NAME OF THE MEDICINAL PRODUCT

Metronidazole B. Braun 5 mg/ml Solution for Infusion

COMPOSITION

1 ml of solution contains 5 mg of metronidazole
100 ml of solution contain 500 mg of metronidazole

Excipients with known effect:
1 ml solution contains

Sodium chloride	7.4 mg
Disodium phosphate dodecahydrate	1.5 mg

Electrolyte content (per 100 ml):

Sodium	14 mmol
Chloride	13 mmol

Excipients:
Sodium chloride, disodium phosphate dodecahydrate, citric acid monohydrate, water for injections.

THERAPEUTIC INDICATIONS

Treatment and prophylaxis of infections caused by metronidazole susceptible microorganisms (mainly anaerobic bacteria).

Metronidazole is indicated in adults and children for the following indications:

Infections of the central nervous system (e.g. brain abscess, meningitis); infections of lung and pleura (e.g. necrotising pneumonia, aspiration pneumonia, lung abscess); endocarditis; infections in the gastrointestinal tract and the abdominal area (e.g. peritonitis, liver abscess, postoperative infections after colonic and rectal surgery, purulent diseases in the abdominal and pelvic cavities); gynaecologic infections (e. g. endometritis, after hysterectomy or caesarean section, childbed fever, septic abortion); infections in the ear-nose-throat and tooth-mouth-jaw regions (e.g. *PLAUT-VINCENT*-angina); bone and joint infections (e. g. osteomyelitis); gas gangrene; septicaemia with thrombophlebitis.

In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to Metronidazole B. Braun 5 mg/ml.

A prophylactic use is always indicated prior to operations with a high risk of anaerobic infections (gynaecologic and intra-abdominal operations).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

CONTRAINDICATIONS

Hypersensitivity to metronidazole or other nitroimidazole derivatives or to any of the excipients.

UNDESIRABLE EFFECTS

Undesirable effects are mainly associated with prolonged use or high doses. The most commonly observed effects include nausea, abnormal taste sensations and the risk of neuropathy in case of long term treatment.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Rare: (≥ 1/10 000 to < 1/1000)
Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

System organ class

Infections and infestations
Common: Superinfections with candida (e.g. genital infections)
Rare: Pseudomembranous colitis, which may occur during or after therapy, manifesting as severe persistent diarrhoea

Blood and lymphatic system disorders
Very rare: During therapy with metronidazole, decreases of leukocyte and platelet counts (granulocytopenia, agranulocytosis, pancytopenia and thrombocytopenia)
Not known: Leucopenia, aplastic anaemia

During prolonged administration regular monitoring of blood cell counts is mandatory.

Immune system disorders
Rare: Severe acute systemic hypersensitivity reactions: Anaphylaxis, up to anaphylactic shock.
Severe skin reactions, see “Skin and subcutaneous disorders” below.
These severe reactions demand immediate therapeutic intervention.
Not known: Mild to moderate hypersensitivity reactions, e. g. skin reactions (see “Skin and subcutaneous disorders” below) angioedema

Metabolism and nutrition disorders
Not known: Anorexia

Psychiatric disorders
Very rare: Psychotic disorders, including states of confusion, hallucination
Not known: Depression

Nervous system disorders
Very rare: Encephalopathy, headache, fever, drowsiness, dizziness, disturbances in sight and movement, vertigo, ataxia, dysarthria, convulsions
Not known: Somnolence or insomnia, myoclonus, seizures, peripheral neuropathy manifesting as paraesthesia, pain, furry sensation, and tingling in the extremities, aseptic meningitis

If seizures or signs of peripheral neuropathy or encephalopathy appear, the attending doctor should be informed immediately.

Eye disorders
Very rare: Disturbance of vision, e.g. diplopia, myopia
Not known: Oculogyric crisis, optic neuropathy/neuritis (isolated cases)

Cardiac disorders
Rare: ECG changes like flattening of T-wave

Gastro-intestinal disorders
Not known: Vomiting, nausea, diarrhoea, glossitis and stomatitis, eructation with bitter taste, epigastric pressure, metallic taste, furred tongue, dysphagia (caused by central nervous effects of metronidazole)
Very rare: Pancreatitis

Hepatobiliary disorders
Very rare: Abnormal values of hepatic enzymes and bilirubin, hepatitis, jaundice

Skin and subcutaneous tissue disorders
Very rare: Allergic skin reactions, e.g. pruritus, urticaria, *Stevens-Johnson* syndrome , toxic epidermal necrolysis (isolated reports)
The two latter reactions demand immediate therapeutic intervention.
Not known: Erythema multiforme

Musculoskeletal and connective tissue disorders
Very rare: Arthralgia, myalgia

Renal and urinary disorders
Uncommon: Dark coloured urine (due to a metabolite of metronidazole)

General disorders and administration site conditions
Not known: Vein irritations (up to thrombophlebitis) after intravenous administration states of weakness, fever

Cases of severe irreversible hepatotoxicity/acute liver failure, including cases with fatal outcomes with very rapid onset after initiation of systemic use of metronidazole, have been reported in patients with Cockayne Syndrome.

Paediatric population
Frequency, type and severity of adverse reactions in children are the same as in adults.

WARNINGS

Keep out of sight and reach of children. Only to be used if solution is clear and colourless or slightly yellowish and container and closure are undamaged.

NOTE

Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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