

ELUDRIL PRO PIERRE FABRE MEDICAMENT

Solution for Mouthwash

1. WHAT IS ELUDRILPRO, solution for mouthwash AND WHAT IT IS USED FOR ?

It is recommended as a local adjuvant treatment for disorders of the oral cavity and post-operative care in dentistry and stomatology.

2. WHAT DO YOU NEED TO KNOW ABOUT ELUDRILPRO, solution for mouthwash BEFORE USING IT?

Never use ELUDRILPRO, solution for mouthwash:

The use of ELUDRILPRO, solution for mouthwash is contraindicated in the event of hypersensitivity (allergy) to chlorhexidine, chlorobutanol or other ingredients in the solution.

Take special care when using ELUDRILPRO, solution for mouthwash:

Do not let the product come into contact with the eyes or nose. Do not insert the product into the auditory canal.

If symptoms persist for more than 5 days and/or in the event of concomitant fever, treatment must be re-assessed.

Long-term use may lead to a risk of staining of teeth, fillings and dental prostheses.

Intake or use of other drugs

The simultaneous or successive use of other antiseptics must be avoided given the possible interferences (antagonism, inactivation, etc.).

If you're taking or have recently taken another drug, including over-the-counter drugs, please talk to your doctor or your pharmacist about it.

Pregnancy and breast-feeding

During pregnancy or breast-feeding, do not hesitate to ask your doctor or your pharmacist for advice before taking any medicine.

List of excipients with a recognised effect:

Alcohol.

Cochineal red A (E 124).

3. HOW TO USE ELUDRILPRO, solution for mouthwash?

FOR ADULTS AND CHILDREN OVER 6 YEARS OF AGE ONLY

Method of administration

Mouthwash for topical use.

Do not swallow.

Usual dose: 10 to 15ml of solution twice daily (to be diluted in the measuring cup by filling with warm water up to the top line): use the mouthwash until all of the contents of the measuring cup have been used up.

If necessary, the dose may be increased to 3 times daily, bearing in mind that the maximum dose is 20 ml (to be diluted), 3 times daily.

Brush your teeth before each use and rinse your mouth carefully with water before using ELUDRILPRO, solution for mouthwash.

For the single-dose bottle, dilute the contents of the bottle in half a glass of water and use the mouthwash.

Treatment duration

Treatment may last 2 weeks for gingival inflammation and periodontitis. The treatment duration may only be extended beyond 2 weeks on medical advice.

If you used more ELUDRILPRO, solution for mouthwash than you should have:

Overdose is not expected under normal conditions of use of this mouthwash. However, if it passes into the general circulation (by systemic use), signs of neurological toxicity may develop. This requires treatment in a specialised environment.

If you forgot to use ELUDRILPRO, solution for mouthwash:

Do not take a double dose to make up for forgotten individual doses.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like any other medicine, ELUDRILPRO, solution for mouthwash may cause some undesirable side effects, although not everybody gets them.

Risk of sensitisation to one of the ingredients in the solution.

Do not hesitate to consult your dental specialist and report any unwanted and unpleasant effect not listed in this patient information leaflet.

5. HOW TO STORE ELUDRILPRO, solution for mouthwash?

Keep out of the reach and sight of children.

Do not use ELUDRILPRO, solution for mouthwash after the expiry date stated on the box.

No special precautions for storage.

Medical product must not be thrown away in wastewater and household sewage or with domestic garbage. Please ask your pharmacist what to do with the unused drugs.

These measures will allow to protect the environment.

6. FURTHER INFORMATION**What does ELUDRILPRO, solution for mouthwash contain?****The active substances are:**

Chlorhexidine digluconate solution 0.500 ml

Chlorobutanol hemihydrate 0.500 g

in 100 ml

Alcohol content: 42.8% (V/V)

The other ingredients are: glycerol, 96 percent ethanol, sodium docusate, levomenthol, alcoholic solution of essential oil of mint, purified water, cochineal red A (E 124).

What is ELUDRILPRO, solution for mouthwash and what is its outer packaging?

This medicine is supplied in the form of a mouthwash solution in 15-ml, 90-ml, 200-ml or 500-ml bottles.

Holder/Distributor:

PIERRE FABRE MEDICAMENT

45, place Abel-Gance - 92100 BOULOGNE

Manufacturer:

PIERRE FABRE MEDICAMENT PRODUCTION

Rue du Lycée

Zone Industrielle de Cuiry - 45500 GIEN

This leaflet has been approved on April 2014.

Detailed information on this product is available on the ANSM website (French authorities).