Recommended by Doctor of Pharmacy, professor T.G.Yarnykh

UDC 615.451.3:615.276:616.216

DETERMINATION OF PROSPECTS OF USING SINUFORTE DRUG IN THE CURRENT PHARMACOTHERAPY OF SINUSITIS AND THE MERCHANDISING ANALYSIS OF ITS PACKAGE

T.V.Diadiun, O.V.Dorovskyy

National University of Pharmacy

Key words: sinusitis; European cyclamen; lyophilized powder; Sinuforte; spray; merchandising analysis

Medicines in the form of sprays are the most suitable forms for treating respiratory diseases. The introduction of a clearly defined amount of the drug prevents the possibility of overdose and development of side effects. The drug Sinuforte created on the basis of the freeze-dried juice and the aqueous extract from fresh tubers of cyclamen is produced according to the standards of GMP, thus avoiding the bacteriological load. The mechanism of action of the drug is associated with activation of natural physiological processes of the nasal mucosa cleaning. The high clinical efficacy and safety have been proven by numerous clinical studies in advanced ENT clinics in more than 15 countries of the world. As a result of the study of Sinuforte the prospects of the drug use in the current pharmacotherapy of sinusitis have been determined; the compliance with the release specifications has been proven by conducting the merchandising analysis of the drug package.

Chronic inflammatory diseases of paranasal sinuses occupy a leading position in otorhinolaryngological practice [7]. Rhinosinusitis (RS) is one of the most common diseases of ENT – organs, various forms of RS affect 15% of the population [6].

Antritis (sinusitis of the maxillary sinus) is an acute inflammation of the mucosa of the maxillary paranasal sinuses. The main cause of the disease is an infection – inflammation may be caused by bacteria or viruses that penetrate the maxillary sinuses through the nasal cavity or blood.

The choice of the treatment method often presents a challenge for the otolaryngologist and despite the large number of ways to treat acute purulent sinusitis (including antritis) this issue remains very important [1, 2, 4, 5].

For the treatment of sinusitis the comprehensive treatment should be applied:

- use of drugs that promote elimination of the symptoms;
- local procedures aimed at strengthening the immune system;
- surgical manipulation in the case of emergency.

All therapeutic measures should be aimed at improving the outflow of purulent secretions from the sinuses. If necessary, the puncture is done for the pus removal and sinus lavage. In Ukraine the maxillary sinus puncture remains one of the most common methods of conservative treatment. Abroad the puncture is done infrequently; the use of antibacterial agents is preferred although the widespread use of antibiotics leads to a significant increase in fungal sinusitis.

The European Cyclamen – *Cyclamen europaeum*, which birthplace is considered the Mediterranean, is known as a medicinal plant for more than 2 thousand years. The tincture of cyclamen tubers is used in gynecological diseases, neuralgia, headaches, liver diseases, intestinal colic, colds. The juice is used in gynecological diseases, hemorrhoids. The fresh juice of tubers diluted in the ratio of 1:10 is also considered one of the best remedies to treat sinusitis (without surgery). As the main component the plant contains saponins, namely cyclamin, with isocyclamin, methylcyclamin and other structurally related compounds. The content of free amino acids (including 8 essential acids) and a significant amount of mono- and polyunsaturated acids with dominance of linoleic, linolenic, oleic and palmitic acids have been also determined. In Cyclamen tubers small amounts of glycosides and flavonoids have been found. Due to the fact that the plant is poisonous its application requires certain caution.

The experience of cyclamen application in traditional medicine led academic medicine to creation of the drug that would be standardized and thus contribute to the accurate and individual approach in treating different groups of the population. Sinuforte has become such medicine; it is based on the freeze-dried juice and the aqueous extract from fresh tubers of the European cyclamen [2, 5, 9] and is present at the Ukrainian market [1, 4, 8, 9, 10].

The aim of the work is to determine the prospects of using Sinuforte drug in the current pharmacotherapy of sinusitis and conduct the merchandising analysis of its package.

