceutical entrepreneur and manufacturer

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This Package leaflet was last revised in December 2013.

Transtoyou

Further information according to § 11 paragraph 1 sentence 7 AMG:

Dear patients, dear parents.

In you or your child was worm infestation determined and you have Molevac from your doctor prescribed received or over-the-counter at the pharmacy purchased. Of course you are concerned, how you the pests get rid of again. Therefore we have compiled some information that provides you with the background of this disease in more detail and should help help are, the treatment professionally to perform.

Pinworm infestation – the most common worm disease

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

Pinworms are the most common type of worm, that affects humans in the temperate climates infects. In many countries harbor approximately one third of all children these parasites. The transmission from human to human occurs very easily through smear and dirt infection and is already through mere handshaking possible.

How does an infection with pinworms?

If you or your child from pinworms infested are, so is this not necessarily the result of poor personal hygiene. Easily can a transmission within community facilities. Community facilities, how e.g. kindergartens, through shared use of toilets, toys or clothing items occur.

Also when playing on public playgrounds is through contaminated sand an infection possible. Pinworm eggs are very stable. They can in dry environments up to 3 weeks contagious be and with the room dust stirred up become. Therefore can the pinworm not only through direct contact, but also through inhalation transmitted are.

Once in the body enters, mature the eggs within 14 days into adult worms develop, which can live up to 11 mm long are. A in the colon located female crawls at night, when the affected patient sleeps, out of the anus and lays there in the area of the anus at once up to 10000 eggs off. This leads to a severe itching and the patient begins to scratch in sleep partially unnoticed to scratch. On this way reach thousands worm eggs under the fingernails.

Especially children put then the fingers in the mouth and already begins the cycle of anew.

How do I recognize a pinworm infection? Pinworm infection

There are many people who are infested with pinworms affected are, dies however not notice.

Frequently causes the worm infestation namely only mild or no symptoms. If you however notice, that yourself your child often at the anus scratches, should you always consider a worm infection. Signs can be: fatigue

- and therefore lack of concentration
- sleep disturbances, during the day irritability
- loss of appetite
- pallor
- weight loss
- general malaise

After a female its eggs laid has, dies it. They can then possibly the up to to 11 mm long worms in pajamas or in the bedding with the naked eye detect.

How is a pinworm infestation treated?

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

The active ingredient pyrvinium, which both in Molevac suspension as also in Molevac Dragees contained is, has been for several decades in many countries for treatment of worm infections used.

Pyrvinium is practically not in the human bloodstream absorbed.

Therefore is Molevac usually extremely well tolerated. It acts only where it should act should: In the intestine, where are located the worms are.

What can I else still do?

The application of Molevac is conceivable simple. In addition to the your doctor prescribed intake should you however additionally absolutely some hygiene measures observe.

- Make sure that, that yourself Your child after the playing in outdoors as well as after every toilet visit thoroughly the hands washes.
- Keep the fingernails Your child's as short as possible and clean.
- Ensure adequate hygiene in the anal area.
- Wash all clothes and bedding, with the Your child in Contact was (60 °C Laundry is sufficient).
- Avoid you as much as possible the dust stirring (e.g. when making the bed).

Now and then hear we, that even with correct use of Molevac and careful observance of all hygiene measures the worm infection apparently does not disappear. In such cases is often a family member, which worms harbors, but does not notice, for the reinfection responsible. Consult with this Case absolutely with your doctor.

In persistent courses may a simultaneous treatment of all family members necessary become.

Get well soon wishes

INFECTOPHARM Pharmaceuticals and Consilium GmbH