

Product Information for Ovex/Ovex Family Pack, Ovex Suspension

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>

**Adverse events should also be reported to
McNeil Products Limited on freephone
0808 238 9999.**

Ovex/Ovex Family Pack (Mebendazole) Product Information:

Presentation:

Flat circular pale orange tablets with 'ME 100' on one side and 'JANSSEN' on the other, containing mebendazole 100 mg.

Uses:

For the treatment of gastrointestinal infestations of *Enterobius vermicularis* (threadworm).

Dosage:

Adults and children over 2 years: One tablet, chewed or swallowed whole. Crush the tablet before giving to a young child. It is recommended that all family members are treated at the same time to avoid re-infection and that a second dose is taken after two weeks if re-infection is suspected. Always supervise a child while they are taking this medicine. Ovex Suspension should be considered for patients such as young children who are unable to swallow the tablet.

For the indication Taeniasis: Paediatric population / Children and adolescents (≥ 2 to 16 years). Data on efficacy and safety limited in this age group. Mebendazole should be used only if there is no therapeutic alternative.

Contraindications:

Hypersensitivity to the product or any components and pregnancy.

Precautions:

Not recommended in children under 2 years. If symptoms do not disappear within a few days, consult a doctor. Avoid concomitant use with metronidazole. Orange Yellow S (E110) may cause allergic reactions. Ovex Suspension should be considered for patients such as young children who are unable to swallow the tablet. This product has not been extensively studied in children below the age of 2 years and should only be given to very young children if their worm infestation interferes significantly with their nutritional status and physical development. Therefore, Ovex tablets should be used in children aged 1-2 years only if the potential benefit justifies the potential risk. Because of the lack of sufficient safety data, this product should not be used in children below the age of 1 year. Glomerulonephritis and agranulocytosis have been very rarely reported with dosages substantially above those recommended and with treatment for prolonged periods of time. As higher doses and longer treatment is recommended in patients with echinococcosis, careful consideration should be given when treating patients with severe chronic hepatic diseases and/or bone marrow depression. These patients should be closely monitored with haematological, liver, and renal function tests. Consider discontinuing Ovex Tablets if clinically significant laboratory abnormalities are found. Official guidelines should be taken into consideration. For full details refer to the SPC.

Pregnancy and lactation:

Ovex is contraindicated in pregnancy and not recommended in breast-feeding women.

Side-effects:

Common: abdominal pain.

Uncommon: abdominal discomfort, diarrhoea, flatulence.

Rare: neutropenia, hypersensitivity including anaphylactic and anaphylactoid reactions, convulsions, dizziness, hepatitis, abnormal liver function tests, rash, toxic epidermal necrolysis, Stevens-Johnson syndrome, exanthema, angioedema, urticaria, alopecia.

Very rare: agranulocytosis, nausea, vomiting, glomerulonephritis.

Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 1 tablet: £4.74, 4 tablets: £11.08

Legal category: 1 tablet: P, 4 tablets: P

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL numbers: 15513/0314

Date of preparation: 13 July 2023

Ovex Suspension (Mebendazole) Product Information:**Presentation:**

Oral Suspension containing mebendazole 100mg/5ml.

Uses:

For the treatment of gastrointestinal infestations of *Enterobius vermicularis* (threadworm).

Dosage:

Adults and children over 2 years: 1 x 5 ml (1 dosing cup). It is recommended that all family members are treated at the same time to avoid re-infection and that a second dose is taken after two weeks if re-infection is suspected.

For the indication Taeniasis: Paediatric population / Children and adolescents (≥2 to 16 years). Data on efficacy and safety limited in this age group. Mebendazole should be used only if there is no therapeutic alternative.

Contraindications:

Hypersensitivity to the product or any components and contraindicated in pregnancy.

Precautions:

Not recommended in children under 2 years. If symptoms do not disappear within a few days, consult a doctor. Avoid concomitant use with metronidazole and mebendazole. Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrose isomaltase insufficiency should not take this medicine. Methyl (E218) and propyl (E216) parahydroxybenzoate may cause acute or delayed allergic reactions. Ovex Suspension has not been extensively studied in children below the age of 2 years and should only be given to very young children if their worm infestation interferes significantly with their nutritional status and physical development. Therefore, this product should be used in children aged 1-2 years only if the potential benefit justifies the potential risk. Because of the lack of sufficient safety data, Ovex Suspension should not be used in children below the age of 1 year. Glomerulonephritis and agranulocytosis have been very rarely reported with dosages substantially above those recommended and with treatment for prolonged periods of time. As higher doses

and longer treatment is recommended in patients with echinococcosis, careful consideration should be given when treating patients with severe chronic hepatic diseases and/or bone marrow depression. These patients should be closely monitored with haematological, liver, and renal function tests. Consider discontinuing Ovex Suspension if clinically significant laboratory abnormalities are found. Official guidelines should be taken into consideration. For full details refer to SPC.

Fertility, pregnancy and lactation:

Contraindicated in pregnancy. Not recommended to breast feed following administration of Ovex.

Side-effects:

Common: abdominal pain.

Uncommon: abdominal discomfort, diarrhoea, flatulence.

Rare: neutropenia, hypersensitivity including anaphylactic and anaphylactoid reactions, convulsions, dizziness, hepatitis, abnormal liver function tests, rash, toxic epidermal necrolysis, Stevens-Johnson syndrome, exanthema, angioedema, urticaria, alopecia.

Very rare: agranulocytosis, nausea, vomiting, glomerulonephritis.

Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 30 ml bottle, £13.33

Legal category: P

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL numbers: 15513/0313

Date of preparation: 30 July 2024