

PACKAGE LEAFLET: INFORMATION FOR THE USER

Septolete plus

Septolete plus oral mucosa spray, (2 mg + 10 mg) / mL

CETYLPYRIDINIUM, BENZOCAINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What SEPTOLETE PLUS is and what it is used for
2. Before you take SEPTOLETE PLUS
3. How to take use SEPTOLETE PLUS
4. Possible side effects
5. How to store SEPTOLETE PLUS
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1. WHAT SEPTOLETE PLUS IS AND WHAT IT IS USED FOR

SEPTOLETE PLUS oral mucosa spray has local analgesic and anti-microbial effect.

Oral mucosa spray contains cetylpyridinium chloride, an antiseptic that destroys a range of bacteria and fungi, and to a certain extent impedes the development of the virus.

Oral mucosa spray disinfects the mouth and pharynx facilitating the pain and a feeling of discomfort associated with inflammation of the mouth and pharynx, and they prevent the development of severe bacterial infections.

Because of the good moisturizing ability and reduction of surface tension, cetylpyridinium chloride penetrates into parts of the lining of the mouth and throat that are hard to reach, and prevents the growth of bacteria.

Benzocaine is a local anesthetic, suitable for the relief of pain often associated with infection and inflammation in the mouth and pharynx.

SEPTOLETE PLUS oral mucosa spray is recommended for relieving the symptoms of pain, dryness and sore throat caused by:

- Mild infections of the mouth and throat (pharyngitis, laryngitis)
- Inflammation of the gums and oral mucosa (stomatitis, gingivitis), and
- Cold and flu.

2. BEFORE YOU TAKE SEPTOLETE PLUS

Do not take SEPTOLETE PLUS

- If you are allergic to Benzocaine, cetylpyridinium, or other ingredients of this medicine
- If you are allergic (hypersensitive) to other local anesthetics,
- If you are addicted to alcohol,
- If you have methemoglobinemia, a rare blood disease in which the hemoglobin can no longer carry oxygen around the body,
- If your doctor says that you have a deficiency of a certain enzyme, eg. pyruvate kinase, glucose-6-phosphate dehydrogenase and NADH-methemoglobin reductase.

Take special care with SEPTOLETE PLUS

Tell your doctor:

- If you experience any difficulty breathing,
- If you are older than 65 years,
- If you smoke,
- If you have any heart disease.

In the above-mentioned cases, you may be at increased risk of methemoglobinemia (blood disease), which is a serious side effect (see section 4. The side effects).

Important

- Septolete plus oral mucosa spray are not recommended for children under 12 years.
- If you have open sores in the mouth, because cetylpyridinium chloride slows wound healing.
- If you have serious infection accompanied by high fever, headache and vomiting, be sure to check with your doctor, especially if your symptoms do not improve after 3 days.
- do not spray Septolete plus in the eyes or in the vicinity of the eyes, nor breathe it in.
- After using Septolete plus you may experience temporary burning sensation, numbness of the lining of the mouth and throat or difficulty swallowing. Consuming food and drinks may be difficult, and the likelihood of biting the lip or tongue is increased. Do not eat, do not drink, do not chew and do not brush your teeth at least one hour after use of the medicine.

Do not use Septolete plus for a long time continuously or often, because taking a larger dose than recommended increases the chance of methemoglobinemia, which is a serious side effect.

Since Septolete plus does not contain sucrose, it can be used and patients with diabetes mellitus.

Taking other medicines

It is unknown if Septolete plus oral mucosa spray can affect the action of other medicines.

SEPTOLETE PLUS with food and drink

Do not take Septolete plus oral mucosa spray together with milk, because milk reduces their efficiency.

Do not take Septolete plus oral mucosa spray before or during meals. Do not eat or drink for at least one hour after taking Septolete plus oral mucosa spray.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Since there is no enough data on the safety during pregnancy and breastfeeding, the use of this medicine during pregnancy and lactation is not recommended.

Driving and using machines

No specific precautions are required.

Important information about some of the ingredients of SEPTOLETE PLUS

Septolete plus contain a small amount of ethanol (alcohol), 49.5 mg per spray (330 mg / mL solution).

