

FAQ CILIACELL NASAL SPRAY

THIS DOCUMENT CONTAINS IMPORTANT INFORMATION TO KNOW BEFORE USING CILIACELL NASAL SPRAY

The information contained in this document, answers the most frequently asked questions by users of Ciliacell nasal spray.

For all information on the Ciliacell nasal spray not contained in this document, you can contact Nevia Biotech SA through the communication ways indicated below:

- By email to the following email address: <u>customer@neviabiotech.it</u>
- By Social Network Facebook and Instagram: IG: @nevia biotech Fb: neviabiotech
- By our website page: https://neviabiotech.ch/contact-us/?lang=en





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1) WHAT SHOULD I KNOW BEFORE USING CILIACELL?

a. Ciliacell is a product that acts on the three clinical-pathological characterizations of sinusitis (nose-sinusal mucosa oedema, reduction or blockage of ciliary mobility and motility, accumulation of mucus-pus in the nose-sinusal district and in the auditory tubes), the true causes of typical symptoms of sinusitis:

Yellow, greenish, or white mucus discharge from the nose or throat

ii. Craniofacial pain (facial pain) in correspondence with one or more paranasal sinuses

iii. Anosmia (feeling of not smelling)

iv. Nose bleeding

v. Nasal obstruction and/or oppression

vi. Exhalation of bad odors from the nose

vii. Feeling of muffled ears

viii. Sleep disorders

ix. General malaise

b. The active ingredients of Ciliacell nasal spray are four biomolecules extracted from Ecballium Elaterium plant, namely: Cucurbitacins B-D-I-E.

c. The therapeutic action of Ciliacell and its mechanism of action is not comparable to any of the drugs, medical devices or natural products used to treat sinusitis. Ciliacell differs from any other pharmaceutical product used to treat sinusitis as it exerts its action not only in the nose, but on the entire respiratory epithelium; therefore, also in the ostia (canals that connect the nose to the paranasal sinuses) and in the paranasal sinuses, which represent the real anatomical parts of the respiratory system affected by sinusitis:

i. Ciliacell is NOT an isotonic saline solution

ii. Ciliacell is NOT a hypertonic saline solution

iii. Ciliacell is NOT a súlphurous water

iv. Ciliacell is NOT a nasal wash

v. Ciliacell is NOT sea water

vi. Ciliacell is NOT a vasoconstrictor decongestant drug

vii. Ciliacell is NOT an antibiotic drug viii. Ciliacell is NOT a corticosteroid drug

ix. Ciliacell is NOT a hyaluronic acid solution

x. Ciliacell is NOT a mucolytic drug or medical device

xi. Ciliacell is NOT a drug or natural product with anti-inflammatory activity.

Ciliacell exerts a hydragogue action (elimination of water from an organism tissue) on the entire nose-sinusal respiratory mucosa, that is: from the nose to the paranasal sinuses, through the production of an electrolytic and osmotic alteration on the surface of the epithelium of the same mucosa, which is followed by a physiological process of expulsion of the mucus-purulent secretions present in the nose-sinusal district and in the auditory tubes, the restoration of ciliary mobility and motility, the reduction of the edema of the nose-sinusal mucosa.

d. Ciliacell generates an invisible effect essential in the treatment of sinusitis, i.e. the restoration of mucociliary clearance on the entire nasal-sinus respiratory epithelium (reactivation of ciliary mobility and motility): frequent and repeated inflammations of the respiratory mucosa over time, as well as the presence of dense and sticky mucus, generate, in fact, the reduction or blockage of ciliary mobility and motility, which prevents, or at







1) WHAT SHOULD I KNOW BEFORE USING CILIACELL?

least makes difficult, the evacuation of the same mucus-pus from the nose or throat, with

consequent possible propagation of the infection.

e. The action of Ciliacell is very energetic, so its effect is clearly visible and can lead to an intensification of symptoms for a few days after its administration, especially if the sinusitis has become chronic and is in the acute phase. The symptoms that can be highlighted and/or intensified are the following: sensation of nasal obstruction and oppression; pain in correspondence of the affected paranasal sinuses; pain around the eyes and tearing; ear pain; profuse rhinorrhea with or without sneezing.

