





## **CORPUS MEDICA**



**Since 1993 year Corpus Medica, UAB** provides customer-oriented pharma services: from product development to post-marketing monitoring. Our market analysis, product development, regulatory affairs, pharmacovigilance, batch release site, logistics and marketing service helps our partners to transfer product from laboratory to Lithuania and Baltic States market.

## Corpus Medica has the following authorizations:

- GMP Manufacturing authorization and import from non-EU countries
- Good Distribution Practice (GDP) certificate
- Wholesale distribution license



REGULATORY AFFAIRS



BATCH RELEASE TESTING



PHARMACOVIGILANCE



PHARMACEUTICAL MARKETING



CLINICAL TRIALS



WAREHOUSING AND DISTRIBUTION



## **Regulatory & Product Development service**

## Product dossier pre-submission assessment and creation of strategic plan for product registration procedure

More than twenty years experience in pharma regulatory practice has shown that successful way to marketing authorization is relevant product development program along with selection of appropriate type of application and authorization procedure. We elaborate product dossier according to generic, hybrid, OTC, herbal and/or well established use type of application and handle Centralized, Decentralized (DCP) and/or National authorization procedures.

We provide for our partners:

- Pre-submission assessment of product dossier
- Scientific advice for product development program
- Selection and justification of reference product and type of application in accordance with national legislation and EU guidelines
- Elaboration of strategic plan for product registration procedure (Centralized, Decentralized (DCP) and/or National marketing authorization procedure
- Submission and management of authorization procedure

## Quality Control and Batch release service

Good Manufacturing Practice for Medicinal Products requires batch release within the European Community (EC) of medicinal products holding a marketing authorization.

We serve our partners with:

- Method transfer and Analytical exchange
- Batch release testing and analysis of various finished products to customers or pharmacopoeia release specifications
- On-site auditing of manufacturing facilities and GMP inspection prior to pre-approval agency inspection
- Comprehensive EU GMP audit report detailing the level of EU GMP compliance and suggesting actions to be implemented for compliance improvement
- Off-site auditing of Site Master File, Standards of Procedure, Validation Master File
- Qualified Person (QP) service on request

#### Pharmacovigilance service

- Registration of the Marketing authorization holder (MAH) in EudraVigilance system
- Formulation of safety report and its transmission via the EudraVigilance system
- Periodic Safety Update Report (PSUR), including harmonization and submission
- Risk Management Plan (RMP)
- Generation of Pharmacovigilance System Master File (PSMF) and creation of Module
  1.8.1 Summary of the PV system
- Writing and Maintenance of Client specific SOPs and Process Guidelines
- Fully Operational PV Safety Database System & EMEA Certified QPPV

## **CEMEX FARMA**



CeMex Farma was founded in 2009 by young and proactive pharmaceutical professionals. The pharmacists came together to offer their knowledge and provide high quality services in market research, development, registration and marketing of food supplements and cosmetic products.

High trained personnel with innovative thinking and "know-how" studies in cooperation with university academicians is a basic principal for development of new innovative food supplements and cosmetics. Our product development and contract manufacturing solutions allow us and our partners to produce a new innovative product and/or to upgrade the well known product giving new characteristics and/or use opportunities.



Being aware of the effect of nature to humans and the growing importance of herbal medicine to health, CeMex Farma introduced the first FytoLab line products to the market. FytoLab is a label of exclusively natural plant-based, high-quality products.



