

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be supplied without physician's prescription

Siran 200mg

Effervescent Tablets

(no sugar added, no colouring agents, lemon flavour)

Composition :

Active ingredient:

Each tablet contains

Acetylcysteine 200 mg

This medicine contains:

Sodium 146.5 mg

Aspartame 10 mg

For Inactive ingredients and their quantity in each tablet – see section 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine is supplied without physician's prescription. The medicine is intended for adults and children above the age of two years, under this age refer to the physician. The medicine should be used in a proper manner. For more information consult a pharmacist. Refer to the physician if the signs of the illness (symptoms) get worse or do not improve after 4-5 days.

What is this medicine intended for?

Mucolytic in respiratory tract disorders where reduction of sputum viscosity is required.

Therapeutic group: sputum viscosity reducer (mucolytics).

Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient Acetylcysteine or to any of the other ingredients that this medicine contains (please see 'Additional information').
- Do not use this medicine in children under the age of two years, due to the high level of active substance.

Special warnings regarding the use of this medicine

- In very rare cases, severe skin reactions associated with acetylcysteine treatment may develop, such as Stevens-Johnson Syndrome and Lyell Syndrome. If you have noticed any changes in the skin and/or mucous tissue, contact a physician immediately and stop using **Siran**.
- If you suffer from asthma, or if you suffer or had previously suffered from gastric ulcer or intestinal ulcer, consult a physician prior to use.
- Patients with histamine intolerance should exercise extreme caution and consult a physician prior to initiating treatment. Avoid prolonged treatment in these patients since **Siran** affects histamine metabolism, which may cause symptoms of intolerance (such as: headaches, rhinitis and itching).

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist. In particular inform the physician or the pharmacist if you are taking:

- Medicines for relief/ prevention of cough – Use of these medicines in combination with **Siran** may lead to pulmonary congestion due to increased cough reflex, which means that this drug combination should be used with extreme caution. Consult the physician prior to receiving combined treatment with these medicines.

- Antibiotics – (other than Cefixime and Loracarbef): **Siran** reduces the effect of antibiotics, especially those belonging to the following groups: tetracyclines, aminoglycosides and penicillin. Take the antibiotic at least two hours apart from taking **Siran**.

Using Siran with food

Siran should be taken after a meal.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, planning to get pregnant or breast-feeding, consult a physician before taking **Siran**.

Driving and using machines

No dangerous effect on driving or operating machines is expected.

Important information about some of the medicine's ingredients

- Siran** contains 10 mg aspartame in each tablet. Aspartame is a source of phenylalanine and may cause harm if you have phenylketonuria (PKU) – an inherited metabolic disease.
- Siran** contains 146.5 mg of sodium in each tablet. If you maintain a low sodium diet, you have to consider the amount of sodium contained in the medicine.

How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

- The recommended dose is:**

Age	Dosage per one dose	Total daily dosage
Children 2 - 5 years of age	Half a tablet 2 – 3 times per day	1 – 1.5 tablets (equivalent to 200 – 300 mg acetylcysteine)
Children and adolescents 6 - 14 years of age	One tablet twice a day	2 tablets (equivalent to 400 mg acetylcysteine)
Children and adolescents above the age of 14 years	One tablet 2 – 3 times per day	2 – 3 tablets (equivalent to 400 – 600 mg acetylcysteine)

- Dissolve the **Siran** tablet in a glass of water and then drink the entire glass content.
- You may split the tablet into two parts.
- Treatment duration:
 - Consult the physician or the pharmacist if you have the impression that the effect of **Siran** is too strong or too weak.
 - If your condition worsens or remains without improvement after 4-5 days, consult the physician.

If you have accidentally taken a higher dose, you may experience effects of irritation in the gastrointestinal system (such as: abdominal pain, nausea, vomiting, diarrhea).

No severe or toxic side effects have been observed, even at especially high dosages.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, continue taking the medicine according to the instructions provided in the dosage table. Do not take a double dose.

Ensure taking the medicine at appropriate times to maintain treatment efficacy and safety.

Even if there is an improvement in your health, do not stop treatment with this medicine or change the dosage without consulting the physician or the pharmacist.

If you stop taking the medicine, you may impair treatment efficacy, which may lead to worsening of your condition.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

Side effects

As with any medicine, use of **Siran** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Uncommon side effects:

- Headaches, fever, allergic reaction: sensation of tingling in the skin, rash, itching, shortness of breath, rapid or accelerated heart rate, decrease in blood pressure, inflammation of the oral mucosa, abdominal pain, nausea, vomiting and diarrhea.

Rare side effects:

- Shortness of breath, bronchial spasm – especially in patients with asthma.

Very rare side effects:

- Association between treatment with **Siran** and bruising has been reported; this may be related to a drug sensitivity reaction.

If any side effects get worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting side effects

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Close the tube immediately after taking out the tablet.
- May be used up to 4 weeks after the first opening.

Additional information

- In addition to the active ingredient Acetylcysteine, the medicine also contains: Aspartame, Sodium hydrogen carbonate, Lemon flavor, Citric acid anhydrous.
- What does **Siran** 200mg Effervescent tablets look like and what are the contents of the package:

White, flat, round tablets with a score line on one side.

The tablets have an odour typical of acetylcysteine and a lemony aroma.

The medicine is marketed in 20 tablet packs.

- Registration holder and address: MegaPharm Ltd., P.O.B 519, Hod Hasharon 4510501.
- Manufacturer and his address: Temmler Pharma, Marburg, Germany.
- This leaflet was checked and approved by the Ministry of Health in August 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 112-05-27057