f. Immediately after administration of Ciliacell you may feel a slight burning sensation on the nasal mucosa, i.e. the area of the nose that comes into contact with the product. In some cases, the intensity of the burning may be more accentuated, this depends on the presence of lesions of the nasal mucosa originating from frequent and repeated inflammation of the same mucosa. In any case, the burning sensation should end after a

few seconds, in some cases after a few minutes.

g. The effect of Ciliacell is always visible, even in the absence of sinusitis: this takes the form of the evacuation from the nose or throat of greenish-yellow, white, or even transparent mucus-pus. The evacuation of transparent mucus highlights the leakage of liquids contained in the nose-sinusal mucosa responsible for edema (congestion of the respiratory mucosa); this effect highlights the decongestant action of Ciliacell necessary to restore the patency of the mucus drainage routes and the entry of oxygen into the paranasal sinuses. In many cases, before evacuating the yellow-greenish or white mucus-pus present in the paranasal sinuses and/or auditory tubes, for a few days only transparent mucus will be evacuated, this is normal, indeed, necessary.

h. When greenish-yellow or white mucus-pus begins to be evacuated from the nose or throat, you may experience irritation and burning in the pharynx, larynx, nose, or even the roof of your mouth. This irritation is due to the presence of bacteria, fungi and viruses in the evacuated mucus, but above all of pro-inflammatory and irritating substances produced by some cells present in the respiratory mucosa such as mast cells and eosinophils. These substances accumulate in the paranasal sinuses during continuous and repeated inflammatory and infectious processes following the onset of chronic sinusitis, but also

when there is an allergic rhinopathy or a non-allergic cell-mediated rhinopathy.

To soothe the effect of irritation due to the evacuation of irritating substances contained in the mucus-pus (burning and sneezing), it may be appropriate to carry out nasal washes in order to remove the same irritating substances more quickly. In this case, nasal washes must be carried out at least three hours after administration of Ciliacell.

i. The use of Ciliacell by subjects with vascular fragility (fragility of the blood vessels of the nasal mucosa) due to continuous and repeated irritation and inflammation of the respiratory mucosa, or even to the prolonged use of topical nasal drugs such as: antihistamines, corticosteroids, non-steroidal anti-inflammatories and vasoconstrictor drugs (decongestants), in rare cases it can produce epistaxis (nosebleeds).

j. Ciliacell must be used when you are sure you have sinusitis or when the typical symptoms of sinusitis are present. An indication of the possible diagnosis can be formulated using the OCHEMA multimedia application by Nevia Biotech: https://neviabiotech.ch/

diagnosi-online/







1) WHAT SHOULD I KNOW BEFORE USING CILIACELL?

k. The evaluation of the effectiveness of Ciliacell must be carried out 24-48 hours after the last administration of the product at the end of the treatment cycle (7 or 14 days). An evaluation of the efficacy before the completion of the treatment cycle is inappropriate and unreliable, since, up to 24-48 hours after the last administration of the product, the evacuation of transparent mucus from the nose or throat may still be observed.

2) WHY IS CILIACELL THE MOST SUITABLE PRODUCT FOR TREATING SINUSITIS?

- a. Ciliacell is the only product on the market capable of acting effectively on the three clinical/pathological characterizations of sinusitis (edema of the nose-sinusal mucosa; reduction or blockage of ciliary mobility and motility; accumulation of mucus-pus in the rhino-sinusal district and in the auditory tubes), true causes of the typical symptoms of sinusitis.
- b. Ciliacell not only acts in the nose but on the entire epithelium of the upper respiratory system, therefore also in the ostia and paranasal sinuses, which represent the real anatomical parts of the respiratory system affected by sinusitis.

3) WHEN IS THE USE OF CILIACELL INDICATED?

