MEDICAL DEVICES

NASAL

OTIC

THROAT
BIOFAKTOR sp. z o.o. – the best quality since 2000.

Biofaktor was one of the first GMP certified pharmaceutical manufacturer in Poland.

Respecting the agriculture values and taking care of the surrounding environment are the fundaments of our business activity. Since 2000, we have manufactured and introduced numerous of medicinal products. RX veterinary medicines, medical devices and dietary supplements have become our specialty.

Human pharmaceuticals and supplements division of contract manufacturing business has been developing successfully since 2006. In case of the human products, Biofaktor manufactures and distributes under the Private Label of our clients.

Biofaktor has two manufacturing plants located in Gorzów Wielkopolski for solid dosage forms and in Skierniewice where liquid forms are produced.

Both plants work in pharma GMP quality standards.
We have been implementing a modern line of eye and ear drops production. The solution preparation section has an extremely flexible construction consisting of two main mixers and two buffer tanks. The entire solution preparation line is closed with sterile conditions inside. The main mixers have a capacity of 300L and 1000L. The capacity of each buffer tank is 1000L. It is possible to freely combine the product path between the tanks.

The final sterilization is carried out by the sterilizing filtration.

The use of the above configuration of mixers and buffer tanks, apart from flexibility, also allows achieving large production capacities due to the possibility of preparing the next batch simultaneously with the previous filling.

It is also possible to introduce sterile nitrogen into the system to remove air.

The solutions are being packed by a fully automated dispensing line. The packaging of the solution takes place in the cleanliness class A for sterile direct packaging. We have a wide range of packaging formats for drops or spray.

The most important of the proposed direct packaging is the 3K system. It is the most modern dispensing system for eye drops, which ensures sterility of the solution remaining in the package. Due to that system, we can produce eye preparations without preservatives. 3K dispensers can be combined with bottles of different capacities.

Additionally to the 3K dispensers, there are also overlays that facilitate handling of the dispenser as well as improving the appearance of the packaging.

Filled direct containers are being packed in properly selected cartons and supplemented with a leaflet for the patient.

The entire process, starting with dispensing the solution to placing the cartons on the pallet, takes place completely automatically without the participation of operators.

The maximum filling capacity reaches up to 200 packages per minute. With the most complex packaging combination, the production speed does not drop below 100 packages per minute.

Since the beginning, our production line was designed in order to guarantee high flexibility and easy adaptation to various types of products manufactured for our clients. Therefore, both devices in the solution preparation section as well as in the packaging section show wide configuration possibilities allowing the best adaptation of the line.

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Nasal medical devices

„RHINO” LINE

Pharmaceutical form – Aerosol (Spray)
20 ml or 10 ml package with a dosing pump

Rhino line offers twelve formulations intended for solving the most commonly occurring nasal mucosa health problems, such as:
Drying out of mucous membrane as a result of exposure to dry air (from central heating or air-conditioning),
• The build-up of excess thick secretion (occasionally dry), which is difficult to naturally remove from the nasal cavity (by blowing the nose),
• Mucous membrane swelling, associated with various types of inflammation,
• Mucosal injury caused by drying out or chronic inflammation

Health issues listed above can lead directly to dysosmia, dysgeusia, respiratory disorders and decreased oxygen supply to the tissues. General fatigue, irritation, low mood and immunodeficiency. Residual secretion in nasal cavities or prolonged inflammation can lead to lower respiratory tract health complications. Quick treatment of nasal cavity health problems is vital to keep the whole organism in good health.

Rhino line offers solutions to the above-listed health issues.

All products of the Rhino line are packaged into the bottles of 20 ml or 10 ml volume, equipped with an applicator with dosing pump producing a small-molecule aerosol.
The dosing pump has been equipped with a special mechanism preventing pollution of the product with nasal secretion when removed from the nasal cavity. There is no need to remove the tip of the applicator from the nasal cavity while administering another dose of the aerosol.
Due to the transparency of the bottle, the volume of the product left can be easily observed.
The moisturizing effect on the nasal mucosa is obtained by using aqueous isotonic solutions (Rhinaqua Natura), hypertonic sea salt water (Rhinaqua Mare) and sea salt water with the addition of glycerol (Rhinaqua Plus).

The addition of glycerol increases the viscosity of the solution and prevents quick coming of the aerosol from the nasal cavity. Hypertonic sea salt water has a stronger and more aggressive moisturizing effect than an isotonic solution since it draws the water from the blood vessels to the surface of the mucous membrane.

**Rhinaqua Natura**

The product contains an isotonic solution of sea salt with the addition of a preservative to ensure adequate stability.

