



The Interregional Public Institution  
**“Institute of Engineering Physics”**  
(scientific, educational and industrial one)



THE **TAMERON** SERIES INNOVATIVE DRUGS

Serpukhov, 2021

# PHARMACEUTICAL MANUFACTURING



## Has the following advantages:

- high-tech manufacturing facilities;
- annual inspection of all engineering systems (the entire list of qualification and validation works);
- highly qualified staff;
- effective pharmaceutical quality system;
- collecting prototypes for research;
- technological development to expand production;
- distribution of finished pharmaceutical lyophilized products that do not require special separation;
- long-term mutually beneficial partnership.

**The license for drug manufacturing** was issued to the interregional public institution "Institute of Engineering Physics" by the Ministry of Industry and Trade of the Russian Federation on January, 27, 2016, №00168-LS, **for unlimited time.**





## ACTIVE PHARMACEUTICAL SUBSTANCE (APS),

manufactured in accordance with Russian technology (patent № 2673452, dated 11/27/2018. "Method of obtaining active pharmaceutical substance, presenting aminodihydrophthalazinedione of sodium")

### TECHNOLOGY BENEFITS:

- **substance production in accordance with the Good manufacturing practice (GMP)** requirements, using the patented sterile filtration technological process;
- **complete suppression of the formation** of resinous substances, linear oligo- and polyimides, isomeric phthalimides;
- production of an APS in the form of **stable crystals** with precise fixation of the amount of water in the substance, which **guarantees quality and a high degree of reproducibility** during the production;
- it is characterised by **the exclusion of the use of toxic hydrazine hydrate** and other raw materials, high conversion, increased ergonomics and environmental friendliness;
- the use of the patented Russian technology for the production of the APS aminodihydrophthalazinedione sodium **guarantees high quality and reproducibility of the result in the complete absence** of mechanical, chemical and biological impurities;
- this method of producing the APS in the form of a lyophilizate allows to achieve **better absorption of the drug** and, thus, increases its bioavailability;
- **one-step process** for obtaining the APS and the possibility of using inexpensive commercial reagents allows achieving low cost price.



**Developer:** Institute of Engineering Physics, The Interregional Public Institution  
**Entry number in the Russian State Register of Medicines:** №FS-002112  
dated 18.11.2020  
**Producer:** BION LLC

# THE MEDICINAL PRODUCT TAMERON

## LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION



МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ  
РОССИЙСКОЙ ФЕДЕРАЦИИ

**Регистрационное удостоверение  
лекарственного препарата для медицинского применения**

ЛП-006592  
(номер регистрационного удостоверения лекарственного препарата)

Наименование держателя (бюллетя) регистрационного удостоверения лекарственного препарата	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Адрес местонахождения держателя (бюллетя) регистрационного удостоверения лекарственного препарата	142210, Московская обл., г. Серпухов, Большой Ударный пер., л. 1а
Дата государственной регистрации лекарственного препарата	24.11.2020
Срок действия регистрационного удостоверения лекарственного препарата	со срока действия 5 лет
Дата внесения изменений в регистрационное удостоверение лекарственного препарата (дата замены регистрационного удостоверения лекарственного препарата)	выдано впервые

Информация о зарегистрированном лекарственном препарате:

Торговое наименование	TAMERON®
Международное непатентованное, или группировочное, или химическое наименование	Аминодигидрофалезинидон натрия
Лекарственная форма	лиофилизат для приготовления раствора для внутримышечного введения

Дозировка

Качественный состав и количественный состав действующих веществ и качественный состав вспомогательных веществ

аминодигидрофалезинидон натрия 100,0 мг

Форма выпуска (лекарственная форма, дозировка, первичная упаковка, количество лекарственной формы в первичной упаковке, количество первичных упаковок в потребительской упаковке, комплектность)

лиофилизат для приготовления раствора для внутримышечного введения, 100 мг (флакон) x 5 (штук в картонке)

Ресурсы нормативной документации

ЛП-006592-24.11.20

033315

Страница 2 регистрационного удостоверения № ЛП-006592

Производственные площадки, участвующие в процессе производства лекарственного препарата, с указанием стадий производства, названий и фактических адресов местонахождения	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Производство готовой лекарственной формы	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Московская обл., г. Серпухов, Большой Ударный пер., л. 1а, стр. 1	
Первичная упаковка	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Московская обл., г. Серпухов, Большой Ударный пер., л. 1а, стр. 1	
Вторичная/потребительская упаковка	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Московская обл., г. Серпухов, Большой Ударный пер., л. 1а, стр. 1	
Производитель (Выпускающий контроль качества)	Международное общественное учреждение "Институт инженерной физики" (МООУ "Институт инженерной физики"), Россия
Московская обл., г. Серпухов, Большой Ударный пер., л. 1а, стр. 1	

Заместитель Министра

О.В. Гривнев

М.П.