- a. Ciliacell is indicated when you are sure you have sinusitis or when the typical symptoms of sinusitis are present:
- i. Yellow, greenish, or white mucus discharge from the nose or throat
- ii. Craniofacial pain (facial pain) in one or more paranasal sinuses
- iii. Anosmia (feeling of not smelling)
- iv. Nose bleeding
- v. Nasal obstruction and/or oppression
- vi. Exhalation of bad odors from the nose
- vii. Feeling of muffled ears
- viii. Sleep disorders
- ix. General malaise
- x. The above symptoms have been present for more than a week
- xi. When you have a doctor's diagnosis of sinusitis.

An indication of the possible diagnosis can be formulated using the OCHEMA multimedia application by Nevia Biotech: https://neviabiotech.ch/diagnosi-online/







4) WHEN TO ADMINISTER CILIACELL DURING THE DAY?

- a. It is advisable to administer Ciliacell morning and evening. Ciliacell can also be effective with once-a-day administration: in this case it is preferable to administer the product in the morning.
- b. Especially for the first administration, it is recommended not to do it in the evening.
- c. For the evening administration of Ciliacell it is recommended to do it at least three hours before going to bed.

5) WHAT IS THE MOST CORRECT WAY TO USE CILIACELL?

- a. Ciliacell nasal spray should be taken in an upright position, taking care not to insert the spray dispenser very deeply into the nostrils.
- b. Administer the product by directing the tip of the spray nozzle towards the outside of the nose. In this regard, it is recommended to administer the product with the right hand into the left nostril and with the left hand into the right nostril.

6) WHAT SHOULD I EXPECT AFTER ADMINISTERING CILIACELL?

- a. The action of Ciliacell begins to be visible approximately two hours after administration; in some cases, more time is needed.
- b. Sneezing may occur immediately after administration; if not excessive, the effect is considered acceptable; nevertheless, normally, in the absence of damaged mucosa, sneezing does not occur or sneezing is infrequent.
- c. Dryness of the lips may occur, in which case it is advisable to hydrate by drinking water or other liquid you like.
- d. A few hours after administration you may have a slight fever, if this subsides within a few hours it is normal.







6) WHAT SHOULD I EXPECT AFTER ADMINISTERING CILIACELL?

- e. A few hours after administration you may feel mucus flowing down your throat, or mucus evacuation from your nose (rhinorrhea): this effect is normal, indeed, it represents clear evidence that the product is carrying out its action effectively.
- f. After the administration of Ciliacell you may feel an intensification of the typical symptoms of sinusitis: this effect is to be considered normal if the same symptoms are bearable and do not last for more than 2-3 days.

7) DURING TREATMENT WITH CILIACELL I HAVE COUGHS: IT IS NORMAL?

a. Some coughing during treatment with Ciliacell is to be considered normal if these are sporadic or infrequent. If coughing is frequent, it is advisable to stop treatment.

8)I DON'T FEEL ANY EFFECTS IMMEDIATELY AFTER ADMINISTRATION OF CILIACELL: WHY?

a. The effect of Ciliacell begins to be perceptible after about two hours after administration, in some cases more time is needed. Continue to administer the product according to the dosage indicated in the package leaflet even without any visible effect; in any case do not increase the dosage, both in terms of delivery per day and delivery per nostril.







9) IMMEDIATELY AFTER ADMINISTRATION OF CILIACELL I SNEEZE FREQUENTLY: IS THIS NORMAL? WHEN SHOULD I WORRY?

- a. Sneezing after administration of Ciliacell can be normal if not very frequent, in any case, sneezing should stop after 10-20 minutes. There is usually no sneezing after administration, except for some sporadic sneezing.
- b. During the period of administration of Ciliacell, sneezing to evacuate mucus must be considered normal, unless the evacuated mucus is mixed with blood or actual nosebleeds occur: in this case it is necessary to stop the administration of the product and consult a doctor. Small streaks of blood in the evacuated mucus are considered normal if they occur sporadically when blowing your nose.
- c. It is advisable to suspend treatment when sneezing during the treatment period is excessive, does not ease over time and is not related to the evacuation of mucus-pus.

