

Annex 24
to the Procedure for Conducting Expert
Evaluation of Registration Materials Pertinent
to Medicinal Products Submitted for the State
Registration (Re-registration) and for Expert
Evaluation of Materials about Introduction of
Changes to Registration Materials during the
Validity Period of Registration Certificate
(item 2 of section V)

LIST
of excipients to be obligatory specified on package and information to be
stated in instructions for medical use of medicinal product

| Name of excipient | Substance code | Route of Administration | Threshold | Information in instructions for medical use |
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| Azo colouring agents: tartrazine sunset yellow FCF azorubine, carmoisine amaranth ponceau 4R red, cochineal red A brilliant black BN, black PN | E 102 E 110 E 122 E 123 E 124 E 151 | Oral | Zero | May cause allergic reactions. |
| Aprotinin | | Topical | Zero | May cause hypersensitivity or severe allergic reactions. |
| Aspartame | E 951 | Oral | Zero | Contains a source of phenylalanine, may be harmful for people with phenylketonuria. |
| Benzalkonium chloride | | Ocular | Zero | May cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses. |
| | | Topical | | Irritant, may cause skin reactions. |
| | | Respiratory | 10 micrograms/dose | May cause bronchospasm. |
| Bergamot oil Bergapten | | Topical | Zero | May increase sensitivity to UV light (natural and artificial sunlight). |
| Bronopol | | Topical | Zero | May cause local skin reactions (e.g. contact |

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| | | | | dermatitis). |
| Butylated hydroxytoluene | E 321 | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. |
| Butylated hydroxyanisole | E 320 | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. |
| Galactose | | Parenteral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product |
| | | Oral | Zero | If you have been diagnosed with an intolerance to some sugars contact your doctor before taking this medicinal product |
| | | Oral Parenteral | 5 g | |
| Heparin (as an excipient) | | Parenteral | Zero | May cause allergic reactions and may affect the blood clotting system. Patients with a history of heparin-induced allergic reactions should avoid the use of heparin-containing medicines. |
| Glycerol | | Oral | 10g/dose | May cause headache, stomach upset and diarrhoea |
| | | Rectal | 1 g | May have a mild laxative effect. |
| Glucose | | Oral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product |
| | | Oral Parenteral | 5 g | Contains ... g glucose per dose. This should be taken into account in patients with diabetes |

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| | | | | mellitus. |
| | | Oral liquids, pastilles, lozenges and chewable tablets | Zero | May be harmful to the teeth. |
| Dimethyl sulphoxide | | Topical | Zero | May be irritant to the skin. |
| Ethanol (alcohol) | | Oral and Parenteral | Less than 100 mg/dose | This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg/dose. |
| | | | 100 mg – 3 g/dose | This medicinal product contains ... vol % ethanol (alcohol), i.e. up to ... mg per dose, equivalent to ... ml beer, ... ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and patients with liver disease, or epilepsy. |
| | | Oral and Parenteral | 3 g/dose | This medicinal product contains ... vol % ethanol (alcohol), i.e. up to ... mg per dose, equivalent to ... ml beer, ... ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and patients with liver disease or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines. The amount of alcohol in this medicinal product may impair your ability to drive or use machines. |

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| Potassium | | Parenteral | Less than 1 mmol/dose | This medicine contains potassium, less than 1 mmol (39 mg)/dose, i.e. essentially 'potassium-free'. |
| | | Parenteral Oral | 1 mmol/dose | This medicine contains ... mmol (or ... mg) potassium/dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet. |
| | | Parenteral (intravenous) | 30 mmol/l | May cause pain at the site of injection. |
| Benzoic acid and benzoates: benzoic acid sodium benzoate potassium benzoate | E 210 E 211 E 212 | Topical | Zero | Mildly irritant to the skin, eyes and mucous membranes. |
| | | Parenteral | Zero | May increase the risk of jaundice in newborn babies. |
| Sorbic acid and salts | | Topical | Zero | May cause local skin reactions, (e.g. contact dermatitis). |
| Wheat starch | | Oral | Zero | Suitable for people with coeliac disease. Patients with wheat allergy (different from coeliac disease) should not take this medicine. |
| Xylitol | | Oral | 10 g | May have a laxative effect. Calorific value 2.4 kcal/g xylitol. |
| Lactitol | E 966 | Oral | Zero | If you have been diagnosed with an intolerance to some sugars contact your doctor before taking this medicinal product. |
| | | | 10 g | May have a mild laxative effect. Calorific value 2.1 kcal/g lactitol. |
| Lactose | | Oral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product. |
| | | | 5 g | Contains ... g lactose (.../2 g glucose and .../2 |