# THE MEDICINAL PRODUCT **TAMERON** LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION



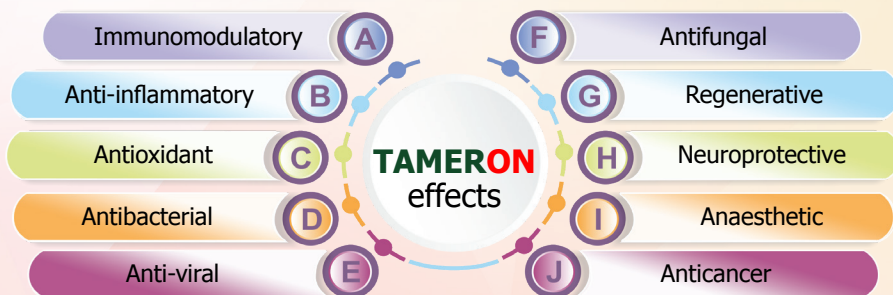


## THE MEDICINAL PRODUCT **TAMERON**

LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION



The use of **TAMERON** medicinal drug in the prevention and treatment of acute viral infections may reduce oxidative stress in cells and tissues, and thus inhibits the cytokine storm and the overreaction of the immune system. It prevents viral replication, promotes alveolar and other cells preservation, including the immune ones (in particular monocytes and T-cells). It also activates the immune response at the level of T-cells, which destroy cells infected with the virus. **TAMERON** shows its high efficiency in the treatment of neurogenic pathological processes caused by coronavirus infection. It's worth to note that **TAMERON** can also be used in the comprehensive treatment with other immunomodulators and specific anti-viral medications.



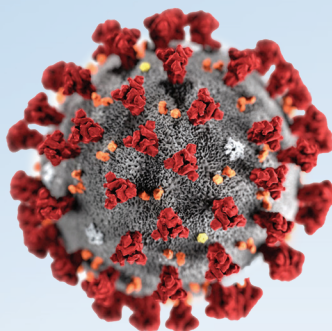
**Developer:** Institute of Engineering Physics, The Interregional Public Institution.

**Entry number in the Russian State Register of Medicines:** №LP-006597 dated 24.11.2020.

**Producer:** Institute of Engineering Physics, The Interregional Public Institution.

## THE MEDICINAL PRODUCT **TAMERON** AND CORONAVIRUS SARS-COV-2

Coronavirus infects lung cells after its transmission from one person to another even if it goes without showing any symptoms. Coronavirus interacts with human cells receptors, particularly with the ACE2 receptor, which is extensively represented in the upper respiratory tract epithelial tissue and epithelial cells of the mucous tunic of the mouth. In the early stages of disease progression



COVID-19 leads to the hyperactivation of the immune response, known as cytokine storm or acute respiratory distress syndrome (ARDS), which damages multiple organs. Then in late stages this disease comes along with the immune suppression as a decrease in lymphocytes and in the type I interferon production. Nowadays there is no yet highly effective specific treatment for the coronavirus infection and that's why the use of well known drugs for non specific immunotherapy is still relevant. But **TAMERON** is likely to become such an effective drug.

**TAMERON** can affect two main virus pathogenicity factors as its replication in human cells and it also prevents the hyperactivation of the immune system and the cytokine storm progression. Coronavirus replication goes along with the oxidative stress in cells. **TAMERON** affecting the genetic apparatus of human cells suppresses reactive oxygen species generation.

### THE USE OF **TAMERON** DRUG

in treatment of Coronavirus infection:

#### **NORMALIZES**

oxidation-reduction potential  
of infected human cells.

#### **PREVENTS**

viral replication in cells.

#### **RESULTS**

in infected cells death.

