A Polish Biotechnology Company
Expert in Probiotics and Vaccines

Products catalogue
We have been operating in the pharmaceutical market for over sixty-five years!

We develop exceptional products for women and children – the result of synergy between our expertise and knowledge of reputable scientific centres, and the latest technologies put into practice.

We are experts in the development and production of preventive vaccines and unique non-specific vaccines.

The Company’s History
- 1945 – a Vaccine Production Plant is established in Krakow
  - operation is based on the knowledge and expertise of Odo Bujwid – a student of Koch and Pasteur, and a pioneer in the production of Polish vaccines
    - first Polish preventive vaccines
    - first Polish probiotic
    - products for specific immune therapy (allergens)
    - products for diagnostic purposes
- 2001 – privatization

Areas of cooperation
- R&D of company’s own products
  - clinical trials
  - registration
- Production
  - company’s own products
  - additional option: contract manufacturing and research
- Sales and marketing
  - Polish market
- Exports
- Imports
ALIMENTARY SYSTEM

Lactoral
Orsalit

ALLERGY

Latopic

IMMUNE SYSTEM

Polyvaccinum submite, mite, forte (suspension for injection)
Polyvaccinum mite (nasal drops)
Pseudovac

UROGENITAL SYSTEM

HydroVag
inVag
Lactovaginal
prOVag
prOVag gel

PREVENTIVE VACCINES

Clodivac
Tetana
Alimentary System

Lactoral

Description: Product contains 3 strains of exceptionally valuable lyophilized living lactic acid bacteria: *Bifidobacterium longum* PL 03, *Lactobacillus rhamnosus* KL 53A, *Lactobacillus plantarum* PL 02. These bacteria are natural inhabitants of the alimentary tract in infants, children and adults and are highly desirable for them.

Indications: Lactic acid bacteria are usually recommended to be consumed auxiliary: during and after antibiotic treatment, to support the proper intestinal motor activity, to support the cell-mediated immunity, to support the protective function of the human intestinal barrier, to support the work of the digestive tract in case of intestinal microflora disturbances. Lactic acid bacteria are an essential component of the normal intestinal microflora. Situations, which may lead to the decreased number of lactic acid bacteria, are for example: antibiotic treatment, loose stools, stress or travels.

Storage: Store in a refrigerator (2°C - 8°C)

Status: Food supplement

Shelf life: 24 months

Form: Powder to dissolve in water

Packaging: 10 sachets in a cardboard box with a leaflet
Orsalit

Description: Orsalit is an oral rehydration solution (ORS) with reduced osmolarity. Using ORS is recommended by ESPGHAN and WHO/UNICEF to supplement body fluids and mineral substances mainly during diarrhoea and/or vomiting.

Indications: Orsalit is intended for the dietary management of body dehydration, especially during diarrhoea and/or vomiting and in situations associated with a risk of dehydration. The product supplements body fluids and mineral substances in case of water-electrolyte balance disturbances. Orsalit provides effective rehydration as it uses the most effective mechanism of common absorption of water, sodium and glucose.

Storage: Store at room temperature

Status: Dietary food for special medical purpose

Shelf life: 36 months

Form: Powder to dissolve in water

Packaging: 10 sachets, a plastic container for water measuring and two straws in a cardboard box with a leaflet
Allergy

Latopic

Description: Latopic contains three carefully selected Lactobacillus strains from the lactic acid bacteria group: *Lactobacillus paracasei* LOCK 0919, *Lactobacillus casei* LOCK 0908, *Lactobacillus casei* LOCK 0900.

Indications: Latopic is intended for dietary management of food allergy and atopic dermatitis (AD). Food allergy (allergy to cow’s milk, eggs, soya) is manifested as AD. Skin lesions with itching are typical in atopic dermatitis. The intestinal barrier was proved to be weakened in atopic dermatitis patients, and may become more permeable to allergens. Lactic acid bacteria may help recover the intestinal barrier function, stimulate mucus secretion, and maintain microbiological and immunological balance. This is why lactic acid bacteria may have a positive effect on the course of atopic dermatitis.

Storage: Store in a refrigerator (2°C - 8°C)

Status: Dietary food for special medical purpose

Shelf life: 18 months

Form: Powder to dissolve in water

Packaging: 10 sachets in a cardboard box with a leaflet; 30 sachets in a cardboard box with a leaflet
Poyvaccinum submite, mite, forte
(suspension for injection)

Description: Non-specific bacterial vaccine contains inactivated bacteria: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus salivarius*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, *Corynebacterium pseudodiphtheriticum*, *Moraxella catarrhalis*. Individual vaccines differ by tenfold in the number of bacterial cells.

Indications: Therapeutic and prophylactic use:

- administer in case of long-lasting, chronic and recurrent inflammatory conditions of upper and lower airways including paranasal sinusitis, rhinopharyngitis, recurrent laryngitis, tracheitis, bronchitis (prophylactic treatment is recommended in the remission period) and otitis media.

Adjunctive treatment

- administer in case of chronic bladder, vagina, adnexa and endometrium inflammations.

