

PerioChip®

2.5 mg dental insert [chlorhexidine digluconate]

Read all of this leaflet carefully before you start using 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 dentist.
- 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 dentist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PerioChip is and what it is used for
2. What you need to know before you use PerioChip
3. How to use PerioChip
4. Possible side effects
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6. Contents of the pack and other information

1. What PerioChip is and what it is used for

What is PerioChip

PerioChip is a small chip containing the antimicrobial agent chlorhexidine digluconate.

What is PerioChip for

Most people will at some stage of their lives suffer from gingivitis, which is inflammation of the gums. If gingivitis is left untreated, it may lead to periodontitis which can result in tooth loss. Periodontitis is a disease in which the tissues that support the teeth become inflamed and degenerate. This disease can be prevented by treating gingivitis in the early stages. If, however, gingivitis is not treated, the gums will be attacked by bacterial build-up known as plaque, causing the gum to become separated from the tooth and resulting in the formation of a periodontal pocket. Once a pocket has formed, plaque can build up and the disease can become worse.

PerioChip is inserted by a dentist into the periodontal pocket to eliminate most of the disease-causing bacteria, to reduce the pocket inflammation and to decrease the depth of the pocket.

PerioChip is used in combination with the mechanical removal of plaque in the treatment of chronic inflammatory periodontal disease in adults.

2. What you need to know before you use PerioChip

Do not use PerioChip if you are allergic (hypersensitive) to chlorhexidine gluconate or any of the other ingredients of PerioChip (see section 6).

Special warnings and precautions

PerioChip may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness. Early symptoms of a severe allergic reaction may be skin rash or asthma. If you notice these symptoms, contact your dentist or doctor as soon as possible (see under section 4: "Possible side effects").

Children and adolescents

PerioChip is not recommended for use in children and adolescents.

Other medicines and PerioChip

Tell your dentist if you are taking **nystatin** (for the treatment of fungal infections) as it may reduce the effectiveness of PerioChip.

Please tell your dentist if you are taking, have recently taken or might take any other medicines including medicines obtained without prescription, although it is unlikely that any problems will arise if you take any other medicines.

Pregnancy and breast-feeding

You should inform your dentist if you are pregnant or breast-feeding. Your dentist will decide whether you should receive this treatment.

3. How to use PerioChip

After cleaning your teeth mechanically to remove as much plaque as possible, your dentist will put PerioChips into all those tooth pockets, which need to be treated. The chips will then dissolve slowly over about 7 days and do not need to be removed. Your dentist may ask you to return within about three months to check how your treatment is

working and perhaps to continue your treatment with more PerioChips.

Your dentist will advise you if any other medication is needed while you are receiving treatment with PerioChip.

You should continue to clean your teeth as normal. No change in your diet is necessary while being treated with PerioChip.

4. Possible side effects

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

If you experience any of the following reactions, get immediate medical help:

swelling e.g. of the face, lips, tongue or throat; skin rash; itch; wheezing or difficulty breathing; feeling faint and dizzy; rapid heart rate; upset stomach or diarrhoea. You may be having an allergic reaction.

During the first few days following PerioChip insertion, you may temporarily experience pain or discomfort of the gum and teeth and swelling and/or redness of the gums, this may be due to the scaling procedure or the physical placement of the chip.

The following side effects have been reported:

Very common side effects (probably affecting more than 1 in 10 people)

- toothache

Common side effects (probably affecting up to 1 in 10 people)

- swelling, pain and/or bleeding of the gums

Uncommon side effects (probably affecting fewer than 1 in 100 people)

- swelling of the lymph glands
- dizziness
- pain
- enlargement, shrinkage and itching of the gums
- mouth ulcers
- sensitivity of teeth
- neuralgia (pain from irritation of the nerve)
- flu like illness
- general tiredness
- other infections such as throat infection
- fever

The following side effects have also been reported:

- tooth abscess
- more severe tissue damage and infection spreading from where the chip is placed
- loss of taste
- discoloration of gums

Reporting of side effects

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

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PerioChip

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use PerioChip after the expiry date, which is stated on the pack.

6. Contents of the pack and other information

What PerioChip contains

The active substance is chlorhexidine digluconate. Each orange-brown, bullet shaped dental insert contains 2.5 mg of chlorhexidine digluconate.

The other ingredients are hydrolysed gelatin (cross-linked with glutaraldehyde), glycerol and water.

PerioChip is available in blister packs of: 2, 10 or 20 chips.

Manufacturer/ Marketing Authorisation Holder

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