Studies conducted on volunteers infected with Coronavirus showed **TAMERON's high efficiency** in treatment like intense reduction of virus RNA titres, and that means strong suppression of virus replication. **TAMERON** reveals protective and anti-oxidative effects in cells of nerve tissue. **The use of TAMERON drug provides neuroprotective effect and reduces the level of side effects and their severity in terms of the human nervous system damage caused by COVID-19.**

The generation of reactive oxygen and nitrogen species is the reason for massive release of cytokines (cytokine storm), a massive immune response in the body and extensive tissue damage. COVID-19 tissue disease results in minor interferon production, stronger cells damage and enhanced sensitivity to microbial threats. Cytokine storm can be successfully suppressed by using **TAMERON** which affects functioning of antioxidant defence genes and thus dramatically reduces the generation of reactive oxygen and normalizes interferon production.

Coronavirus also damages the immune system cells like thymocytes and macrophages. During the studies of the **TAMERON** biological activity it was revealed that this drug regulates cytoskeleton of thymocytes, the immune cells. Once entered in macrophages, the virus activates inflammatory genes and production of reactive oxygen species. This leads to the global oxidative stress in the alveole and nearby areas. These processes favor one of the key COVID-19 pathologic conditions - pulmonary tissue thrombosis.

#### **The use of TAMERON drug**

##### **ALLOWS**

to stop straight the oxidative stress caused by macrophages during the Coronavirus disease.

##### **HELPS TO PREVENT**

the massive thrombosis.

##### **HELPS TO KEEP**

the pulmonary alveoli out of damage.





## THE INNOVATIVE DRUG **TAMERON-S** SUPPOSITORIES

(developed in conjunction with LC Stoletika)

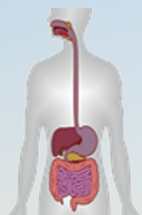
**TAMERON-S** - synthetic polyfunctional immunomodulatory drug producing anti-inflammatory, antibacterial and antioxidant effects **in the form of suppositories**.

**With a wide spectrum of action it is used to treat diseases of:**

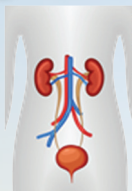
- the urogenital tract;
- the gastrointestinal tract;
- the genitourinary system;

**It is also effective in the treatment of:**

- viral diseases;
- purulent inflammatory diseases of pelvic organs,
- gynecological diseases,
- in the postoperative rehabilitation, including for women of reproductive age;
- for preventive purposes.



Gastrointestinal tract



Genitourinary system



Urogenital tract

**TAMERON-S** acts both systemically and locally (it has a direct effect on the source of inflammation, provides quick relief of the pathological process and adjusts immune responses to the development of infection).

**TAMERON-S** has a diuretic and antiedematous effect and makes positive impact on the entire urinary system.

**TAMERON-S** can be widely used in psychiatry, pediatrics, geriatrics, in cases of the liver damage, swallowing and absorption disorders, and toxicosis of pregnancy.

**TAMERON-S** is used both rectally and vaginally. The drug accelerates recovery after acute and chronic diseases, promotes rapid wound healing, stimulates cell and tissue defense factors. It shows significant anti-inflammatory, antioxidant and regenerative activity.

The mucous membranes of the rectum and vagina are rich in blood vessels, so **TAMERON-S** is rapidly absorbed, falling into the bloodstream, bypassing the protective liver barrier.



## THE INNOVATIVE DRUG **TAMERON-K** FOR NASAL USE (developed in conjunction with LC Stoletika)



Entering the mucous membrane, **TAMERON-K** is absorbed into the systemic blood circulation and circulates for a long time in the blood, guaranteeing its systemic effect. **TAMERON-K** can interact with free radicals, this leads to their elimination and reduction of oxidative stress in tissue cells. The drug boosts antioxidant defense and detoxification processes.

### Pharmacology:

Compatible with most antibiotics.

Reduces the probability of relapses of chronic inflammatory diseases.

Relieves allergic ailments.

Suitable for treatment and prevention in children and adults.

### Advantages:

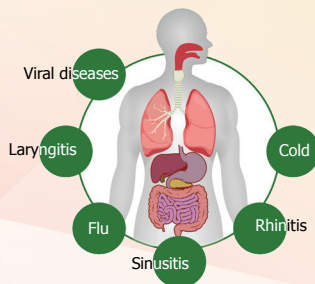
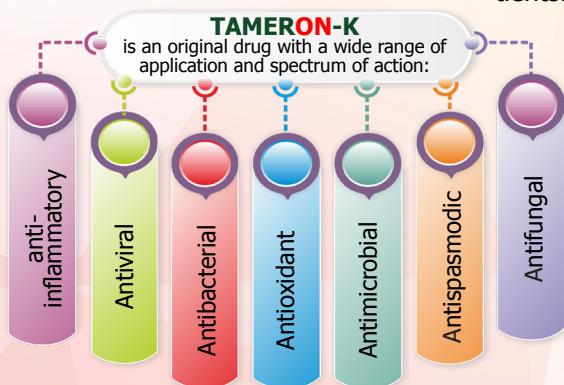
Direct effect on the respiratory mucosa.