10) A FEW HOURS AFTER ADMINISTRATION OF CILIACELL I FEEL DRYNESS OF THE LIPS, WHETHER OR NOT ASSOCIATED WITH GENERAL DEHYDRATION: IS THIS NORMAL? WHY DOES THIS HAPPEN?

- a. Dryness of the lips associated or not with general dehydration can be considered normal; in this case hydrate yourself with water or other liquid you like.
- b. Dryness is highlighted precisely following the action of Ciliacell, as it acts by evacuating liquids from the tissues.







11) AFTER THE FIRST ADMINISTRATION OF CILIACELL, AFTER HOW LONG SHOULD I EXPECT TO FEEL ITS EFFECT?

- a. The effects of Ciliacell's action are evident approximately 2-3 hours after its administration.
- b. The effects of Ciliacell's action last for approximately 24-36 hours after administration, which is why a single administration every 24 hours is sufficient in most cases.
- c. The effect of Ciliacell is always visible, even in the absence of sinusitis, this takes the form of the evacuation, from the nose or throat, of greenish-yellow, white or even transparent mucus-pus. The evacuation of transparent mucus highlights the leakage of liquids contained in the rhino-sinusal mucosa responsible for the edema; therefore, this effect highlights the decongestant action of Ciliacell, necessary to restore the patency of the mucus drainage routes and the entry of oxygen into the paranasal sinuses. In many cases, before evacuating the yellow-greenish mucus-pus present in the paranasal sinuses, for a few days only transparent mucus will be evacuated, this is normal, indeed, necessary.

12) WITHIN THE FIRST 12 HOURS AFTER ADMINISTRATION OF CILIACELL I HAVE A SLIGHT FEVER: IS THIS NORMAL?

a. After the administration of Ciliacell, a slight fever (36.5-37.5 °C) can be considered normal if it ends a few hours after its onset, generally after 3-4 hours.







13) AFTER THE ADMINISTRATION OF CILIACELL, I FEEL AN INTENSIFICATION OF THE SYMPTOMS, IN PARTICULAR CRANIOFACIAL PAIN AND THE EVACUATION OF MUCUS PUS FROM THE NOSE OR I FEEL IT GOING DOWN THE THROAT: IS THIS NORMAL? SHOULD I STOP TAKING CILIACELL?

- a. It is possible that after the administration of Ciliacell there may be an intensification of symptoms, in particular craniofacial pain (widespread pain on the face in correspondence with the paranasal sinuses or around the eyes) and tearing, as the ostia of the paranasal sinuses could be completely closed and do not allow air to enter in the paranasal sinuses. As soon as the ostia of the paranasal sinuses become patent again, oxygen will enter the paranasal sinuses again, re-establishing their normal pneumatization, making the pain and tearing quickly disappear: if this does not occur within 2-3 days from the start of treatment, or these symptoms are not easily tolerable, it is advisable to stop treatment and, if necessary, consult a doctor.
- b. It is normal that after the administration of Ciliacell there is an intensification of the evacuation of mucus (whether yellow-green, white, or even transparent): this effect highlights the clear action of Ciliacell. The evacuated mucus could be smelly and of various colors (from yellow to green or white), in some cases pieces of solid mucus or streaks of blood may be visible in the evacuated mucus.

14) AFTER THE ADMINISTRATION OF CILIACELL, DURING THE NIGHT WHEN I LIE DOWN IN BED, I FEEL MUCUS GOING DOWN MY THROAT: WHAT CAN I DO?

a. After the administration of Ciliacell it is completely normal that in a lying position with the belly up the mucus can go down the throat, to limit this phenomenon it is recommended to lie on your side to allow the mucus to flow out of the nostrils of the nose.





