Adiclair® Dosage recommendations

Dosage form	Indications, dosage		Duration of application
	Fungal infections in the mouth (oral thrush), throat and oesophagus		
	Infants	**Children and adults**	
Adiclair® Suspension	0.5-1 ml suspension 3-6 times daily	1 ml suspension 3-6 times daily	At least 2 weeks
	Oral thrush		
Adiclair® Film-coated tablets	–	Supplementary therapy to reduce or eliminate gastrointestinal yeast reservoirs: 1-2 film-coated tablets 3 times daily	Until the disease risk has passed
Adiclair® Nystatin Mouth Gel	1 g Mouth Gel 3-6 times daily, in severe cases every 2 hours, respectively		At least 2 days after symptoms have subsided (up to 28 days)
	Diaper dermatitis, interdigital mycoses, fungal infections of the large skin folds (Candidosis intertriginosa)		
Adiclair® Ointment	Use 2-3 times daily, also more frequently in severe cases		Continue for a further 8-10 days after symptoms have subsided
	Intestinal fungal infections		
	Infants	**Children and adults**	
Adiclair® Suspension	1-2 ml of suspension 3-6 times a day	–	At least 2 weeks
Adiclair® Film-coated tablets	–	2 film-coated tablets 3 times daily, if required up to 12 coated tab. daily	At least 2 weeks
	–	during therapy with medications which favour yeast growth (such as: cytostatics, corticosteroids or antibiotics): 1 film-coated tablet 3 times daily	Until the disease risk has passed
	Oral thrush, vaginal mycoses		
Adiclair® Film-coated tablets	Supplementary therapy to reduce or eliminate gastrointestinal yeast reservoirs: 1-2 film-coated tablets 3 times daily		Until the disease risk has passed

Adiclair® Active Pharmaceutical Ingredient: Nystatin

Adiclair® Film-coated tablets. Qualitative and quantitative composition: 1 Adiclair® Film-coated tablet contains 500,000 I.U. nystatin. Other excipients: lactose monohydrate; stearic acid (Ph. Eur.); magnesium stearate, Povidone K 25; talc; propylene glycol; poly(O-carboxymethyl) starch, sodium salt; hypromellose; titanium dioxide; cellulose powder; colloidal silicon dioxide; iron(III)-hydroxide oxide x H_2O. **Indications:** For topical therapy of proven nystatin-sensitive, intestinal yeast infections, in particular after or during therapy with cytostatic drugs, corticosteroids or antibiotics. For the elimination or reduction of gastrointestinal yeast reservoirs as a supplement to local therapy of existing oral or vaginal yeast infections. **Contraindications:** hypersensitivity to the active ingredient nystatin or one of the other excipients of this medicine. **Precautions for use:** due to the high osmolarity of nystatin, use in very underweight and premature babies is not advised. Pregnancy and breast-feeding: nystatin is hardly absorbed in therapeutic doses after oral administration, by the intact skin or the mucous membranes. Nystatin does not pass the placental barrier and transfer into the breast milk is also not to be expected. Adiclair® can be used during pregnancy and breastfeeding. **Side effects:** daily doses which are too high can occasionally temporarily favour gastrointestinal disturbances in sensitive patients. Stevens-Johnson syndrome has only been rarely observed (fever and painful blistering of skin and mucous membranes). In rare cases, allergic reactions of the skin and mucous membranes have been observed. **Warnings:** contains lactose. Do not store above 30 °C. Store the blister strips in the outer carton. Status: 07.2015

Adiclair® Suspension. Qualitative and quantitative composition: 1 ml suspension contains: 100,000 I.U. nystatin. Other excipients: methyl-4-hydroxybenzoate (Ph. Eur.), propyl-4-hydroxybenzoate (Ph. Eur.), glycerol, sucrose, highly dispersed silicon dioxide, raspberry flavouring, purified water. **Indications:** For the topical treatment of nystatin-sensitive yeast infections of the mouth and throat, the oesophagus and the gastrointestinal tract (Candida infection). **Contraindications:** hypersensitivity to nystatin, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate or one of the other excipients of this medicine. **Precautions for use:** due to the high osmolarity of nystatin, use in very underweight and premature babies is not advised. Adiclair® can damage the teeth (caries). Nystatin is hardly absorbed in therapeutic doses after oral administration, by the intact skin or the mucous membranes. Nystatin does not pass the placental barrier and transfer into the breast milk is also not to be expected. Adiclair® Suspension can be used during pregnancy and breastfeeding. **Side effects:** in general, the nystatin contained in Adiclair® Suspension is well tolerated after oral application. In rare cases, allergic reactions of the skin and mucous membranes have been observed. Stevens-Johnson syndrome has only been rarely observed. Methyl-4-hydroxybenzoate (E 216) and propyl-4-hydroxybenzoate (E218) can cause hypersensitivity reactions, also late reactions, **Warnings:** contains parabens E 216 and E 218, contains sucrose (sugar). Do not store above 30 °C. After opening, the product has a shelf-life of 6 months. Shake well before use! Store the bottle in the outer carton. Status: 07.2015

