

Package Leaflet: Information for the patient

PERIOCHIP®

2.5mg Periodontal 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
5. How to store PerioChip
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).

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, breathing difficulties, itch, generalised swelling, light headedness, rapid heart rate, upset stomach or diarrhoea. If you notice these symptoms, contact your dentist or doctor immediately (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.

PerioChip with foods, drink and alcohol

No change in your diet is necessary while being treated with PerioChip.

Pregnancy, breast-feeding and fertility

You should inform your dentist if you are pregnant, think you may be pregnant or are planning to have a baby or breast-feeding. PerioChip should be avoided during pregnancy and breast-feeding.

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.

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 a severe 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 (may affect more than 1 in 10 people)

- toothache

Common side effects (may affect up to 1 in 10 people)

- swelling, pain and/or bleeding of the gums

Uncommon side effects (may affect fewer than 1 in 100 people)

- upper respiratory tract infection (e.g. throat infection)
- swelling of the lymph glands
- dizziness
- enlargement, shrinkage and itching of the gums
- mouth ulcers
- sensitivity of teeth
- neuralgia (pain from irritation of the nerve)
- flu like illness
- general tiredness
- fever

Not known (frequency cannot be estimated from the available data)

- allergic skin reactions such as dermatitis (inflammation of the skin), itch, redness of the skin, hives, skin irritation and blisters

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 national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

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 periodontal 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

Dexcel[®]-Pharma GmbH, Carl-Zeiss-Straße 2, 63755 Alzenau, Germany

This leaflet was revised in June 2020