



Paidoflor[®]

20 mg Chewable tablets

For use in adults, adolescents and children

Active ingredient: dry powder of *Lactobacillus acidophilus*

Dear patient!

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.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What Paidoflor[®] is and what it is used for

1.1 Paidoflor[®] is a traditionally used medicine.

Paidoflor[®] is traditionally used as a mild medicine for support of the function of the intestine, e.g. in case of under-activity of the intestine and diarrhea.

2. What you need to know before you take Paidoflor[®]

2.1 Do not take Paidoflor[®],

if you are allergic (hypersensitive) to dry powder of *Lactobacillus acidophilus* or any of the other ingredients of this medicine (listed in section 6).

Due to the as yet not assessable risk of a systemic colonization with *Lactobacillus acidophilus*, patients with a heavily impaired immune defense system (e.g. HIV infections, organ transplantation, leukemia, malignant tumors, radiotherapy, chemotherapy or after long-term large-dose cortisone treatment) should not use Paidoflor[®].

Do not use Paidoflor[®] in cases with acute diarrhea accompanied by extreme fever or amounts of blood and also not in children under the age of 1.

2.2 Warnings and Precautions

Talk to your doctor or pharmacist before taking Paidoflor[®].

As a traditional medicinal product Paidoflor[®] has as supportive character. In cases of illness it should be used only as an addition to other effective therapeutic measures. Particularly in cases of diarrhea, especially in children and older persons, Paidoflor[®] is not intended to replace necessary forms of care and treatment like fluid replacement or temporarily abstinence from solid food.

With diarrhea lasting longer than 2 days or accompanied by blood in the stool or a rise in temperature, you should consult a doctor.

In Children

In children from 2 years of age up to the age of 6 Paidoflor[®] has only to be used under medical surveillance.

2.3 Other medicines and Paidoflor[®]

No interactions are known.

Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

2.4 Pregnancy and breast-feeding

Lactobacillus acidophilus is a natural colonizer of the human gut and is not absorbed. Therefore, there are no effects on pregnancy and breast-feeding to be expected.

2.5 Driving and using machines

No special precautions are necessary.

2.6 Important information about some of the ingredients of Paidoflor[®]

Paidoflor[®] contains lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

1 chewable tablet contains 0.97 g lactose (corresponding to 0.485 g glucose and 0.485 g galaktose) equivalent to approx. 0.08 bread units (BU).

You should keep this in mind when you are following a diabetic diet.

3. How to take Paidoflor[®]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

3.1 The recommended dose is

Adults take 1–3 x daily 3 chewable tablets.

Children take 1–2 x daily 3 chewable tablets.

Smaller children take 1–3 x daily 1 chewable tablet.

3.2 Route of administration

Adults and children take the tablets chewed with meals.

Before directed to smaller children the chewable tablet should be crushed and given into lukewarm milk or porridge.

3.3 Duration of treatment

With acute intestinal complaints treatment has to be continued until symptoms improved. With chronic functional disorders administration over 6 weeks is recommended.

3.4 If you take more Paidoflor® than you should

If you take more Paidoflor® than you should, no special measures are necessary.

3.5 If you forget to take Paidoflor®

Do not take a double dose to make up for a forgotten dose. Taking should be continued as prescribed by your doctor or described in this package leaflet.

3.6 If you stop taking Paidoflor®

You can stop or discontinue taking Paidoflor® at any time, no special precautions are necessary. If you are not sure or if you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. For the assessment of side effects, the following data on frequency are used as a basis:

| | |
|--------------------|---|
| Very common | More than 1 of 10 patients treated |
| Common | Less than 1 of 10, but more than 1 of 100 patients treated |
| Uncommon | Less than 1 of 100, but more than 1 of 1,000 patients treated |
| Rare | Less than 1 of 1,000, but more than 1 of 10,000 patients treated |
| Very rare | Less than 1 of 10,000 patients treated, or unknown |

4.1 List of possible side effects

Side effects are not known.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.2 Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paidoflor®

Keep out of the reach and sight of children.

Do not use Paidoflor® after the expiry date which is stated on the carton and on the blister after "Expiry date:".

Storage conditions:

Keep at 2 °C to 8 °C!

6. Content of the pack and further information

6.1 What Paidoflor® contains

The active substance is:

1 chewable tablet contains: 20 mg dry powder of *Lactobacillus acidophilus* with 10^9 – 10^{10} viable bacteria per g.

Excipients: Riboflavine, nicotinic acid, magnesium stearate, manganese(II)sulfate, magnesium sulfate $7H_2O$, lactose, lactose mono-hydrate.

6.2 What Paidoflor® looks like and contents of the pack:

Appearance

Round, on both sides arched chewable tablet without coating.

Packs

Packs with 20, 50 or 100 chewable tablets.

6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstr. 20, 58313 Herdecke, Germany

This leaflet was last approved in December 2014.

Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version. This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.