

Mutaflor® Suspension



For use in infants, toddlers and children

Active substance: Escherichia coli strain Nissle 1917

Dear parents!

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® Suspension 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® Suspension is and what it is used for

Pharmacotherapeutic group and mode of action

Mutaflor® Suspension is a remedy for the treatment of diarrhoea in infants, toddlers, and children. Moreover, Mutaflor® Suspension promotes the development of the defence powers of the human body. The bacterium E. coli strain Nissle 1917 contained as active substance, acts against disease-causing microorganisms in the gut and prevents their colonization (infection prophylaxis). Furthermore, E. coli strain Nissle 1917 releases substances into the gut that strengthen the intestinal mucosa and enhance its natural function.

Mutaflor® Suspension is used with

- Diarrhoea in infants, toddlers, and children
- Diarrhoea in infants, toddlers, and children under tube feeding
- Enhancement of natural defence powers of the body of pre-term and full-term infants (infection prophylaxis)
- Prevention of colonization of harmful bacteria in the gut of pre-term and full-term infants (colonization prophylaxis)

2. Before you use Mutaflor® Suspension

Do not use Mutaflor® Suspension

If your child is allergic (hypersensitive) to E. coli strain Nissle 1917 or any of the other ingredients of Mutaflor® Suspension.

Take special care with Mutaflor® Suspension

- If you observe your child developing intolerance reactions please turn to your doctor or pharmacist.
- With diarrhoea, the risk of dehydration exists. Therefore, even under treatment with Mutaflor® Suspension, sufficient intake of liquid and electrolytes must be ensured.

Using other medicines

Please tell your doctor or pharmacist if you are administering or have recently administered any other medicines to your child, including medicines obtained without a prescription.

Certain antibiotics and sulphonamides may reduce the efficacy of Mutaflor® Suspension. Therefore, please tell your doctor or pharmacist which antibiotics or sulphonamides are administered to your child.

Pregnancy and breast-feeding

The bacterium E. coli strain Nissle 1917 as contained in Mutaflor® Suspension is a natural inhabitant of the gut. With any use according to the instructions no risks are known during pregnancy and breast-feeding. However, Mutaflor® Suspension is intended for the treatment of infants, toddlers, and children only.

3. How to use Mutaflor® Suspension

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

The usual dose is:

Diarrhoea:

Infants, toddlers, and children: 1 to 3 times per day 1 ml.

Diarrhoea under tube feeding:

Infants, toddlers, and children: Once per day 1 to 5 ml.

Enhancement of natural defence powers of the body (infection prophylaxis):

Pre-term and full-term infants: First week of life 1 ml once per day; second to third week 1 ml per day for three times in each week.

Prevention of colonization of harmful bacteria in the gut (colonization prophylaxis):

Pre-term and full-term infants: Once per day 1 ml.

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

Method of administration

Tear off a single dose container from the block in order to open it. Shake well and twist off cap before use. The suspension can directly be administered from the containers into the mouth, with infants before nursing, with toddlers after a meal. Filling up to the indication mark results in 1 ml. The content of the dosing spoon can directly be given into the mouth. Clean the dosing spoon with warm water and dry it with a clean tissue after use.

Duration of administration

Diarrhoea; acute: at least 5 days.
Diarrhoea; prolonged: at least 15 days.
Diarrhoea when fed by a probe: up to 5 days with each diarrhoeal episode.
The treatment should be continued for several days after therapeutic success has been reached.
Infection prophylaxis: 1st – 3rd week of life.
Colonization prophylaxis: at least 5 days.

If you administer more Mutaflor® Suspension to your child than you should

Special measures are not necessary.

If you forget to use Mutaflor® Suspension

Do not take a double dose to make up for a forgotten dose.

If you stop using Mutaflor® Suspension

Special precautions are not necessary.

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® Suspension 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:	affects more than 1 user in 10
Common:	affects 1 of 10 users in 100
Uncommon:	affects 1 of 10 users in 1,000
Rare:	affects 1 of 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

List of possible side effects

Side effects in the gastrointestinal tract such as flatulence, abdominal pain, diarrhoea or vomiting were reported very rarely.

Again very rarely, cases of urticaria or allergic reactions may occur.

In isolated cases the occurrence of blood poisoning (sepsis) was observed in very immature pre-term infants with a very low birth weight of less than 1000 g. The frequency is not known. It cannot be estimated from the available data.

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.

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® Suspension

Keep out of the reach and sight of children.

Do not use Mutaflor® Suspension after the expiry date which is stated on the carton and on the container after "EXP:". The expiry date refers to the last day of that month.

Storage precautions

Keep in the refrigerator (2 °C to 8 °C).

Information on the shelf-life after opening

Use up the contents of 5 ml ampoules within 5 days after opening them. After opening, store 5 ml ampoules in a refrigerator at 2 °C - 8 °C standing upright in their carton!

6. Content of the package and further information

What Mutaflor® Suspension contains

The active substance is: Escherichia coli strain Nissle 1917

1 ml suspension contains bacterial culture of Escherichia coli strain Nissle 1917 corresponding to 10⁸ viable cells (CFU).

The other ingredients are

Purified water, sodium chloride, potassium chloride, magnesium-sulfate heptahydrate, calcium chloride dihydrate, magnesium-chloride hexahydrate, sodium hydroxide solution 32 %.

What Mutaflor® Suspension looks like and contents of the pack

Appearance:

Beige, milky turbid, watery liquid, packed in polyethylene ampoules.

Packs:

Mutaflor® Suspension is available in the following packs:

Packs with 5 x 1 ml, 10 x 1 ml or 25 x 1 ml suspension

Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstr. 20, 58313 Herdecke, Germany, www.ardeypharm.de

This leaflet was last approved in March 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.