15) MORE THAN THREE DAYS HAVE PASSED SINCE I STARTED TAKING CILIACELL, BUT I DON'T FEEL ANY TANGIBLE EFFECTS, OTHER THAN A STRONG WATERY RHINORRHEA ASSOCIATED WITH SNEEZING AND BURNING: SHOULD I STOP THE TREATMENT?

- a. If you are sure that you have sinusitis with accumulation of muco-purulent secretions in the nose-sinusal discrit and/or in the auditory tubes and, the symptoms described are tolerable, continue the treatment according to the dosage indicated in the Ciliacell information leaflet;
- b. During treatment with Ciliacell, if a watery rhinorrhea occurs in association with sneezing and burning, it is possible that the infectious sinusitis is associated with an allergic rhinopathy or a non-allergic cell-mediated rhinopathy: in this case, if the same symptoms are not tolerable, it is recommended to stop the treatment;
- c. In the presence of infectious sinusitis with accumulation of mucus-purulent secretions in the rhino-sinusal district and in the auditory tubes, only watery rhinorrhea with sporadic sneezing is preparatory to the evacuation of the mucus-pus: therefore, continue the treatment according to the dosage indicated in the product leaflet.

16) DURING TREATMENT WITH CILIACELL I EXPERIENCE CONSTANT HEADACHES: SHOULD I STOP ADMINISTERING THE PRODUCT?

a. It is possible that during treatment with Ciliacell you may experience a headache (widespread pain in the temples or high forehead): administration of the product must be suspended if the pain is difficult to tolerate and does not go away within a few hours, usually 3-4 hours.

17) DURING THE TREATMENT WITH CILIACELL I FEEL EXHAUST-ED, ALMOST LIKE BEING INFLUENCED, IS THIS NORMAL?

a. Feeling exhausted during treatment with Ciliacell should be considered normal if motor and mental functions are not particularly debilitating; otherwise, it is necessary to suspend treatment.







18) CAN I ADMINISTER A HIGHER DOSE OF CILIACELL THAN INDICATED IN THE PRODUCT'S LEAFLET?

- a. It is absolutely not recommended to increase the dosage of Ciliacell compared to what is indicated in the product's leaflet. Increasing the dose of the product will inevitably give rise to an intensification of the side effects reported in the product's leaflet or an intensification of the painful symptoms typical of sinusitis.
- b. It is not necessary to increase the dosage of the product administered, as Ciliacell exerts its effects perfectly at the prescribed dosage, indeed, the product is effective even with just one administration per day.

19) HOW DO I UNDERSTAND THAT CILIACELL IS EFFECTIVELY CARRYING OUT ITS ACTION?

a. The effect of Ciliacell is visible approximately 2-3 hours after its administration. The most obvious effect is the evacuation of mucus from the nose or throat, in some cases dryness of the lips.

20) MY SON IS 10 YEARS OLD: IS THE DOSAGE OF CILIACELL THE SAME AS FOR ADULTS?

a. From ten years of age the dosage of Ciliacell is the same as for adults; nevertheless, it is recommended to start with a single administration per nostril once a day, and then increase it to the prescribed dose after 2-3 days if the product is well tolerated, otherwise continue to administer Ciliacell with the initial dosage.

21) HOW LONG SHOULD I ADMINISTER CILIACELL?

a. Generally, a seven-day cycle of treatment is sufficient to restore the physiological conditions of the upper respiratory system and make the painful symptoms typical of sinusitis disappear, if present.







21) HOW LONG SHOULD I ADMINISTER CILIACELL?

- b. In case of full-blown chronic sinusitis, which has persisted for some time (several years), it may be necessary to extend the treatment for 14 consecutive days. In any case, it is recommended to do an initial seven-day treatment cycle, suspend treatment for another seven days, and then repeat the treatment cycle for another seven days.
- c. After the first treatment with Ciliacell ends successfully, i.e. the disappearance of the typical symptoms of sinusitis, the episodes of exacerbation of sinusitis will be much less frequent: in this case, a few applications of Ciliacell will be enough to re-establish the normal physiological conditions and make the symptoms disappear (generally 2-3 days of treatment are sufficient).