Adiclair® Nystatin Mouth Gel. Qualitative and quantitative composition: 1 g Mouth Gel contains: 100,000 I.U. nystatin. Other excipients: methyl-4-hydroxybenzoate (Ph. Eur.), propyl-4-hydroxybenzoate (Ph.EUR.), glycerol, sucrose, hyetellose, raspberry flavouring, purified water. **Indications:** nystatin-sensitive yeast infections of the oral cavity (oral thrush). **Contraindications:** hypersensitivity to nystatin, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate or one of the other excipients of Adiclair® Nystatin Mouth Gel. In the case of hypersensitivity to nystatin or one of the other excipients (e.g. burning, itching), discontinue using the product. Experience in patients treated with cytostaticsis not available. **Precautions for use:** due to the high osmolarity of nystatin, use in very underweight and premature babies is not advised. Adiclair® Nystatin Mouth Gel can harm the teeth (caries). Due to its molecular size, nystatin is not absorbed after oral administration in normal doses, does not pass the placental barrier, and transfer into the breast milk is also not to be expected. **Side effects:** Due to its molecular size, nystatin is not absorbed after oral administration in normal doses, so that systemic side effects are not to be expected. At extremely high doses, occasionally nausea, or more rarely vomiting and diarrhoea can occur. In this case, discontinue using the drug. In rare cases, allergic reactions may occur during local application of nystatin, which can manifest themselves as itching, redness, papules, blisters but also extending beyond the contact areas (so called spreading reactions). Stevens-Johnson syndrome has only been rarely observed. Methyl-4-hydroxybenzoate (E 216) and propyl-4-hydroxybenzoate (E 218) can cause hypersensitivity reactions, also late reactions. **Warnings:** contains parabens E 216 and E 218, contains sucrose (sugar). Do not store above 25 °C. Usability of the tube after first opening: 28 days. Status: 02.2015

Adiclair® Ointment. Qualitative and quantitative composition: 1 g ointment contains: 100,000 I.U. nystatin. Other excipients: viscous paraffin, zinc oxide, polyethylene. **Indications:** for the treatment skin infections with nystatin-sensitive yeasts, especially mycoses in the nappy area (diaper dermatitis). **Contraindications:** Adiclair® Ointment should not be used in known hypersensitivity to nystatin or one of the other excipients of the preparation. **Precautions for use:** due to the high osmolarity of nystatin use in very underweight and premature babies is not advised. Nystatin is hardly absorbed in therapeutic doses after oral administration, by the intact skin or the mucous membranes. Nystatin does not pass the placental barrier and transfer into the breast milk is also not to be expected. Adiclair® can be used during pregnancy and breastfeeding. **Side effects:** the nystatin contained in Adiclair® Ointment is generally well tolerated following external application. In rare cases, hypersensitivity reactions may be observed. **Warnings:** Do not store above 25 °C. Usability of the tube after first opening: 6 month. Status: 07.2015

Adiclair® Cream. Qualitative and quantitative composition: 1 g cream contains: 100,000 I.U. Nystatin. Other excipients: methyl 4-hydroxybenzoate (Ph. Eur.) as preservative, Macrogol stearate 2000, Macrogol stearate 5000, cetyl alcohol (Ph. Eur.), sorbitan sesquioleate, glycerol monostearate, viscous paraffin, propylene glycol, purified water. **Indications:** skin infections with nystatin-sensitive yeasts. **Contraindications:** Adiclair® Cream should not be used in known hypersensitivity to nystatin, methyl 4-hydroxybenzoate (paraben) or one of the other excipients of this medicine. **Precautions for use:** due to the high osmolarity of nystatin use in very underweight and premature babies is not advised. Cetyl alcohol can cause localised skin irritation (e.g. contact dermatitis). Propylene glycol can cause irritation of the skin Due to its molecular size, nystatin is not absorbed after oral administration in normal doses, does not pass the placental barrier, and transfer into the breast milk is also not to be expected. Adiclair® can be used during the pregnancy and breastfeeding. **Side effects:** the nystatin contained in Adiclair® is generally well tolerated following external application. In rare cases, hypersensitivity reactions may be observed. Methyl 4-hydroxybenzoate (E 218) can cause hypersensitivity reactions, also late reactions. **Warnings:** contains paraben (E 218), cetyl alcohol and propylene glycol. Usability of the tube after first opening: 6 month. Do not store above 25 °C. Status: 07.2015.

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