Materials and Methods

The published data on the use of Sinuforte drug in the modern drug therapy of sinusitis were analysed. The merchandising analysis analysis was conducted on the example of Sinuforte drug (Batch: 1249 UA1).

Results and Discussion

Acting intranasally Sinuforte drug activates the normal physiological processes to clean the mucous mem-

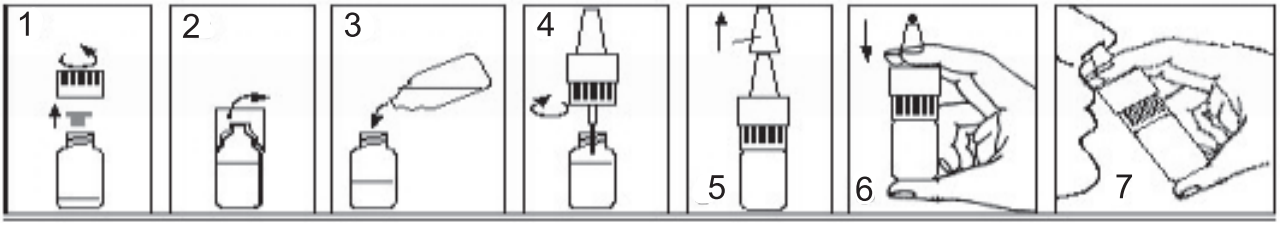

Fig. The method of Sinuforte drug application: 1. Unscrew the cap from the vial with the drug and pull out the cork. 2. Open the ampoule with the solvent and break off the top. 3 Completely pour the solvent into the vial with the drug. 4. Screw the spray dispenser on the vial and shake it until complete dissolution of the drug. 5. Remove the cap from the spray-dispenser. 6. Make 2-3 test sprays into the air. 7. Insert the sprayer dispenser into each nostril with the head upright and make a spray with one touch.

brane of the nose and has a constructive effect on the mucous membrane and suppurations that accumulate in the nasal cavity and paranasal sinuses.

Due to these properties the drug is widely used in the modern drug therapy of ENT-organs when treating sinusitis, otitis, acute and chronic rhinitis; postoperative rehabilitation after endoscopic surgery [4, 5, 10].

When included in the therapy of mild and moderate forms of acute rhinosinusitis the high efficiency (90% or more) of monotherapy with Sinuforte compared to the efficiency of traditional treatment has been found. Information about cases of the drug overdose have not been identified, but most likely its manifestations may be a burning sensation in the nasal mucosa and mild nose bleeds [1, 3, 4, 5, 11].

To achieve the therapeutic effect 6-8 applications of the drug are sufficient, but the decrease or complete cessation of headaches is observed already after 3-5 applications. The dose regimen and duration of use do not depend on the disease nosology. After endoscopic surgery the intranasal administration of Sinuforte is started the next day with the aim of draining the airways and reducing rhinedema.

The drug is recommended to use in a day; if necessary, its daily use is possible. Using the drug every other day the duration of treatment is 12-16 days, when using daily – 6-8 days.

Table

The merchandising analysis of Sinuforte drug package

Name of the indicator	Characteristics	
	requirements of the release specifications	sinuforte
1	2	3
Organoleptic Visual inspection of the package	– Control of the secondary package: the presence or absence of defects; – control of the primary package; – integrity of the container, closure, tamper proof, etc.	The secondary package – a cardboard pack, any possible defects are absent. The primary package – 1 vial with the powder in set with one ampoule with the solvent and a spray dispenser. The primary package is intact, not damaged, meets all the requirements of the release specifications.
Labeling of the secondary package	Country of origin, the manufacturer, its trademark and addresses	Spain; Pharma Mediterania Ltd., San Sebastia st., San Giusto Desverne, 08960 Barcelona, Spain;
	Name of the drug in Ukrainian and Latin, dosage form	Синуфорте/Sinuforte; Lyophilized powder for intranasal application;
	The amount of the drug, concentration, activity or the dose, the qualitative and quantitative composition of ingredients	35 doses, 1 vial contains the powdered freeze-dried juice and the aqueous extract from fresh tubers of the European cyclamen (Cyclamen europaeum), the hemolytic index 1: 6,000 – 1: 12,000;
	method of administration	intranasally (in accordance with the patient information leaflet);
	batch number	Batch: 1249 UA 1;
	expiration date	Expiry date: 12/2015;
	registration number	Registration certificate №UA/6478/01/01;
	storage conditions; bar code	Protect from light and keep out of the reach of children at a temperature not exceeding 25°C; 8437008498010.

