

Annex 23
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
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 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	5 g	Contains ... g glucose per dose. This should be

		Parenteral		taken into account in patients with diabetes 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.
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 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.
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	Zero	May cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
Respiratory				
Balsam of Peru		Topical	Zero	May cause skin reactions.
Propylene glycol and esters		Topical	Zero	May cause skin irritation.
		Oral	400mg/kg (adults)	May cause alcohol-like symptoms.
		Parenteral	200mg/kg (children)	
Sorbitol	E 420	Oral	Zero	If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicinal product.
		Parenteral		
		Oral	10 g	May have a mild laxative effect. Calorific value 2.6

				kcal/g sorbitol
Benzyl alcohol		Parenteral	less than 90 mg/kg/day	Must not be given to premature babies or neonates. 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, pastilles, lozenges and chewable tablets	Zero	May be harmful to the 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}