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| | | | | g galactose) per dose. This should be taken into account in patients with diabetes mellitus. |
| Lanolin | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis). |
| Latex Natural Rubber | | All | Zero | The container of this medicinal product contains latex rubber. May cause severe allergic reactions. |
| Maltitol Isomaltitol Maltitol Liquid (Hydrogenated Glucose Syrup) | E 965 E 953 | Oral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product. |
| | | | 10 g | May have a mild laxative effect. Calorific value 2.3 kcal/g maltitol (or isomaltitol). |
| Mannitol | E 421 | Oral | 10 g | May have a mild laxative effect. |
| Sodium | | Parenteral | Less than 1 mmol/dose | This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'. |
| | | Oral Parenteral | 1 mmol/dose | This medicinal product contains ... mmol (or ... mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet. |
| Arachis oil (peanut oil) | | All | Zero | Medicinal product contains arachis oil (peanut oil). If you are allergic to peanut or soya, do not use this medicinal product. |
| Sesame oil | | All | Zero | May rarely cause severe allergic reactions. |
| Castor oil polyoxyl and castor oil polyoxyl hydrogenated | | Parenteral | Zero | May cause severe allergic reactions. |
| | | Oral | Zero | May cause stomach upset and diarrhoea. |
| | | Topical | Zero | May cause skin reactions. |

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| Soya oil (and Hydrogenated Soya oil) | | All | Zero | Medicinal product contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product. |
| Organic Mercury compounds For example Thiomersal Phenylmercuric nitrate Phenylmercuric acetate Phenylmercuric borate | | Ocular | Zero | May cause allergic reactions. |
| | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis) and discolouration |
| | | Parenteral | Zero | This medicinal product contains (thiomersal) as a preservative and it is possible that you/your child may experience an allergic reaction. Tell your doctor if you/your child have/has any known allergies. |
| Parahydroxybenzoates and their esters: Ethylhydroxybenzoate Propylhydroxybenzoate Sodium propylhydroxybenzoate Methylhydroxybenzoate Sodium methylhydroxybenzoate | E 214 E 216 E 217 E 218 E 219 | Oral | Zero | May cause allergic reactions (possibly delayed). |
| | | Ocular Topical Parenteral Respiratory | Zero | |
| Balsam of Peru | | Topical | Zero | May cause skin reactions. |
| Propylene glycol and esters | | Topical | Zero | May cause skin irritation. |
| | | Oral Parenteral | 400mg/kg (adults) 200mg/kg (children) | May cause alcohol-like symptoms. |
| Sorbitol | E 420 | Oral Parenteral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product. |
| | | Oral | 10 g | May have a mild laxative effect. Calorific value 2.6 kcal/g sorbitol |
| Benzyl alcohol | | Parenteral | less | Must not be given to premature babies or neonates. |

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| | | | than 90 mg/kg/day | May cause toxic reactions and allergic reactions in infants and children up to 3 years old. |
| | | | 90mg/kg/day | Must not be given to premature babies or neonates. Due to the risk of fatal toxic reactions, this product should not be used in infants and children up to 3 years old. |
| Stearyl alcohol | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis). |
| Cetyl alcohol | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis). |
| Cetostearyl alcohol | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis). |
| Sulphites including metabisulphites For example: sulphur dioxide sodium sulphite sodium bisulphite Sodium metabisulphite Potassium metabisulphite Potassium bisulphite | E 220 E 221 E 222 E 223 E 224 E 228 | Oral Parenteral Respiratory | Zero | May rarely cause severe hypersensitivity reactions and bronchospasm. |
| Phenylalanine | | All | Zero | This medicine contains phenylalanine. May be harmful for people with phenylketonuria. |
| Formaldehyde | | Topical | Zero | May cause local skin reactions (e.g. contact dermatitis). |
| | | Oral | Zero | May cause stomach upset and diarrhoea. |
| Fructose | | Oral Parenteral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product. |
| | | | 5 g | Contains ... g fructose per dose. This should be taken into account in patients with diabetes mellitus. |
| | | Oral liquids, | Zero | May be harmful to the |

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| | | pastilles, lozenges and chewable tablets | | teeth. |
| Chlorocresol | | Topical Parenteral | Zero | May cause allergic reactions. |
| Invert sugar | | Oral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product . |
| | | | 5 g | Contains ... g of a mixture of fructose and glucose per dose. This should be taken into account in patients with diabetes mellitus. |
| | | Oral liquids, pastilles, lozenges and chewable tablets | Zero | May be harmful to the teeth. |
| Sucrose | | Oral | Zero | If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product. |
| | | | 5 g | Contains ... g of sucrose per dose. This should be taken into account in patients with diabetes mellitus. |
| | | Oral liquids, pastilles, lozenges and chewable tablets | Zero | May be harmful to the teeth. |

{Annex 24 in wording of MoH Ukraine Order №460 as of 23.07.2015 }