3. HOW TO TAKE SEPTOLETE PLUS

If you think that Septolete plus oral mucosa spray have too weak or too strong effect on you, you should contact a doctor.

Adults and adolescents older than 12 years

For a single dose, double-press the dispensing head. The procedure can be repeated every 2-3 hours, up to 8 times a day.

Due to insufficient data on safety, use in children under 12 years of age is not recommended.

Patients over 65 years

The recommended dose for elderly patients is the same as the dose for adults. Due to the simultaneous intake of other medicines and other diseases, older patients may be at increased risk for the appearance of methemoglobinemia.

Do not use it for more than 3 consecutive days.

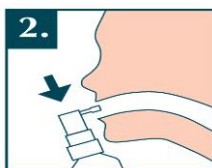
How to use it

Before first use or if you did not use Septolete plus for some time, press the dispensing head several times (5-9 times), and free up some medicine into the air or into the sink. Press as many times as needed until finely dispersed mist appears.



Before use, remove the plastic cover.

Widely open the mouth, point the spray tube to the throat and press the dispensing head.



Hold your breath during spraying.

After each use, set the plastic cover on the dispensing head.

Septolete plus should be used by only one patient.

In one pressure on the spray head, 0.15 mL of a solution containing 1.54 mg of benzocaine and 0.3 mg of cetylpyridinium chloride is released.

If you take more SEPTOLETE PLUS than you should

Considering the amount of active substances in each pastille, the risk of overdose is minimal. Taking a larger amount of oral mucosa spray can cause digestive problems, nausea, vomiting and diarrhea. In this case, stop taking the medicine, drink plenty of water or milk and consult your doctor or pharmacist.

If you use Septolete plus too often or in larger doses for a long time, it may cause blood disease methemoglobinemia, in which blood hemoglobin can no longer carry oxygen around the body. If after using the spray you notice symptoms such as headache, fatigue, dizziness and difficulty breathing, you must immediately inform your doctor and stop taking the medicine.

If you forget to take SEPTOLETE PLUS

Never double-up on a dose to make up for the one you have missed.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (occurring in more than 1 in 10 patients); **common** (less than 1 in 10 patients); **uncommon** (less than 1 in 100 patients); **rare** (less than 1 in 1,000 patients) and **very rare** (less than 1 in 10,000 patients), frequency not known.

Uncommon:

- Hypersensitivity reactions, which may manifest as skin rash, itching, skin swelling, difficulty breathing, dizziness and low blood pressure.

Hypersensitivity reaction contact dermatitis occurs in less than 1% of patients. If you are allergic to benzocaine (also known as ester 4-aminobenzoic acid), there is a possibility that you are allergic to other local anesthetics of the same class, for example, procaine, tetracaine.

Rare:

- Gastro-intestinal problems, such as nausea, vomiting and diarrhea
 - Difficulty swallowing, burning sensation
 - Transient numbness of lining of the mouth and throat
 - Methaemoglobinaemia, blood disease in which methemoglobin can no longer carry oxygen around the body.
- If you notice symptoms such as headache, fatigue, dizziness and difficulty breathing, you must immediately inform your doctor and stop taking the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SEPTOLETE PLUS

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Shelf life: 2 years.

Store below 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What SEPTOLETE PLUS contains

- The active substances are benzocaine and cetylpyridinium chloride. 1 ml oral spray, a solution, contains 10 mg of benzocaine and 2 mg of cetylpyridinium chloride. 1 spray contains 0.15 ml spray of a solution containing 1.54 mg of benzocaine and 0.3 mg of cetylpyridinium chloride.
- Other ingredients are 96 percent ethanol, glycerol (E422), sodium saccharin (E954), peppermint essential oil, and purified water.

What SEPTOLETE PLUS looks like and contents of the pack

Oromucosal spray, the solution is clear, colorless to yellowish solution.

There are boxes with 30 ml of spray for oral mucosa, in a plastic container for the spray. There is also the cover with a mechanical dispenser.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

KRKA, d. d., Novo mesto

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