PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CHLORZYD ANTISEPTIC GARGLE

Each 15 ml contains:

Benzydamine hydrochloride 22,5 mg

Chlorhexidine gluconate 18 mg

Contains sugar: Sorbitol (70%): 1,5 g

Contains sweetener: Sucralose: 5,25 mg

Solvent: Propylene glycol: 1,5 g

Oral rinse (solution)

Read all of this leaflet carefully because it contains important information for you

CHLORZYD ANTISEPTIC GARGLE is available without a doctor's prescription, for you to treat a condition. Nevertheless, you still need to use CHLORZYD ANTISEPTIC GARGLE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CHLORZYD ANTISEPTIC GARGLE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet:

1. What CHLORZYD ANTISEPTIC GARGLE is and what it is used for.
2. What you need to know before you take CHLORZYD ANTISEPTIC GARGLE.
3. How to take CHLORZYD ANTISEPTIC GARGLE.

4. Possible side effects.
5. How to store CHLORZYD ANTISEPTIC GARGLE.
6. Contents of the pack and other information.

1. What CHLORZYD ANTISEPTIC GARGLE is and what it is used for

CHLORZYD ANTISEPTIC GARGLE contains two active ingredients:

- Benzydamine hydrochloride, one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and
- Chlorhexidine gluconate which is an antibacterial medicine that reduces the formation of dental plaque.

CHLORZYD ANTISEPTIC GARGLE is used in adults and children over the age of 6 years for the relief of minor infections and pain and inflammation of the throat and mouth.
CHLORZYD ANTISEPTIC GARGLE also helps reduce the development of plaque.

2. What you need to know before you take CHLORZYD ANTISEPTIC GARGLE:

Do not take CHLORZYD ANTISEPTIC GARGLE:

- If you are hypersensitive (allergic) to benzydamine, chlorhexidine or any of the other ingredients of CHLORZYD ANTISEPTIC GARGLE (see “WHAT CHLORZYD ANTISEPTIC GARGLE CONTAINS”).
- CHLORZYD ANTISEPTIC GARGLE should not be used during pregnancy and breastfeeding.

Warnings and precautions

- You should not use CHLORZYD ANTISEPTIC GARGLE for more than 7 consecutive days; unless your healthcare provider has instructed you to do so.
- Avoid contact with the eyes. Should it come in contact with the eyes, wash out thoroughly with water.

- You should not use CHLORZYD ANTISEPTIC GARGLE, if you are hypersensitive (allergic) to aspirin or other NSAIDs.
- You should not use CHLORZYD ANTISEPTIC GARGLE, if you have a history of asthma.
- If you experience any soreness, swelling or irritation in your mouth, you should stop using CHLORZYD ANTISEPTIC GARGLE and consult your healthcare provider.
- If you use for a long period, your CHLORZYD ANTISEPTIC GARGLE teeth and/or tongue may become stained.

Children and adolescents

CHLORZYD ANTISEPTIC GARGLE should not be used in children under 6 years of age.

Other medicines with CHLORZYD ANTISEPTIC GARGLE:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Toothpastes can stop CHLORZYD ANTISEPTIC GARGLE from working. Rinse your mouth thoroughly with water and wait 30 minutes after brushing your teeth before using CHLORZYD ANTISEPTIC GARGLE.

You can also use CHLORZYD ANTISEPTIC GARGLE at a different time of day.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

The safety and efficacy of CHLORZYD ANTISEPTIC GARGLE during pregnancy and lactation have not been established.

Driving and using machines

It is not always possible to predict to what extent CHLORZYD ANTISEPTIC GARGLE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CHLORZYD ANTISEPTOC GARGLE affects them.

Important information about some of the ingredients of CHLORZYD ANTISEPTIC GARGLE:

This medicine contains 1,5 g propylene glycol in each 15 ml.

As CHLORZYD ANTISEPTIC GARGLE should not be swallowed, the quantity of propylene glycol does not necessitate warning.

This medicine contains 1,5 g sorbitol in each 15 ml.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

3. How to use CHLORZYD ANTISEPTIC GARGLE:

Do not share medicines prescribed for you with any other person.

Always use CHLORZYD ANTISEPTIC GARGLE exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

For external (oral) use only.