## PRODUCTS

#### Aroma Balm ointment 25 g

Composition

Product status Pharmaceutical form Use

Menthol/Camphor/Eucalyptus globulus oil/ Eugenia caryophyllus oil Body care product Ointment Adjuvant aid to facilitate breathing. Can be used for inhalations

## Aroma Balm Baby cream 30 ml

Composition	Lavandula Angustifolia Oil/Thymus Vulgaris Oil/ Pinus Sylvestris Oil
Product status	Body care product
Pharmaceutical form	Ointment
Use	Adjuvant aid to facilitate breathing





#### Calendula (Medetkų) ointment 25 g

Composition **Product status** Pharmaceutical form Use

Use

Calendula officinalis extract Body care product Ointment Skin care

Medetkų tepalas Barna	A CONTRACTOR
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Balsamic liniment by Vishnevsky 40 g			
cinus communis seed oil/Betula alba oil/Bismuth ıbgallate			
ody care product			
intment			



Flebofyt cream-gel 25 g Diosmin/Hesperidin and other ingredients (Urea, Composition Menthyl lactate) **Product status** Body care product Cream Pharmaceutical form Helps to maintain good venous blood flow and reduces the severity of swelling Use

Skin care



Composition Product status Pharmaceutical form Use

#### Diosfyt 500 mg tablets, N60

Diosmin/Hesperidin Food supplement Tablets Helps to maintain good venous blood flow and elasticity



## Heparsil 35 mg tablets, N80

Composition Product status Pharmaceutical form Use

Silymarin Food supplement Tablets Helps to maintain a normal liver function



**OINTMENTS** 

## **PRODUCTS**

Dionit + Fibers	nowdor for a	kal cuchanc	ion E 2E a
	powuei ioi (	ai suspens	1011 3,23 (

Composition **Product status** Pharmaceutical form Use

## Diosmectitum/Fibers

Medical device Powder for oral suspension Acute diarrhea or chronic painful gastrointestinal disorders



Composition **Product status** Pharmaceutical form Use

## Carbofyt 250mg tablets, N20

Carbo activatus Food supplement Tablets Absorbent



Cardio	(Korvalol	Fytolab)	drops 25 n	n

Composition **Product status** Pharmaceutical form Use

Alpha-bromizovaleric acid ethyl ester/Menthol	
Food supplement	
Oral drops	
Sedative	



l Fytolab tablets, N10
lenthyl isovalerate
ood supplement
ablets
edative



Sinovex arthro 32 mg solution for injection			
Composition	Sodium Hyaluronate		
Product status	Medical device		
Pharmaceutical form	Solution for injection (intra-articular)		
Use	Injected into the knee to relieve pain and de- creased articular mobility associated with dege- nerative knee lesions and other synovial joints		



Sinovex arthro 44 mg solution for injection			
Composition	Sodium Hyaluronate		
Product status	Medical device		
Pharmaceutical form	Solution for injection (intra-articular)		
Use	Injected into the knee to relieve pain and de- creased articular mobility associated with dege- nerative knee lesions and other synovial joints		



## **PRODUCTS**

TRIBUMEN 350 mg capsules, N30

Composition **Product status** Pharmaceutical form Use

Tribulus terrestris (60% protodioscin) Food supplement Capsules Helps to maintain a sexual desire and good sexual function

# Tribumen 31

## **TRIBUMEN PRO capsules, N20**

Composition

Use

Product status Pharmaceutical form

Serenoa Repens/Tribulus terrestris/Ecklonia Bicyclis K./Biovis® Food supplement Capsules Helps to maintain a good prostate and urinary function in men. Helps to maintain a sexual desire and good sexual function







Ellamé Anti-aging face mask 30 ml 1 FL.OZ x 5		
Composition	Compositum	
Product status	Skin care product	
Pharmaceutical form	Sheet mask	
Use	Skin firming and regenerating	

Ellamé Hydro Complex face mask 30 ml 1 FL.OZ x 5			
Composition	Compositum		
Product status	Skin care product		
Pharmaceutical form	Sheet mask		
Use	Skin moisturizing		



Composition **Product status** Pharmaceutical form Use

## Ellamé Scrub 30 ml Compositum Skin care product Scrub Exfoliation of the skin to keep skin smooth and glowing



Composition Product status Pharmaceutical form Use

#### Ellamé Scrub 3 ml

Compositum Skin care product Scrub Exfoliation of the skin to keep skin smooth and glowing