The best efficiency within a short time.

Easy to use.

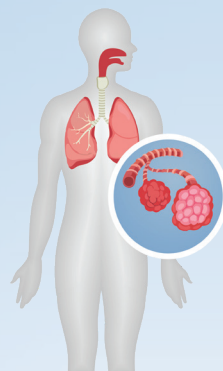
Deep penetration into the respiratory tract due to the aerosol fine dispersion.

Possibility to use in children of tender age and in seriously ill patients.





## THE INNOVATIVE DRUG **TAMERON-SPRAY** SPRAY (developed in conjunction with LC Stoletika)



**TAMERON-Spray** enters the bloodstream through the nasal mucosa and reaches all parts of the immune system: from the central and peripheral immune organs (thymus, spleen, lymph nodes) to the specific populations of blood cells (lymphocytes, granulocytes, monocytes) and tissues (tissue macrophages).

### Pharmacology:

Reduces the incidence of acute respiratory infections.

Reduces illness duration.

Decreases the risk of complications of viral respiratory infections (otitis, bronchitis, pneumonia and others)

Reduces and totally prevents episodes of broncho-obstructive syndrome related to the ARVI in children (bronchial obstruction, preasthma etc).

Stimulates the regeneration of the nasal mucosa.

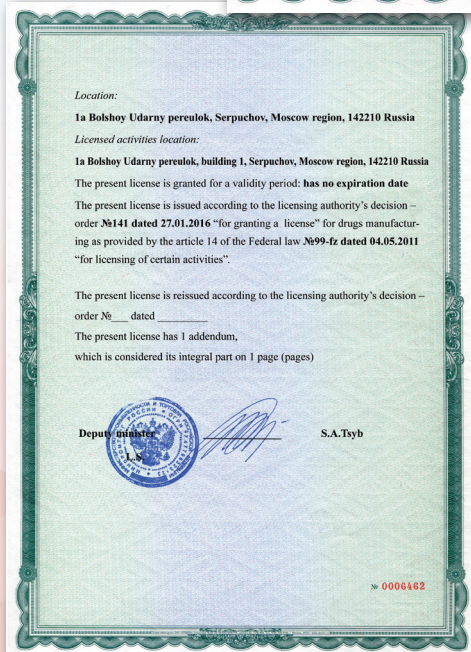
Supports the production of interferon and secretory immunoglobulin A.

### **TAMERON-SPRAY** regulates the immune system functions:

- boosts the decreased activity of the immune system;
- decreases the inadequately high immune response (in allergies);
- elicits complex responses in non involved immune cells and puts the cells in active mode, i.e. it boosts inactive immune cells;
- activates the immune cells that protect the body by absorbing (phagocytosis) harmful foreign particles (bacteria, viruses);
- participates in the formation of mature immunocompetent cells.







RUSSIAN FEDERATION

**PATENT**  
FOR THE INVENTION

№ 2673452

**METHOD OF OBTAINING ACTIVE  
PHARMACEUTICAL SUBSTANCE, PRESENTING  
AMINODIHYDROPHTHALAZINEDIONE  
OF SODIUM**

Assignee: *Institute of Engineering Physics, The interregional public institution (RU)*  
Authors: *Tsarkov Aleksey Nikolaevich (RU), Smurov Sergey Vladimirovich (RU), Prezent Michail Avramovich (RU), Volskiy Vladimir Stanislavovich (RU), Sedova Irina Vladimirovna (RU), Krasnova Yulia Valerjevna (RU), Chistyakova Anna Valerjevna (RU)*

Application number **2017129096**  
Invention priority date - **THE 15TH OF AUGUST 2017**  
State registration date in the state registry of inventions of the Russian Federation - **THE 27TH OF NOVEMBER 2018**  
Expiration date of the exclusive right to the invention - **THE 15TH OF AUGUST 2037**