Storage: Store in a refrigerator (2°C - 8°C)

Status: Medicinal product (Rx) - Dossier in CTD format.

Shelf life: 18 months

Form: Suspension for intramuscular injections

Packaging: 5 glass ampoules (type I) of 1 ml suspension each in a cardboard box with a leaflet.
Non-specific bacterial vaccine contains inactivated bacteria: *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus salivarius, Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Klebsiella pneumoniae, Haemophilus influenzae, Corynebacterium pseudodiphtheriticum, Moraxella catarrhalis*, which most frequently cause upper respiratory tract infections or which accompany upper respiratory tract inflammations.

The vaccine acts as an immunostimulator enhancing general nonspecific activity of the immune system intensifying the anti-infectious immunity. At the same time it induces specific immunity against bacteria, which antigens are contained in the vaccine. In this way the vaccine protects against recurrent upper respiratory tract infections.

Store in a refrigerator (2°C - 8°C)

Medicinal product (Rx) - Dossier in CTD format.

18 months

Nasal drops, suspension

10 ml suspension in a bottle (amber glass, type III) with a screw cap and a dropper (polypropylene and thermoplastic elastomer) in a cardboard box with a leaflet.
Immune System

Pseudovac

Description: Specific vaccine against blue pus bacterium *Pseudomonas aeruginosa*, including equal aliquots of supernatants containing structural and extracellular antigens of killed *Pseudomonas aeruginosa* strains. Strains are cultivated on a synthetic medium and represent 7 clinically important immunotypes.

Indications: Prophylactic treatment:
- in order to achieve active immunity against infections caused by *P. aeruginosa*.

Therapeutic treatment:
- in case of existing infections caused by *P. aeruginosa*, in order to augment specific immunity and lower the risk of development of bacteraemia and septicaemia.

Storage: Store in a refrigerator (2°C - 8°C)

Status: Medicinal product (Rx) - Dossier in CTD format

Shelf life: 18 months

Form: Solution for injections

Packaging: 5 glass ampoules (type I) of 1 ml solution each in a cardboard box with a leaflet
## Urogenital System

### HydroVag

<table>
<thead>
<tr>
<th>Description:</th>
<th>HydroVag contains: 10 mg of sodium hyaluronate, glycogen, lactic acid. Hydrates and regenerates the vaginal mucosa, alleviates irritations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications:</td>
<td>HydroVag is indicated:</td>
</tr>
<tr>
<td></td>
<td>- to alleviate the sensation of dryness and discomfort and to support the regeneration of vaginal mucosa,</td>
</tr>
<tr>
<td></td>
<td>- in conditions of atrophy and dystrophy caused by oestrogen deficiency,</td>
</tr>
<tr>
<td></td>
<td>- during perimenopausal period and after hormonal therapy,</td>
</tr>
<tr>
<td></td>
<td>- after radiotherapy and chemotherapy,</td>
</tr>
<tr>
<td></td>
<td>- to stimulate wound healing after childbirth and after gynaecological procedures,</td>
</tr>
<tr>
<td></td>
<td>- to alleviate pain and discomfort in painful sexual intercourse,</td>
</tr>
<tr>
<td></td>
<td>- to help to restore the normal bacterial flora and pH level in the vagina, after antibiotic treatment, etc.</td>
</tr>
<tr>
<td>Storage:</td>
<td>Store at room temperature</td>
</tr>
<tr>
<td>Status:</td>
<td>Medical device intended for vaginal use</td>
</tr>
<tr>
<td>Shelf life:</td>
<td>24 months</td>
</tr>
<tr>
<td>Form:</td>
<td>Oval vaginal pessaries</td>
</tr>
<tr>
<td>Packaging:</td>
<td>1 blister pack with 7 pessaries in a cardboard box with a leaflet</td>
</tr>
</tbody>
</table>
inVag

Description: inVag contains a lyophilised suspension of living lactic acid bacteria: *Lactobacillus gasseri 57C, Lactobacillus fermentum 57A, Lactobacillus plantarum 57B.*

Indications: inVag is used in women to restore or supplement normal vaginal flora and to maintain the correct pH in the vagina. The product is recommended:

- in prevention of genitourinary tract infections: during and after systemic therapies with antibiotics and other antibacterial, antitrichomonal and antifungal drugs, during menopause and after puerperium,
- in prophylaxis in all conditions which can lead to disorders of vaginal flora (for example improper hygienic and sexual habits, contraception),
- in supportive treatment of vaginal inflammations (vaginal infections),
- during and after treatment with antibiotics, other antibacterial and (or) antifungal drugs (including the treatment of vaginal discharge).

Storage: Store in a refrigerator (2°C - 8°C)

Status: Medicinal product (OTC) - Dossier in CTD format.

Shelf life: 18 months

Form: Vaginal capsules

Packaging: 1 blister with 7 capsules in a cardboard box with a leaflet
**Description:**
Lactovaginal contains living lactic acid bacteria *Lactobacillus rhamnosus 573*, which are lyophilized on a milk-saccharose carrier containing monosodium glutamate.

