

Mutaflor[®]

Capsules

For use in adolescents and adults

Active substance: Escherichia coli strain Nissle 1917



Dear patient!

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Mutaflor[®] carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

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

1.1 Pharmacotherapeutic group and mode of action

Mutaflor[®] is a remedy for the treatment of gut diseases. The bacterium Escherichia coli (E. coli) strain Nissle 1917 – the active substance of Mutaflor[®] – is a natural colonizer of the gut. On its release in the colon, it acts anti-inflammatory and against disease-causing micro-organisms. In addition, it enhances the defence powers of the human body. Moreover, the bacterium E. coli strain Nissle 1917 supports digestion. It releases substances into the gut that stimulate the activity of gut muscles (peristalsis) and serve as an energy source for the colonic mucosa and enhance its blood circulation.

1.2 Mutaflor[®] is used with

- Inflammation of the colon (ulcerative colitis) at times without acute attack (remission phase)
- Long-standing (chronic) constipation

2. Before you take Mutaflor[®]

2.1 Do not take Mutaflor[®]

If you are allergic (hypersensitive) to E. coli strain Nissle 1917 or any of the other ingredients of Mutaflor[®].

2.2 Taking other medicinal products

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicinal products, including medicinal products obtained without a prescription.

Especially, certain antibiotics and sulphonamides may reduce the efficacy of Mutaflor[®].

2.3 Pregnancy and breast-feeding

The bacterium E. coli strain Nissle 1917 contained in Mutaflor[®] as the active substance is a natural colonizer of the gut. With any use according to the instructions no risks are known during pregnancy and breast-feeding.

2.4 Driving and using machines

No special precautions are necessary.

3. How to take Mutaflor[®]

Always take Mutaflor[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

3.1 Dosage

In case your doctor did not suggest differently, the usual dose (standard dose) applies to adults and adolescents from 12 years of age:

From day 1 to day 4, 1 capsule Mutaflor[®] daily, then 2 capsules Mutaflor[®] daily.

In case of persistent constipation it may be useful to increase the dose up to 4 capsules Mutaflor[®] per day.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Mutaflor[®] being too strong or too weak.

3.2 Method of administration

The standard dose should be taken with a meal, if possible with breakfast, and an appropriate amount of fluid. Avoid to chew the capsules.

With onset of flatulence or with a daily dose higher than the standard dose, the daily dose may be split and administered with meals spread evenly throughout the day.

3.3 Duration of treatment

With inflammation of the colon (ulcerative colitis) at times without acute attack (remission phase), Mutaflor[®] should be taken continuously and regularly.

With constipation Mutaflor[®] may be taken for up to 6 weeks. In disease which persisted for years Mutaflor[®] should be regarded as a health-maintenance treatment and the therapy therefore be repeated periodically.

3.4 If you take more Mutaflor® than you should

Even after taking too large amounts no special measures are necessary.

3.5 If you forget to take Mutaflor®

Do not take a double dose to make up for a forgotten dose. The taking of Mutaflor® should be continued without considering the forgotten dose.

3.6 If you stop taking Mutaflor®

Here, with any use of Mutaflor® according to the instructions, no special precautions are necessary.

If you take Mutaflor® during a time without acute attack of colonic inflammation and would like to stop taking it, you should tell your doctor. Stopping Mutaflor® administration may facilitate the onset of an acute attack of colonic inflammation.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Mutaflor® 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

After the beginning of administration, flatulence is common. Very rarely, undesired effects of the gastrointestinal tract such as abdominal pain, gut noises, loose stools or diarrhoea, nausea and vomiting may occur.

Again very rarely, cases of skin reddening or rashes may occur.

Also very rarely, cases of headache may occur.

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 Mutaflor®

Keep out of the reach and sight of children.

Do not use Mutaflor® 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 (in the refrigerator)!

6. Further information

6.1 What Mutaflor® contains

The active substance is: Escherichia coli strain Nissle 1917

1 gastro-resistant hard capsule contains 2.5 – 25 x 10⁹ viable cells (CFU) of Escherichia coli strain Nissle 1917

The other ingredients are:

Maltodextrin, talc, methacrylic acid-methylmethacrylate copolymer (1 : 1), macrogol (4000), triethyl citrate, glycerol 85 %, titanium dioxide, iron(III)-oxide, gelatine, white beeswax, carnauba wax, shellac, purified water

6.2 What Mutaflor® looks like and contents of the pack

Appearance

Capsules with complete coating of maroon colour

Packs

Mutaflor® is available in the following packs:

Original pack with 20 gastro-resistant hard capsules

Original pack with 50 gastro-resistant hard capsules

Original pack with 100 gastro-resistant hard capsules

6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstr. 20, 58313 Herdecke, Germany

This leaflet was last approved in August 2015.

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.