#### OTC PRODUCTS

No	PRODUCT	DOSSIER
1	Ambroxol 30 mg tablets	Available
2	Ambroxol 15 mg/5ml syrup, 100 ml	Available
3	Ambroxol 30 mg/5 ml syrup, 100 ml	Available
4	Diosmectite 3 g powder for oral suspension	Available
5	Diosmin 500 mg film-coated tablets	Available
б	Drotaverine 40 mg tablets	Q3 2016
7	Ibuprofen 400 mg film-coated tablets	Available
8	Ibuprofen 100 mg/5 ml syrup, 100 ml	Available
9	Omeprazole 20 mg capsules	Q3 2016
10	Pancreatin 10.000 IU film-coated tablets	Q4 2016
11	Paracetamol 120 mg/5 ml syrup, 100 ml	Q3 2016
12	Paracetamol/Acetylsalicylic acid/Caffeine 180 mg+240 mg+30 mg tablets	Q3 2016
13	Paracetamol/Pseudoephedrine hydrochloride/Dextromethorphan hydrobromide 500 mg/300 mg/15 mg film-coated tablets	Available
14	Ranitidine 150 mg film-coated tablets	Q3 2016
15	Silymarin 150 mg tablets	Available
16	Silymarin 35 mg tablets	Available
17	Vitamin $B_1 + B_6 + B_{12}$ 100 mg + 200 mg + 0,2 mg film-coated tablets	Q1 2017

#### HOSPITAL PRODUCTS

#### No PRODUCT

## DOSSIER

1	Analgin 500 mg/ml solution for injection, 2 ml	Q4 2016
2	Ascorbic acid 50 mg/ml solution for injection/infusion, 2 ml	Q4 2016
3	Cefazolin 1000 mg powder for solution for injection/infusion	Available
4	Cefepime 1000 mg powder for solution for injection/infusion	Q3 2016
5	Cefoperazone 1000 mg powder for solution for injection/infusion	Q3 2016
б	Cefoperazone/Sulbactam 1000 mg/1000 mg powder for solution for injection/infusion	Q3 2016
7	Cefotaxime 1000 mg powder for solution for injection/infusion	Q3 2016
8	Ceftazidime 1000 mg powder for solution for injection/infusion	Q3 2016
9	Ceftriaxone 1000 mg powder for solution for injection/infusion	Available
10	Ceftriaxone/Sulbactam 1000/500 mg powder for solution for injection/infusion	Q3 2016
11	Cefuroxime 750 mg powder for solution for injection/infusion	Available
12	Cefuroxime 1500 mg powder for solution for injection/infusion	Available
13	Dexamethasone 4 mg/ml solution for injection, 1 ml	Q3 2016
14	Diclofenac 25 mg/ml solution for injection, 3 ml	Q3 2016
15	Drotaverine 20 mg/ml solution for injection, 2 ml	Q3 2016
16	Fluconazole 2 mg/ml solution for infusion, bottle 100 ml	Available
17	Furosemide 10 mg/ml, solution for injection, 2 ml	Q3 2016
18	Glucose 50 mg/ml solution for infusion, bottle 250 ml/500 ml	Available
19	Ketorolac 30 mg/ml solution for injection/infusion, 1 ml	Q4 2016
20	Magnesium sulfate 250 mg/ml solution for injection, 5 ml	Available
21	Metronidazole 2 mg/ml solution for infusion, bottle 100 ml	Available
22	Ondansetron 8 mg/4 ml solution for injection/infusion, 4 ml	Q3 2016
23	Sodium chloride 9 mg/ml solution for injection, 5 ml	Available
24	Sodium chloride 9 mg/ml solution for infusion, bottle 250 ml/500 ml	Available
25	Vitamin $B_1 + B_6 + B_{12}$ 100 mg + 100 mg + 1 mg solution for injection, 2 ml	Q4 2016