**Indications:**
Lactovaginal is recommended to restore or supplement the normal bacterial flora of the vagina:
- in prophylaxis,
- in inflammatory states of genital tract, following the treatment with antibacterial, trichomonadicidal, antifungal medicines,
- in the occurrence of vaginal discharge.

**Storage:**
Store in a refrigerator (2°C - 8°C)

**Status:**
Medicinal product (OTC) - Dossier in CTD format.

**Shelf life:**
24 months

**Form:**
Vaginal capsules

**Packaging:**
1 blister with 10 capsules in a cardboard with a leaflet
**proVag**

**Description:**
proVag contains lyophilized, living lactic acid bacteria: *Lactobacillus gasseri 57C*, *Lactobacillus fermentum 57A*, *Lactobacillus plantarum 57B*. These bacteria in a natural way migrate from the lower part of the gastrointestinal tract and colonise the vagina. Thanks to their properties, they influence on the microbiological balance and maintain the proper vaginal pH. proVag is intended for women and girls for the dietary management of urogenital flora disturbances.

**Indications:**
proVag is recommended for the dietary management: auxiliary for daily supplementation of the normal urogenital bacterial flora and for maintaining the appropriate vaginal pH; auxiliary, in secondary and recurrent female disorders caused by the presence of pathogenic bacteria and fungi in the vagina; during and after the use of antibacterial medicines (including during and after general and locally applied antibiotic therapy); during and after the use of antitrichomonal and antimycotic medicines; during and after treatment with metronidazole; in order to rebuild the normal bacterial flora of the urogenital system and restoration the proper vaginal pH, during the perimenopausal period (climacterium); during and after menstruation; during confinement; for women before and after medical interventions within the urogenital system; for women who attend swimming pools, travel frequently, use a jacuzzi and solarium.

**Storage:**
Store in a refrigerator (2°C - 8°C)

**Status:**
Dietary food for special medical purposes

**Shelf life:**
24 months

**Form:**
Capsules

**Packaging:**
1 blister with 10 capsules in a cardboard box with a leaflet;
2 blisters with 10 capsules each in a cardboard box with a leaflet
Urogenital System

proVag Gel

Description: Gel for protection and care of intimate areas. prOVag gel is recommended for women and children prone to irritations and microbiological imbalances of intimate areas. prOVag gel protects microbiological balance of the intimate areas by maintaining appropriate acidity and has an anti-bacterial activity.

Composition: Lactobacillus ferment, propylene glycol, glycerin, hydroxypropyl methylcellulose, phenethyl alcohol, caprylyl glycol, parfum.

Indications: proVag gel is particularly indicated:
- to maintain proper intimate hygiene,
- to alleviate symptoms of irritations of the external genital area,
- supportively in states of increased risk of indisposition, especially:
  - in antibiotic therapy (oral as well as vaginal),
  - in travel and when hygiene conditions are poor,
  - in immunocompromised states,
  - after menstruation,
  - in climacterium.

Storage: Store at room temperature

Status: Cosmetic

Shelf life: 24 months

Form: Gel

Packaging: 30 g Airless container in a cardboard box with a leaflet
### Preventive Vaccines

#### Specific Vaccines

<table>
<thead>
<tr>
<th>Trade name:</th>
<th>Tetana</th>
<th>Clodivac</th>
</tr>
</thead>
</table>
| **Description:** | Vaccinum tetani adsorbatum.  
Tetanus vaccine, adsorbed.  
1 dose (0.5 ml) contains no less than 40 IU adsorbed tetanus toxoid. | Vaccinum diphtheriae et tetani, antigenio minutum, adsorbatum.  
Diphtheria and tetanus vaccine adsorbed, with reduced antigen content.  
1 dose (0.5 ml) contains no less than 40 IU adsorbed tetanus toxoid and 5 IU adsorbed diphtheria toxoid. |
| **Indications:** | Tetana is indicated for active immunization against tetanus in children, adolescents and adults | Clodivac is indicated for active immunisation of adolescents and adults against tetanus and diphtheria |
| **Storage:** | Store in a refrigerator (2°C - 8°C) | Store in a refrigerator (2°C - 8°C) |
| **Status:** | Medicinal product (Rx) – Dossier in CTD format | Medicinal product (Rx)– Dossier in CTD format |
| **Shelf life:** | 36 months | 36 months |
| **Form:** | 0,5 ml of suspension for injection in a type I glass ampoule | 0,5 ml of suspension for injection in a type I glass ampoule |
| **Packaging:** | 1 ampoule in a cardboard box with a leaflet; 5 ampoules in a cardboard box with a leaflet | 1 ampoule in a cardboard box with a leaflet; 15 ampoules in a cardboard box with a leaflet |
We welcome all companies interested in cooperation to contact:

IBSS BIOMED S.A.
Al. Sosnowa 8
30-224 Kraków
POLAND

phone: +48 12 37 69 200
fax: +48 12 37 69 205
biomed@biomed.pl
www.biomed.pl

Business Development Unit
phone: +48 12 37 69 344
fax: +48 12 37 69 205
bdu@biomed.pl