
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sinuclear[®] extract tablets
Coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 coated tablet contains:

160 mg native dry extract (3-6:1) derived from gentian root, primula flowers, sorrel herb, elder flowers, verbena herb (1:3:3:3:3) 1. Extracting agent: ethanol 51% (m/m)

Excipients with known effect:

Glucose syrup	3.141 mg
Sucrose	133.736 mg
Maltodextrin	34.000 mg

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet

The coated tablets are green, round, biconvex with a smooth surface.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the symptomatic relief of nasal congestion and headaches in those suffering from acute uncomplicated inflammations of the paranasal sinuses (acute uncomplicated rhinosinusitis) in adults and children from the age of 12 years.

4.2 Posology and method of administration

Adults and adolescents from the age of 12 years take 1 coated tablet 3 times daily.

Children

Sinuclear[®] extract tablets should not be used in children under the age of 12 years.

Renal/hepatic dysfunction

There are insufficient data for specific dose recommendations in renal/hepatic dysfunction.

Method of administration

The coated tablets are to be taken without chewing, preferably with some liquid, e.g. a glass of water.

Duration of use

Unless prescribed otherwise, the medicine should be taken for a period of 7-14 days. Please note the information in the section 4.4 "Special warnings and precautions for use".

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Gastric or peptic ulcer.

4.4 Special warnings and precautions for use

Patients with gastritis or with a sensitive stomach must be cautious when taking Sinuclear® extract tablets and should take Sinuclear® extract tablets after meals with a glass of water.

The patient leaflet informs the patient to consult a doctor if complaints persist for more than 7-14 days, if symptoms worsen or reoccur periodically, or if he/she experiences fever, severe pain or unclear complaints.

Patients with rare hereditary fructose intolerance, glucose galactose malabsorption or saccharase isomaltase deficiency should not take Sinuclear® extract tablets.

Children

Children under the age of 12 years should not take Sinuclear® extract tablets because there are no adequate data for the use in children under the age of 12 years.

4.5 Interactions with other medicinal products and other forms of interaction

Systematic studies on interactions with other medicinal products have not been performed. Reinforcing or attenuating effects on other medicines cannot be excluded. The simultaneous administration of other medicines with a narrow therapeutic spectrum must be decided on a case to case basis.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data available with the use of Sinuclear® extract tablets (dry extract) during pregnancy. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid use of Sinuclear® extract tablets during pregnancy.

Lactation

It is not known whether the active substances in Sinuclear® extract tablets pass into human milk. A risk to the breast-fed infant cannot be ruled out. Sinuclear® extract tablets should not be used during lactation.

Fertility

There are no data on the influence of Sinuclear® extract tablets (dry extract) on fertility. In animal studies with a dosage form qualitatively comparable to Sinuclear® tablets no effects were observed on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Sinuclear® extract tablets may have a minor influence on the ability to drive and use machines in patients experiencing the possible undesirable effect dizziness (see section 4.8).

4.8 Undesirable effects

Gastrointestinal disorders

Common ($\geq 1/100$ up to $< 1/10$): Gastrointestinal disorders, e.g. nausea, flatulence, diarrhea, dryness of the mouth, stomach ache

Immune system disorders

Uncommon ($\geq 1/1,000$ up to $< 1/100$): Local hypersensitivity reactions (exanthema, erythema, pruritus of skin or eyes); Systemic allergic reactions (angioedema, dyspnoea, face swelling).

Nervous system disorders

Uncommon ($\geq 1/1,000$ up to $< 1/100$): Dizziness

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

In addition, suspected adverse events can be reported directly to Dr. Samuelov's drug safety department at: drugsafety@drsamuelov.co.il

4.9 Overdose

Intoxications with Sinuclear[®] extract tablets have not yet been observed.

In case of overdose, the described undesirable effects (nausea, stomach ache, diarrhea) may be amplified.

Therapy of intoxication:

Symptoms due to intoxication or overdose require a symptomatic therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: herbal medicine for the treatment of inflamed paranasal sinuses.

ATC-Code: R05X

Clinical studies:

In a double-blind, placebo-controlled clinical trial, 386 patients were randomised into two groups: 194 patients into the group of 480 mg active substance and 192 patients into the placebo group. The aim of the trial was to investigate the efficacy and tolerability of Sinuclear® extract tablets in comparison to placebo as 2-week treatment in patients with acute (viral) rhinosinusitis. The primary endpoint, the MSS (Major Symptom Score consistent of nasal secretion, retronasal secretion, nasal congestion, headache, facial pain/pressure) at Visit 5 (FAS) was 2.38 ± 2.54 points for the active substance and 3.41 ± 3.36 points for placebo and was statistically significant ($p=0.008$). The difference between the groups attained the score of at least one point, defined as clinically relevant. Patients who did not take paracetamol derived greater benefit from Sinuclear® extract tablets. The differences between the groups with regard to individual symptoms were statistically significant at Visit 5 for the symptoms „retronasal secretion“, „nasal secretion“, „headache“ and „facial pain“ (except for „nasal congestion“). The differences between the groups from Visit 1-5 in relation to quality of life, calculated from the SNOT-20 and the 3 subscores (PNS, PRS, ALQ) were statistically significant in favour of the active substance.

A secretolytic effect of Sinupret drops was observed in a rabbit model. In addition, an anti-inflammatory effect was demonstrated in the carrageenan oedema test in the rat paw. Sinuclear® inhibited the multiplication of various respiratory viruses, such as rhinoviruses (HRV14), adenoviruses and RS (respiratory syncytial) viruses *in vitro* and showed a reduction in the mortality rate in mice after infection with the parainfluenza virus.

With regard to the clinical relevance of these results, there have been no human pharmacological studies to date.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction. Studies regarding carcinogenicity and phototoxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, talc, calcium carbonate, microcrystalline cellulose, maltodextrin, cellulose; powdered, hypromellose, dextrin, acacia spray dried, silica; colloidal anhydrous, silica; hydrophobic colloidal, titanium dioxide (E 171), glucose liquid, magnesium stearate, stearic acid 50, chlorophyll powder 25% (E 141), indigo carmine aluminium lacquer (E 132), carnauba wax, riboflavin (E 101).

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Do not store at temperatures above 25°C.
Keep out of reach and sight of children!

6.5 Nature and contents of container

Package with 20 coated tablets, containing 2 blisters of 10 coated tablets each.

6.6 Special precautions for disposal

No special precautions required.

7. MANUFACTURER

BIONORICA SE
Kerschensteinerstrasse 11-15
92318 Neumarkt
Germany

8. ISRAELI MARKETING AUTHORIZATION HOLDER AND IMPORTER:

Dr. Samuelov Importing & Marketing Ltd.
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9. MARKETING AUTHORISATION NUMBER

177-48- 36980-00

10. DATE OF FIRST AUTHORISATION

September 2024

11. DATE OF THE REVISION OF THE TEXT

September 2024

12. GENERAL CLASSIFICATION FOR SUPPLY

Over the counter, Available only in pharmacies

Sinuclear_extract_tablets_SPC0924