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
Azo colouring agents: tartrazine sunset yellow FCF azorubine, carmoisine amaranth ponceau 4R red, cochineal red A brilliant black BN,	E 102 E 110 E 122 E 123 E 124 E 151	Oral	Zero	May cause allergic reactions.
black PN 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	10	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 Parenteral	5 g	Contains g 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.
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	This medicine contains
			1 mmol/dose	potassium, less than 1
			1 1111101/ 4050	mmol (39 mg)/dose, i.e.
				essentially 'potassium-
				free'.
		Parenteral	1 mmol/dose	This medicine contains mmol (or mg)
		Oral		potassium/dose. To be
				taken into consideration
				by patients with reduced
				kidney function or
				patients on a controlled
		Parenteral	30 mmol/l	potassium diet. May cause pain at the
		Falenteral	50 1111101/1	site of injection.
		(intravenous)		
Benzoic acid and benzoates:		Topical	Zero	Mildly irritant to the
benzoic acid	E 210			skin, eyes and mucous
sodium benzoate potassium benzoate	E 211 E 212	Parenteral	Zero	membranes. May increase the risk of
potassium benzoate	L 212	r arcinci ai	Zeit	iaundice 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
			6	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
I a stage		Orel	7.00-	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.
	1	1		-
			5 g	Contains g lactose

Lanolin		Topical	Zero	g galactose) per dose. This should be taken into account in patients with diabetes mellitus. 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 Topical	Zero	May cause stomach upset and diarrhoea. May cause skin
				reactions.

Soya oil (and		All	Zero	Medicinal product
Hydrogenated Soya oil)		All	Zeio	contains soya oil. If you
riyurogenated Soya on)				are allergic to peanut or
				soya, do not use this
				medicinal product.
Organic Mercury		Ocular	Zero	May cause allergic
compounds		Oculai	Zeio	reactions.
For example		Topical	Zero	May cause local skin
Thiomersal		Topical	Zeio	reactions (e.g. contact
Phenylmercuric nitrate				dermatitis) and
Phenylmercuric acetate				discolouration
Phenylmercuric borate		Parenteral	Zero	This medicinal product
		ratemerat	Zelo	-
				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		Oral	Zero	May cause allergic
esters:			2210	reactions (possibly
Ethylhydroxybenzoate	E 214	Ocular		delayed).
Propylhydroxybenzoate	E 216	Topical		
Sodium propylhydroxybenzoate	E 217	Parenteral	Zero	May cause allergic
Methylhydroxybenzoate	E 218	i arcinciai	Zeio	reactions (possibly
Sodium methylhydroxybenzoate	E 219	Respiratory		delayed), and
				exceptionally,
				bronchospasm.
Balsam of Peru		Topical	Zero	May cause skin
		ropical	2010	reactions.
Propylene glycol and esters		Topical	Zero	May cause skin
r ropyrene grycer and esters		ropicui		irritation.
		Oral	400mg/kg	May cause alcohol-like
		Parenteral	(adults)	symptoms.
		i dicilicitai	Ì Í	
			200mg/kg	
			(children)	
Sorbitol	E 420	Oral	Zero	If you have been
				diagnosed with an
		Parenteral		intolerance to some
				sugars, contact your
				÷
				doctor before taking this
				medicinal product.
		Oral	10 g	May have a mild
				laxative effect.
				Colorific volue 2.6
				Calorific value 2.6
				kcal/g sorbitol
Benzyl alcohol		Parenteral	less	Must not be given to
				premature babies or

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Oral liquids, Zero May be harmful to the			Oral liquids,	Zero	May be harmful to the

	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}