Table continuation

1	2	3
Labeling of the primary package	When labeling ampoules, pre-filled syringe-tubes and droppers the drug name, concentration or activity, the amount of the drug, the batch number, the expiration date are indicated.	Labeling of the vial with the powder: Синуфорте/ Sinuforte; 35 doses; Pharma Mediterania; Batch: 1249; Best before: 12/2015.
Completeness of the finished product	When checking the completeness check the presence or absence of the patient information leaflet, dosing devices and other devices.	When analyzing the completeness it has been identified that a cardboard pack contains one contour cellular packaging, in which there is 1 vial with the powder, 1 ampoule with the solvent and a spray dispenser. The package also includes the patient information leaflet.

Sinuforte is used as a spray, which provides the following benefits:

- the fast therapeutic effect like in intravenous introduction;
- the high pharmacological activity due to dispersion and consequently achievement of the therapeutic effect at a lower dose;
- convenience, ease of use.

The spray has advantages of aerosol packing, at the same time it has no disadvantages associated with the use of containers under high pressure and the use of propellants as a gas carrier. Moreover, spraying is stable, and there is no danger of inhaling the particles sprayed (the particle size is always greater than 5 μm).

Fig. shows the way of application of Sinuforte drug. The set includes a special nozzle dispenser, which when pressing sprays a certain amount of the drug – 0.13 ml, this amount corresponds to the required single dose (0.0013 g of the dry extract). The supply of the drug is conducted due to its mechanical extrusion by the piston of the micropump, and the pressure in the vial is equal to the atmospheric one. When the piston moves to its original state, the cavity, from which the drug is extruded, is filled with a new portion. It serves as a liquid gate that prevents the air inside the vial, therefore, the drug in the vial is not in contact with the external environment, the vial is closed hermetically.

After analyzing the prospects of using Sinuforte drug in the current pharmacotherapy of sinusitis the merchandising analysis of the drug package was conducted (Table).

As a result of the merchandising analysis it has been found that the package of the drug Sinuforte (batch: 1249 UA 1) complies with the requirements of the release specifications.

CONCLUSIONS

As a result of the study of Sinuforte the prospects of the drug use in the current pharmacotherapy of sinusitis have been determined, the compliance with the release specifications has been proven by conducting the merchandising analysis of the drug package.

REFERENCES

1. *Бесшапочный С.Б. // Ринол. – 2004. – №3. – С. 63-67.*
2. *Гедеванишвили М.Д., Готидзе Н.М., Сихарулидзе И.С. // Вестник оториноларингол. – 2007. – №3. – С. 54-56.*
3. *Овчинникова А.Ю., Дженжера Г.Е., Лопатин А.С. // Вестник оториноларингол. – 2009. – №5. – С. 54-57.*
4. *Петрова Л.Г. // Журн. ушных, носовых и горловых заболеваний. – 2004. – №2. – С. 85-87.*
5. *Янов Ю.К., Рязанцев С.В., Тимчук Л.Э. // Вестник оториноларингол. – 2007. – №4. – С. 49-51.*
6. *Bachert C., Schapowal A., Funk P. et al. // Rinol. – 2009. – Vol. 47, №1. – P. 51-58.*
7. *Benhakroun Y., Zanin C., Bene M.C., Perruchet A.M. // Intern. J. Immunopharm. – 1994. – Vol. 16, №7. – P. 497-505.*
8. *Bornson D.B., Nadel L.A. Regulation of airway secretion: role of peptides and proteases. Rhinitis and asthma / Ed. N.Myginol, U.Pipkorn, R.Dahl. – Munkagaard: Copenhagen, 1990. – 183 p.*
9. *Dal T., Onerci M., Caglar M. // Eur. Arch. Otorhinolaryngol. – 1997. – Vol. 254, №4. – P. 205-207.*
10. *Galen B.A. // Lippincotts Prim., Care Pract. – 1997. – Vol. 1, №2. – P. 183-198.*
11. *Pfaar O., Mullol J., Anders C. et al. // Rhinol. – 2012. – Vol. 50, №1. – P. 37-44.*