22) AFTER THE FIRST TREATMENT CYCLE, HOW LONG CAN I USE CILIACELL AGAIN?

- a. After the first seven-day treatment with Ciliacell, the same treatment can be repeated after seven days of no treatment.
- b. After the first two seven-day treatment cycle interspersed with seven days of non-treatment, a new cycle of therapy can be carried out after approximately 15 days. It is never recommended to administer Ciliacell uninterruptedly for a period of more than 14 consecutive days.

23) AFTER TAKING CILIACELL, I STILL HAVE A CLEAR MUCUS DISCHARGE FROM MY NOSE: IS THIS NORMAL? WILL THE MUCUS DRAIN DRY UP?

a. At the end of treatment with Ciliacell, the evacuation of transparent mucus must be considered normal if this stops 24-48 hours after the last administration.







24) IS IT RECOMMENDED TO USE OTHER PRODUCTS IN COMBINATION WITH CILIACELL TO TREAT MY SINUSITIS MORE EFFECTIVELY?

a. When sinusitis occour with evidence of craniofacial pain and accumulation of mucuspus in the rhino-sinusal district and in the auditory tubes, it is absolutely not necessary to combine the administration of other medications (indeed it is not recommended), except in the presence of fever: in this case it may be necessary to administer an antibiotic which must be prescribed by a doctor.

25) CAN I DO NASAL WASHING BEFORE OR AFTER THE ADMINISTRATION OF CILIACELL?

- a. Using Ciliacell, nasal washes are not necessary, indeed, if carried out immediately after administration of Ciliacell they could reduce its effect.
- b. If nasal washes are to be carried out during treatment with Ciliacell in order to soothe the effects of mucosal irritation due to the evacuation of irritating substances contained in the mucus-pus evacuated from the paranasal sinuses (burning and sneezing), the same nasal washes must be carried out at least three hours after administration of Ciliacell.

26) I HAVE NASAL POLYPOSIS, CAN CILIACELL BE USEFUL?

- a. Ciliacell is not a specific product to treat nasal polyposis, nevertheless Ciliacell has been shown to reduce its volume, helping to restore the patency of the nose-sinusal cavities.
- b. In most cases, nasal polyposis is associated with an underlying allergic rhinopathy or non-allergic cell-mediated rhinopathy; therefore, it is advisable to exclude the presence of these rhinopathies with specific tests before using Ciliacell to treat any sinusitis related to them.







27) I HAVE BEEN DIAGNOSED WITH NON-ALLERGIC CELL-MEDIATED RHINOPATHY (NARES, NARNE, NARMA, NARESMA): CAN I USE CILIACELL TO TREAT THESE RHINOPATHIES?

a. Ciliacell is not a specific product to treat non-allergic cell-mediated rhinopathies; nevertheless, if they are associated with infectious sinusitis with accumulation of muco-purulent secretions in the paranasal sinuses, it can be used with caution, as it can produce burning and irritation: allergic rhinopathies and non-allergic cell-mediated rhinopathies, over time, generate a remodeling (lesion) of the respiratory mucosa, which can produce burning and irritation following the administration of Ciliacell.

28) I HAVE EAR PAIN: CAN I USE CILIACELL TO SOOTHE THE PAIN?

- a. Ciliacell is not a painkiller, therefore it is not indicated for treating pain; nevertheless, if the pain derives from secretory otitis media, i.e. the presence of muco-purulent secretion in the middle ear and auditory tube, Ciliacell is perfectly indicated for evacuating the same secretions.
- b. In case of secretory otitis media with ear pain, the use of Ciliacell could exacerbate the pain in the first days of treatment: in this case it is recommended to stop the treatment and, if necessary, consult a doctor.
- c. The use of Cucurbitacine B-D-I-E (Ciliacell) in secretory of this media was tested with a specific clinical study in pediatric age, which demonstrated an efficacy greater than 90% and an excellent safety profile. The clinical study was published in the scientific journal: International Journal of Pediatric Otorhinolaryngology.