- Isotonic sea water
- For daily nose hygiene
- Cleans, moisturizes and frees the nose

**Rhinaqua Mare**

The product contains a hypertonic sea salt solution (equivalent to 25 mg sodium chloride per one ml). Does not contain preservatives.

- Hypertonic sea water
- For clearing the nose
- Facilitates the removal of nasal discharge

**Rhinaqua Plus**

The product contains a sea salt solution with the addition of glycerol and a preservative.

- Sea water with glycerol, slightly hypertonic, with increased viscosity
- Thick product does not drip from the nose
- For daily nose hygiene
- Cleans, moisturizes and frees the nose
Excellent prevention against drying out of nasal mucosa is provided by sesame oil (Rhinolil) and sodium hyaluronate (Rhinobald HA), which covers nasal mucosa with a thin layer that binds water. Aloe oil extract combined with sesame oil provides additional soothing effect (Rhinolil Plus).

**Rhinolil**

- The product contains only sesame oil. Does not contain preservatives.
- For daily nose hygiene
- Oils the nasal mucosa, prevents excessive drying

**Rhinolil Plus**

- The product contains sesame oil, aloe vera extract and preservative.
- For daily nose hygiene
- Oils the nasal mucosa, prevents excessive drying
- Relieves irritations

**Rhinobald HA**

- The product contains sodium hyaluronate, preservative and purified water.
- For daily nose hygiene
- Moisturizes the nasal mucosa, prevents excessive drying
- Relieves irritations
- Promotes regeneration
In order to boost nasal mucosa recovery, it is highly recommended to use the tried and tested analogue of pantothenic acid – dexpanthenol. Its effect can be enhanced with the usage of vitamin A, which increases local resistance of the mucous membrane. Recovery is enhanced by providing proper moisture of mucous membrane, which can be reached by using sodium hyaluronate, hypromellose or glycerol.

**Rhinosid**

The product contains: dexpanthenol, glycerol, sodium hyaluronate, preservative, purified water

- Supports and promotes the regeneration of the nasal mucosa
- Moisturizes the mucous membrane and prevents excessive drying
- Relieves irritations

**Rhinoreg**

The product contains: dexpanthenol, glycerol, hypromellose, vitamin E, vitamin A, preservative, phosphate buffer (pH 7.2)

- Supports and promotes the regeneration of the nasal mucosa
- Moisturizes the mucous membrane and prevents excessive drying
- Relieves irritations
- Improves local immunity

**Rhinaqua Mare Plus**

The product contains: hypertonic sea salt solution (equivalent to 25 mg sodium chloride per one ml), betaine hydrochloride, preservative.

- Betaine in hypertonic sea water solution
- For clearing the nose in case of swelling of the mucosa
- Facilitates the removal of nasal discharge
Nasal medical devices

„RHINO” LINE

Products that help remove dense, thick or dry nasal discharge

The secretion in the nasal cavity consists mostly of polysaccharides, proteins and glycoproteins. In order to remove it effectively, it is necessary to break down the chemical structure of the secretion molecules, which leads to its liquidation and easier removal. Solutions intended for that effective breakdown of nasal mucosa secretion molecules are N-acetylcysteine, sodium hydrogen carbonate, potassium iodide and benzalkonium chloride.

**Rhinopur**

The product contains N-acetylcysteine in isotonic sodium chloride solution and preservative
- For clearing a stuffy nose
- Facilitates the removal of dense nasal discharge

**Rhinopur Plus**

The product contains: N-acetylcysteine, sodium chloride, potassium iodide, sodium bicarbonate, preservative, purified water
- Frees a stuffy nose
- Facilitates the removal of dense or dry nasal discharge
- Strong action

**Rhinosol**

The product contains: sea salt, benzalkonium chloride, glycerol, hypromellose, purified water
- For clearing the nose
- Facilitates the removal of dense nasal discharge
- Moisturizes the nasal mucosa
Auri line offers eighteen formulations intended for solving the most commonly occurring external ear canal health problems, such as:

- The residue of excess earwax and creation of earwax build-up
- Drying out and damage of ear canal skin as a result of lack of earwax production
- The residue of water in the ear canal after taking a bath or doing water sports
- Outer ear inflammation

The residue of earwax and earwax build-up are the most common issues related to the outer ear, which further results in deterioration or even loss of hearing. Excess drying of the outer ear canal, as well as the residue of water, occur less frequently, nevertheless may result in severe inflammation. For that reason, such symptoms must not be ignored.

Since Q-tips should not be used to remove excess earwax and provide daily ear hygiene (due to the risk of the ear canal or eardrum damage), products intended for dissolving earwax are an important elements of taking care of ear health.