ВСТАНОВЛЕННЯ ПЕРСПЕКТИВНОСТІ ВИКОРИСТАННЯ ПРЕПАРАТУ «СИНУФОРТЕ» В СУЧАСНІЙ ФАРМАКОТЕРАПІЇ ГАЙМОРИТУ ТА ПРОВЕДЕННЯ ТОВАРОЗНАВЧОГО АНАЛІЗУ ЙОГО ПАКУВАННЯ

Т.В.Дядюн, О.В.Доровський

Ключові слова: *гайморит; цикламен європейський; ліофілізований порошок; Синуфорте; спрей; товарознавчий аналіз*

Лікарські засоби у формі спреїв є найбільш оптимальними формами для лікування захворювань верхніх дихальних шляхів. Введення чітко визначеної кількості лікарського препарату запобігає можливості його передозування і розвитку побічних ефектів. Препарат «Синуфорте», створений на основі ліофілізованого соку та водного екстракту зі свіжих бульб цикламену європейського, виробляється згідно із стандартами GMP, що дозволяє уникнути бактеріологічного навантаження. Механізм дії препарату пов'язаний з активацією природних фізіологічних процесів очищення слизової оболонки носа. Висока клінічна ефективність та безпека доведена численними клінічними дослідженнями у передових ЛОР клініках більш ніж 15 країн світу. В результаті вивчення препарату «Синуфорте» встановлено перспективність його використання у сучасній фармакотерапії гайморит, шляхом проведення товарознавчого аналізу пакування даного препарату встановлена відповідність вимогам нормативної документації.

ОПРЕДЕЛЕНИЕ ПЕРСПЕКТИВНОСТИ ИСПОЛЬЗОВАНИЯ ПРЕПАРАТА «СИНУФОРТЕ» В СОВРЕМЕННОЙ ФАРМАКОТЕРАПИИ ГАЙМОРИТА И ПРОВЕДЕНИЕ ТОВАРОВЕДЧЕСКОГО АНАЛИЗА ЕГО УПАКОВКИ

Т.В.Дядюн, А.В.Доровской

Ключевые слова: *гайморит; цикламен европейский; лиофилизированный порошок; Синуфорте; спрей; товароведческий анализ*

Лекарственные средства в форме спреев являются наиболее оптимальными формами для лечения заболеваний верхних дыхательных путей. Введение строго определенного количества лекарственного препарата устраняет возможность его передозировки и развития побочных эффектов. Препарат «Синуфорте», созданный на основе лиофилизированного сока и водного экстракта из свежих клубней цикламена европейского, производится согласно стандартов GMP, что позволяет избежать бактериологической нагрузки. Механизм действия препарата связан с активацией естественных физиологических процессов очистки слизистой оболочки носа. Высокая клиническая эффективность и безопасность доказаны многочисленными клиническими исследованиями в передовых ЛОР клиниках более чем 15 стран мира. В результате изучения препарата «Синуфорте» установлена перспективность его использования в современной фармакотерапии гайморита, путем проведения товароведческого анализа упаковки данного препарата установлено соответствие требованиям нормативной документации.

.