This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved on May 2017

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sinuclear
Coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active pharmaceutical ingredients:
1 coated tablet contains:
Verbena herb, powdered 36 mg; Gentian root, powdered 12 mg; Common Sorrel herb, powdered 36 mg; Elder flower, powdered 36 mg; Primula flower with calyx, powdered 36 mg.

Excipients:

Glucose syrup	2.750 mg
Lactose monohydrate	48.490 mg
Sucrose	123.816 mg
Sorbitol	0.444 mg

For a 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

Provides relief of symptoms in the nose and its sinuses in connection with common cold, in adults and children older than 12 years.

4.2 Posology and method of administration

Unless prescribed otherwise, adults and adolescents from 12 years of age take 1 coated tablet 3 times a day.
Coated tablets to be taken unchewed – preferably with some liquid.
Crushing/halving: do not crush or halve the coated tablet.

Unless prescribed otherwise, the duration of administration is 7 – 14 days. Also observe the instructions under 4.4 ”Special warnings and precautions for use”.

4.3 Contraindications

Sinuclear must not be taken in case of known hypersensitivity to one of the pharmaceutical ingredients or to any of the excipients of Sinuclear.

4.4 Special warnings and precautions for use

There are no sufficient investigations on the use of Sinuclear in children under the age of 12 years. Therefore, Sinuclear should not be used in children under the age of 12 years.

Patients with the rare hereditary problems of fructose intolerance, galactose intolerance e.g. galacotosaemia, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Sinuclear.

In the package leaflet the patient is instructed to contact a doctor if symptoms last longer than 7 – 14 days or recur periodically.

4.5 Interactions with other medicinal products and other forms of interaction

No interactions with other medicinal products are known to date.

4.6 Pregnancy and lactation

Like all medicines, Sinuclear should only be used during pregnancy and lactation after strict diagnosis.

4.7 Effects on ability to drive and use machines

No special precautions are required.

4.8 Undesirable effects

Like all medicines, Sinuclear can have undesirable effects.

The frequency of undesirable effects is based on the following categories:

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(< 1/10,000)
Not known	(frequency cannot be estimated from the available data)

Gastrointestinal complaints (for instance stomach ache, nausea) are uncommon.
Hypersensitivity reactions of the skin (skin rash, reddening of the skin, itching) and severe allergic reactions (angioedema, dyspnoea, swelling of the face) are rare.

In the package leaflet the patient is instructed to stop taking Sinuclear and to consult a doctor if any of the reactions listed above occur.

Reporting suspected adverse reactions after authorisation 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:

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

No cases of intoxication with Sinuclear have become known to date.

The undesirable effects listed above may possibly occur more intensely in case of overdose.

Treatment of intoxications:
If signs of poisoning or overdose occur, symptomatic treatment is necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: herbal medicinal product for use in inflammations of the paranasal sinuses.

ATC code: R05X

In two different animal models (rat, rabbit) a secretolytic action of the mixed extract and of the individual components was observed.
In the carrageenin-induced oedema test in rats a dose-dependent reduction of the oedema of the paw was observed in comparison with the control group.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No documentation on acute toxicity is available. Subchronic toxicological studies in rats with durations of up to 13 weeks were conducted, using oral doses of Sinuclear drug mixture which were 5 to 100 times higher than the human dose. The NOEL was 50 mg/kg body weight (> 5 times the human dose).
In various test systems no genotoxic, teratogenic or toxic effects on fertility were observed for Sinuclear.

One coated tablet of Sinuclear contains not more than 0.036 mg of hydroxyanthracene derivatives (recorded as emodin) from Common sorrel herb.

Sinuclear contains primula flower with calyx whose primin content lies below the detection limit of 1.25 ppm (with reference to the drug).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, talc, lactose monohydrate, calcium carbonate, potato starch, maize starch, dextrin, silica (colloidal anhydrous), stearic acid, titanium dioxide, liquid glucose, gelatin, shellac, light magnesium oxide, sorbitol, basic butylated methacrylate copolymer, montan glycol wax. Riboflavin (E101), indigo carmine (E132), aluminium hydroxide, cuprum chlorophylline (E141), castor oil (refined).

Note for diabetics:
One coated tablet contains an average of 0.2 g of carbohydrates.
Sinuclear coated tablets are gluten free.

6.2 Incompatibilities

None known.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 30°C.
Keep out of the reach and sight of children.

6.5 Nature and contents of container

Package containing 20 coated tablets, 1 blister strip containing 20 coated tablets

Blister package made of PVC/PVDC and aluminium foil.

6.6 Special precautions for disposal

No special precautions.

7. MANUFACTURER

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9. MARKETING AUTHORISATION NUMBER

158-57-34682- 00

10. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: May 2017

11. DATE OF REVISION OF THE TEXT

October 2017

12. GENERAL CLASSIFICATION FOR SUPPLY

Only for sale in pharmacies, Over the counter (OTC)