

MUTAFLOR®

Escherichia coli strain Nissle 1917

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mutaflor®. Ask your Doctor, Pharmacist or Health Care Practitioner if you need more information or advice.

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

Keep this leaflet with the medicine.

You may need to read it again.

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

You must contact your Doctor or Healthcare Practitioner if your symptoms worsen or do not improve.

If any of the side effects are serious, or if you notice any side effects not listed in this leaflet, please tell your Doctor or Healthcare Practitioner.

In this leaflet:

1. What Mutaflor® is and what it is used for.
2. Before you take Mutaflor®
3. How to take Mutaflor®
4. Possible side effects
5. How to store Mutaflor®
6. Further information

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

1.1 Pharmacotherapeutic group and mode of action

Mutaflor® capsules contain as the active substance the defined non-pathogenic strain *Escherichia coli* (*E.coli*) Nissle 1917.

The therapeutic effects of Mutaflor® are strain specific and have been demonstrated by in-vitro and in-vivo experiments and clinical studies, where the following properties and modes of action were detected.

Mutaflor® is a natural colonizer of the gut.

E.coli strain Nissle 1917 is a normal, non-pathogenic and non-invasive inhabitant of the human gut. By means of special adhesive organelles (fimbriae) the strain is able to attach to the mucin layer of the gut wall. The strain is well mobile by possessing flagellae, an advantage when colonizing the colon.

Motility and stool frequency

E.coli strain Nissle 1917, via the production of short chain fatty acids, modulates colonic motility.

Stimulation of colonic motility, is important for the treatment of chronic constipation.

1.2 Mutaflor® is used for

- For the relief / management of chronic constipation.
- To increase the number of bowel movements per day and the number of days on which bowel movements occur in patients with chronic constipation.

2. Before you take Mutaflor®

Constipation may be associated with other medical conditions. Any change in bowel habits should be discussed with your doctor

to exclude these. Further investigation may be required.

2.1 Do not take Mutaflor®

- If you are allergic (hypersensitive) to *E.coli* strain Nissle 1917 or any of the ingredients of Mutaflor® listed at the end of this leaflet.

2.2 Taking other medicinal products

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

Some medicines may interfere with Mutaflor®. These include:

- Certain antibiotics and sulphonamides as they may reduce the efficacy of Mutaflor®.

2.3 Pregnancy and breast feeding

The bacterium *E.coli* strain Nissle 1917 contained in Mutaflor® is a natural colonizer of the gut. Its presence and mode of action is restricted to the gastrointestinal tract. When used in accordance with the instructions there are no known risks during pregnancy and breast-feeding.

2.4 Driving and using machinery

No special precautions are necessary.

3. How to take Mutaflor®

Always take Mutaflor® exactly as your Doctor or Healthcare Practitioner has told you. You should check with your Doctor or Healthcare Practitioner if you are not sure.

3.1 Dosage

Unless your Doctor or Healthcare Practitioner has suggested otherwise, the usual dose (standard dose) is:

Adults:

For the first 2 days take 2 Mutaflor® capsules 3 times daily. From the third day onwards, take 4 Mutaflor® capsules daily.

Repeat periodically.

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

3.2 Method of administration

The standard dose should be taken with a meal, if possible with breakfast, and an appropriate amount of fluid. Swallow capsule whole, DO NOT break or chew.

With the onset of flatulence or if your Doctor or Healthcare Practitioner recommends 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

Mutaflor® may be taken for up to 8 weeks.

In chronic constipation that has 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.

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. Take it as soon as you

remember and then go back to taking Mutaflor® as you would normally.

3.6 If you stop taking Mutaflor®

There are no special measures necessary.

If you have any further questions on the use of this product, ask your Doctor, Pharmacist or Healthcare Practitioner.

4. Possible side effects

Like other medicines, Mutaflor® can cause some side effects although not everyone will experience them. If they occur, most are likely to be minor and temporary.

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 1000 patients treated
Rare - less than 1 of 1000 but more than 1 of 10000 patients treated
very rare - less than 1 of 10000 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 these side effects were to get serious, or if you notice any side effects not listed in this leaflet, please tell your Doctor or Healthcare Practitioner.

Ask your Doctor or Pharmacist if you do not understand anything in this list.

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 blister.

Do not use Mutaflor® if the packaging is torn or shows signs of tampering.

Storage conditions

Store at 2 °C to 8 °C (Refrigerate. Do not freeze.)

6. Further information

6.1 What Mutaflor® contains

The active substance is *Escherichia coli* strain Nissle 1917.

Each enteric-coated hard capsule contains not less than 250 million CFU of *Escherichia coli* strain Nissle 1917.

The other ingredients are: maltodextrin, talc-purified, methacrylic acid copolymer, macrogol 4000, triethylcitrate, glycerol,

titanium dioxide, iron oxide red, white beeswax, carnauba wax, shellac, gelatine capsule, capsule processing aid, purified water.

6.2 What Mutaflor® looks like and contents of the pack

- Appearance: Capsules coated with reddish-brown enteric-coating.
- Packs: Mutaflor® is available in 20, 50 and 100 pack sizes.

6.3 Manufacturer and Australian sponsor

Manufacturer:

ARDEYPHARM GmbH
Loerfeldstr. 20
58313 Herdecke
Germany

Australian sponsor:

Natural Therapy Imports
Suite 4, 74 Prospect Road
Prospect SA 5082
www.mutaflor.com.au

ARTG Number:

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