Head of Federal service  
for intellectual property

*G.P. Ivliev*

THE MINISTRY OF INDUSTRY AND TRADE  
OF THE RUSSIAN FEDERATION

**Certificate of registration  
for the medicinal product**

**LP-006597**  
(registration number of the medicinal product)

Holder of the marketing authorization certificate for the medicinal product	The Interregional public institution "Institute of Engineering Physics", Russia
Location of the holder of the marketing authorization certificate for the medicinal product	1A Bolshoy Udayny pereulok, Serpukhov 142210, Moscow region, Russia
Date of the medicinal product state registration	24.11.2020
Validity period of the registration certificate for the medicinal product	Valid for 5 years
Date of changes to the certificate of registration for the medicinal product	Issued for the first time
Data on the registered medicinal product	
Trade name	TAMERON®
International nongeneric or generic or chemical name	Aminodihydrophthalazinedione of sodium
Pharmaceutical form	Lyophilizate for solution for intramuscular injection
Dosage strength	100 mg
Qualitative and quantitative composition of active substances and qualitative composition of auxiliary substances	
Aminodihydrophthalazinedione of sodium 100.0 mg	
Release form (pharmaceutical form, dosages, primary packaging, pharmaceutical form quantity in the primary packaging, primary packaging quantity in the consumer packaging, product specification file	Lyophilizate for solution for intramuscular injection, 100 mg (bottle) x 5 (cardboard pack)

083315

Page 2 of the certificate of registration № LP-006597

Industrial sites taking part in the drug production, specifying manufacturing stages, names and actual addresses	
Finished dosage form production	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Finished dosage form production	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Secondary / consumer packaging	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Producer (release quality control)	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	

Deputy minister      Deputy minister

I.S.



RUSSIAN FEDERATION



TRADEMARK CERTIFICATE

№ 598830

**TAMERON**

Owner: *Institute of Engineering Physics, The interregional public institution  
1a Bolshoy Udarny pereulok, Serpuchov, Moscow region,  
142210 Russia*

Application number 2015741327  
Trademark priority date - the 16th of December 2025  
Registered in the Public register of trademarks and service marks of the Russian Federation on the 14th of December 2016  
Trademark registration valid until the 16th of December 2025

Head of Federal service  
for intellectual property

*Reliance* G.P. Ivliev



RUSSIAN FEDERATION



PATENT

FOR THE INVENTION

№ 2744858

Method of obtaining lyophilizate of  
aminodihydrophthalazinedione of sodium - Tameron,  
medicinal product

Assignee: *Institute of Engineering Physics, The interregional public institution (RU)*

Authors: *Vol'skiy Vladimir Stanislavovich (RU), Ermakov Artem Michailovich (RU), Krasnova Yulia Valerjevna (RU), Tsarkov Aleksey Nikolaevich (RU), Tsarkova Elena Aleksandrovna (RU)*

Application number 2020116296  
Invention priority date - the 28th of April 2020  
State registration date in the State registry of inventions of the Russian Federation - the 16th of March 2021  
Expiration date of the exclusive right to the invention - the 28th of April 2040

Head of Federal service  
for intellectual property

*Reliance* G.P. Ivliev





RUSSIAN FEDERATION



TRADEMARK CERTIFICATE

№ 736552

**TAMERON-S**

Owner: *Institute of Engineering Physics, The interregional public institution  
1a Bolshoy Udamy pereulok, Serpuchov, Moscow region,  
142210 Russia*

Application number 2019718014  
Trademark priority date - the 17th of April 2019  
Registered in the Public register of trademarks and service marks of the Russian Federation on  
the 27th of November 2019  
Trademark registration valid until the 17th of April 2029

Head of Federal service  
for intellectual property

*G.P. Isliev* G.P. Isliev



RUSSIAN FEDERATION



TRADEMARK CERTIFICATE

№ 772032

**TAMERON-K**

Owner: *LC Stoletika,  
1a Bolshoy Udamy pereulok, building 4, office 407, Serpuchov,  
Moscow region, 142210 (RU)*

Application number 2019761543  
Trademark priority date - the 2nd of December 2019  
Registered in the Public register of trademarks and service marks of the Russian Federation on the 17th of August 2020  
Trademark registration valid until 2nd of December 2029

Head of Federal service  
for intellectual property

*G.P. Isliev* G.P. Isliev





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**For purchase issues**



**LC Stoletika**

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