CHLORZYD ANTISEPTIC GARGLE must not be swallowed (must be eliminated from the mouth).

CHLORZYD ANTISEPTIC GARGLE should generally be used undiluted, but if stinging occurs, the rinse may be diluted with water.

Adults

Gargle

Gargle with 15 ml (approximately one tablespoon) for at least 30 seconds at 1½ - 3 hourly intervals, as required. The solution should be expelled from the mouth after use.

For oral lesions:

15 ml (approximately one tablespoon) should be held in the mouth and swirled around for at least 30 seconds, repeating every at 1½ - 3 hourly intervals throughout the day, as required. The solution should be expelled from the mouth after use.

Children (6 – 12 years of age)

5 – 15 ml as a gargle if able to do so, or as an oral rinse. Repeat every 3 hours.

Your doctor will tell you how long your treatment with CHLORZYD ANTISEPTIC GARGLE will last. Do not stop treatment early without consulting your doctor. You must see a doctor if your symptoms worsen or do not improve after 7 days.

If you have the impression that the effect of CHLORZYD ANTISEPTIC GARGLE is too strong or too weak, tell your doctor or pharmacist.

If you use more CHLORZYD ANTISEPTIC GARGLE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Tell your doctor if you use more CHLORZYD ANTISEPTIC GARGLE than you should. You may experience the side-effects (see POSSIBLE SIDE EFFECTS and Take special care with CHLORZYD ANTISEPTIC GARGLE). Symptoms of overdose may include nausea, vomiting, stomach pain and / or dizziness

If you forget to use CHLORZYD ANTISEPTIC GARGLE:

It is important that you do not miss any doses. If you miss a dose of CHLORZYD ANTISEPTIC GARGLE, use it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily.

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

.***{proposed product is an oral solution}***

If you stop using CHLORZYD ANTISEPTIC GARGLE

Do not stop using CHLORZYD ANTISEPTIC GARGLE unless your doctor tells you to do so. If you have further questions on the use of CHLORZYD ANTISEPTIC GARGLE, ask your doctor or pharmacist.

4. Possible side effects

CHLORZYD ANTISEPTIC GARGLE can have side effects.

Not all side effects reported for CHLORZYD ANTISEPTIC GARGLEare included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CHLORZYD ANTISEPTIC GARGLE, please consult your doctor, pharmacist or other healthcare professional for advice.

Some people experience allergic reactions to CHLORZYD ANTISEPTIC GARGLE, which could develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- Redness and severe itching of the skin

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Difficulty in breathing
- Coughing and becoming very wheezy
- Chest pain or chest tightness.

These are all serious side effects. You may need medical attention.

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Loss or change in taste
- Burning sensation in the mouth
- A decreased sense of touch or sensation in the mouth
- Coated tongue
- Dry mouth.

Other side effects may include:

- Coughing/wheezing
- Numbness of the mouth
- Pain (stinging) in the mouth
- Stomach disturbances
- Swelling under the skin
- Numbness and stinging sensation in the mouth
- Dryness of the mouth/thirst
- Reversible discolouration of tongue and teeth
- Peeling inside of the mouth
- Swelling of glands.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

pharmacist.

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CHLORZYD ANTISEPTIC GARGLE.

5. How to store CHLORZYD ANTISEPTIC GARGLE:

Store at or below 25 ºC.

Store in the original packaging.

Do not take CHLORZYD ANTISEPTIC GARGLE after the expiry date stated on the carton.

Return all unused CHLORZYD ANTISEPTIC GARGLE to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What CHLORZYD ANTISEPTIC GARGLE contains

The active ingredient are benzydamine hydrochloride and chlorhexidine gluconate.

Other ingredients include citric acid monohydrate, Ecocool MP (flavour), mint essence, Patent V blue, polysorbate 20, propylene glycol, purified water, quinolone yellow, sodium citrate dihydrate, sorbitol (70 %) and sucralose.

What CHLORZYD ANTISEPTIC GARGLE looks like and contents of the pack

Oral rinse.

Clear solution having green colour, sweet-bitter taste, refreshing mint odour.

CHLORZYD ANTISEPTIC GARGLE is packed in an amber PET bottle with a white and blue

scaled cap topped with a measuring cup (15 ml). This is packaged in a cardboard box.

Holder of Certificate of Registration

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