Auri line includes:

- Twelve offers of the products intended for removing excess earwax from the ear canal (with various ingredients and mechanism of action)
- Three products for symptomatic treatment intended for reducing inflammation
- Two products intended for drying the ear canal out of excess water

All Auri line products are provided in a 25 ml or 10 ml volume bottles equipped with a dropper.
Due to various amounts of excess earwax, its consistency, quickness of production and even its composition, there is no one universal product intended for the treatment of all issues related to excess earwax. Comparative studies of the effects of various products indicate, that both products containing lipophilic oils as well as hydrophilic (water-based) products can be equally effective. While removing earwax build-up, one should remember to wait sometimes even more than 24 hours, before the products start to work.

The Auri line medical devices offer takes into consideration the effects of scientific studies and includes both water-based as well as oil-based substances. Gentle-effect lipophilic products include Aurinol (containing only olive oil), Aurinol Plus (with an addition of tea tree oil exhibiting soothing and anti-inflammatory effect) as well as Auriffin. These products can also be used to prevent the outer ear from drying out if it exhibits such a tendency.

Since that natural earwax contains squalene, it is sometimes easier for the products containing squalene to penetrate inside earwax and dissolve it effectively (Aurilen Skwalan). Compound that penetrate well into the dried out earwax is medium-chain triglycerides (MCT) contained in the products Aurilen MCT and Auripur (it is to be noted that Auripur contains significantly more MCT than Aurilen MCT).

Strong earwax dissolving effect is also exhibited in sodium hydrogen carbonate used in the aquatic environment (Auricin Aqua) as well as glycerine environment (Auricin Glycerol). Auricin Aqua is recommended for treatment in case of severe dry-out of earwax build-up. Auricin Balans is a product containing hydrogen carbonate in the aquatic-glycerine environment. Moreover, sodium docusate (Aurivastop) and carbamide peroxide (Aurivaxol) also exhibit strong earwax dissolving effect. Each of these products requires slightly different handling and action time.
Otic medical devices

„AURI” LINE

Products designed to remove accumulated earwax from the ear canal

Very gentle action on earwax

Aurinol

The product contains natural olive oil. Does not contain preservatives.
- Creates a protective film in the external auditory canal
- Prevents earwax accumulation
- Prevents water retention in the external auditory canal

Aurinol Plus

The product contains natural olive oil and tea tree oil. Does not contain preservatives.
- Creates a protective film in the external auditory canal
- Relieves irritations
- Prevents earwax accumulation
- Prevents water retention in the external auditory canal

Auriffin

The product contains natural olive oil and tea tree oil. Does not contain preservatives.
- Creates a protective film in the external auditory canal
- Relieves irritations
- Prevents earwax accumulation
- Prevents water retention in the external auditory canal
Otic medical devices

„AURI” LINE

Products designed to remove accumulated earwax from the ear canal

Aurimare

The product contains isotonic sea water solution and preservative:
- Isotonic sea water solution
- For flushing the external ear canal

Mild action on earwax

Aurilen Skwalan

The product contains: liquid paraffin, phytosqualan, peppermint oil. Does not contain preservatives:
- Helps to remove earwax from the external auditory canal
- Preventing excessive accumulation of earwax
- Average earwax dissolution activity

Aurilen MCT

The product contains: liquid paraffin, MCT (medium chain fatty acid triglycerides), turpentine oil, preservative:
- Helps to remove earwax from the external auditory canal
- Preventing excessive accumulation of earwax
- Average earwax dissolution activity
Auripur

The product contains: MCT (medium chain triglycerides), liquid paraffin, almond oil, petroleum jelly, vitamin E, preservative.

- Dissolves and removes earwax from the ear canal
- Effective for dry and hard earwax
- Preventing excessive accumulation of earwax
- Average earwax dissolution activity

Auricin Aqua

The product contains: sodium bicarbonate, purified water, preservative.

- Dissolves and removes earwax from the ear canal
- Effective for heavily dried, impacted earwax corks
- High earwax dissolution activity

Auricin Balans

The product contains: sodium bicarbonate, glycerol, purified water, preservative.

- Dissolves and removes earwax from the ear canal
- Effective for dry and damp earwax corks
- High earwax dissolution activity

Products designed to remove accumulated earwax from the ear canal

Strong action on earwax, for earwax corks
Otic medical devices

„AURI” LINE

Products designed to remove accumulated earwax from the ear canal

Auricin Glycerol

The product contains: sodium bicarbonate, glycerol, preservative. Does not contain water
- Dissolves and removes earwax from the ear canal
- Effective for damp (also very moist consistency) and dry earwax corks
- High earwax dissolution activity

Aurivastop

The product contains: ethanol, glycerol, sodium docusate, purified water. Does not contain preservatives
- Contains sodium docusate
- Dissolves and removes earwax from the ear canal
- Effective for dry and damp, impacted earwax corks
- High earwax dissolution activity

Aurivaxol

The product contains: glycerol, propylene glycol, carbamide peroxide, purified water, disodium edetate, tartaric acid, sodium citrate, ethyl alcohol
- Contains carbamide peroxide
- Dissolves and removes earwax from the ear canal
- Effective for dry and damp, impacted earwax corks
- High earwax dissolution activity
Drying out the ear canal is vital for those who exhibit a tendency to build up water in an ear canal. The residue water softens the skin and reduces the lipid barrier in the ear canal, which makes it easier for microorganisms to grow as well as contributes to the development of inflammation. The offered products (Aurition and Aurisol) remove or bind water and simultaneously prevent bacteria from growing.

**Aurition**

- The product contains: isopropyl alcohol, purified water, dexpanthenol, lactic acid (pH 5.8). Does not contain preservatives.
  - For removal of moisture from external auditory canal after intensive contact with water (e.g. after swimming, bathing, showering)
  - To prevent inflammation of the external auditory canal

**Aurisol**

- The product contains: propylene glycol, lactic acid (pH 5.8). Does not contain preservatives.
  - It binds water and restores the natural acidity of the skin of the external auditory canal
  - For swimmers and people who have intensive contact with water
Otic medical devices

„AURI” LINE

Products designed to relieve inflammation

Anti-inflammatory effect of the products Auricur and Auricur Natural are provided by vegetable oils (turpentine, geranium, lavender, peppermint). These products differ not only in the type of essential oil but also in the content of substances with different wax dissolving activity. Medical device Auriston is primarily used for treatment (diminishing) of inflamed swelling due to the high content of glycerol. Glycerol binds water, reduces swelling and can soothe pain.

**Auricur**

The product contains: light liquid paraffin, MCT (medium chain triglycerides), turpentine oil, geranium oil, lavender oil, preservative (butylhydroxytoluene)

- Helps to remove earwax from the ear canal
- Prevents excessive accumulation of earwax
- Relieves inflammation

**Auricur Natural**

The product contains: olive leaf oil, sesame oil, chamomile flower extract, lavender oil, peppermint oil. Does not contain preservatives.

- Creates a protective film in the external auditory canal
- Relieves inflammation and irritation
- Prevents earwax accumulation
- Prevents water retention in the external auditory canal

**Auriston**

The product contains: glycerin, panthenol, cetylpyridinium chloride, purified water

- Relieves the symptoms of inflammation of the external auditory canals
- Stimulates regeneration
Pharmaceutical form - Spray
Container - 20 ml or 10 ml with a dosing pump that produces an aerosol

A series of throat medical devices is a proposition of 4 formulations used in the form of a throat spray.

The proposed products are primarily intended for moisturizing of the throat mucosa. They can be used prophylactically, especially when the mucous membrane of the throat is exposed to drying out, e.g. intensive voice work, breathing through the mouth, snoring, dryness in the course of diseases or use of certain drugs. We recommend also use them when staying in adverse environmental conditions (polluted and dusty air, dry air in air-conditioned and heated rooms) and in the elderly.

A dry throat can lead not only to hoarseness or difficulty speaking. The dried mucosa is more easily irritated and damaged. It has a reduced immunity, which facilitates the development of bacterial or viral inflammations that can spread from the throat to the respiratory tract.

The proposed medical devices can be used to alleviate the already existing throat mucosa irritations or have a well-expressed regenerating effect.

Garinosid

The product contains: glycerol, dexamethasone, vitamin A, tea tree oil (Melaleuca alternifolia), peppermint oil (Mentha piperita), polysorbate 20, propylene glycol, phosphate buffer, preservative

- Moisturizes and reduces dryness of throat
- Stimulates the regeneration of damaged throat mucosa
Medical Devices

Medical devices intended for use at the throat
“GARI” and “FARY” LINE

Aerosols moisturizing the throat mucosa

Fargiol
The product contains olive oil, liquid paraffin, honey essence. Does not contains preservatives.
- For everyday use
- Moisturizes and reduces dryness of throat
- Prevents excessive drying

Faryvit
The product contains olive oil, almond oil, vitamin A, vitamin E, peppermint oil. Does not contains preservatives.
- For everyday use
- Moisturizes and reduces dryness of throat
- Prevents excessive drying
- Relieves irritations.

Gariflos
The product contains extract of Irish moss (Chondrus crispus), glycerol, sea salt, sorbitol, mint flavor, citric acid (pH regulator)
- For everyday use
- Moisturizes and reduces dryness of throat
- Protects the throat and vocal cords