PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CHLORZYD ANTISEPTIC THROAT SPRAY

Each 30 ml contains:

Benzydamine hydrochloride 45,00 mg (0,15 % w/v)

Chlorhexidine gluconate 36,00 mg (0,12 % w/v)

Contains sugar: Sorbitol (70%): 3000 mg

Contains sweetener: Sucralose: 10,5 mg

Solvent: Propylene glycol: 3000 mg

Oral spray (solution)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CHLORZYD ANTISEPTIC THROAT SPRAY 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 THROAT SPRAY is and what it is used for.*
2. *What you need to know before you use CHLORZYD ANTISEPTIC THROAT SPRAY.*
3. *How to use CHLORZYD ANTISEPTIC THROAT SPRAY.*
4. *Possible side effects.*

5. *How to store CHLORZYD ANTISEPTIC THROAT SPRAY.*
6. *Contents of the pack and other information.*

1. What CHLORZYD ANTISEPTIC THROAT SPRAY is and what it is used for

CHLORZYD ANTISEPTIC THROAT SPRAY 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 antiseptic and antibacterial medicine that reduces the number of germs in your mouth.

CHLORZYD ANTISEPTIC THROAT SPRAY 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.

2. What you need to know before you use CHLORZYD ANTISEPTIC THROAT SPRAY:

Do not use CHLORZYD ANTISEPTIC THROAT SPRAY:

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

Warnings and precautions

- You should not use CHLORZYD ANTISEPTIC THROAT SPRAY 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 THROAT SPRAY if you are hypersensitive

(allergic) to aspirin or other NSAIDs.

- If you have a history of asthma.
- If you experience any soreness, swelling or irritation in your mouth, you should stop using CHLORZYD ANTISEPTIC THROAT SPRAY and consult your healthcare provider.
- If you use CHLORZYD ANTISEPTIC THROAT SPRAY for a long period, your teeth and/or tongue may become stained.

Children and adolescents

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

Other medicines with CHLORZYD ANTISEPTIC THROAT SPRAY:

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

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

You can also use CHLORZYD ANTISEPTIC THROAT SPRAY 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 taking this medicine.

You should not use CHLORZYD ANTISEPTIC THROAT SPRAY if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent CHLORZYD ANTISEPTIC THROAT SPRAY may interfere with your ability to drive or use machines. Do not drive or use machinery until you are aware of how CHLORZYD ANTISEPTIC THROAT SPRAY affects your ability to do so.

Important information about some of the ingredients of CHLORZYD ANTISEPTIC THROAT SPRAY:

This medicine contains 3000 mg sorbitol in each 30 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 medicines for oral use may affect how other medicines taken at the same time work.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) use this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per 30 ml, that is to say essentially ‘sodium-free’.

3. How to use CHLORZYD ANTISEPTIC THROAT SPRAY:

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

Always use CHLORZYD ANTISEPTIC THROAT SPRAY exactly as described in this leaflet of as your doctor, nurse or pharmacist has instructed you. You should check with your doctor, nurse or pharmacist if you are unsure.

CHLORZYD ANTISEPTIC THROAT SPRAY is an oral spray.

Adults and children over 6 years:

The usual dose is five (5) to ten (10) sprays directly onto the painful or inflamed area and swallow gently. Repeat every 90 minutes to 3 hours as necessary.

Do not use CHLORZYD ANTISEPTIC THROAT SPRAY for more than 7 days, unless instructed by your doctor. If your symptoms worsen, contact your doctor. Do not stop treatment early without consulting your doctor.

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

If you use more CHLORZYD ANTISEPTIC THROAT SPRAY 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.

You may experience nausea, vomiting, sore throat, stomach pain, dizziness, hallucinations, an agitated, irritable or anxious feeling.

If you forget to use CHLORZYD ANTISEPTIC THROAT SPRAY:

Use it as soon as you remember. Do not use a double dose to make up for the forgotten individual doses.

4. Possible side effects

CHLORZYD ANTISEPTIC THROAT SPRAY can have side effects.

Not all side effects reported for CHLORZYD ANTISEPTIC THROAT SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CHLORZYD ANTISEPTIC THROAT SPRAY, please consult your doctor, pharmacist or

other healthcare professional for advice.

Some people experience allergic reactions to CHLORZYD ANTISEPTIC THROAT SPRAY, 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, feeling dizzy or faint.

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:

- Coated tongue
- Dry mouth.

Other side effects may include:

- Numbness of the mouth
- Pain (stinging) in the mouth
- Stomach disturbances
- Burning sensation in the mouth
- A decreased sense of touch or sensation in the mouth
- Dryness of the mouth/thirst
- Reversible discolouration of tongue and teeth
- Loss or change in taste

- 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.

Reporting of side effects

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. Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of CHLORZYD ANTISEPTIC THROAT SPRAY.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of CHLORZYD ANTISEPTIC THROAT SPRAY.

5. How to store CHLORZYD ANTISEPTIC THROAT SPRAY:

Store at or below 25 ºC.

Store in the original packaging.

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

Return all unused CHLORZYD ANTISEPTIC THROAT SPRAY to your pharmacist.

Do not dispose of unused tablets 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 THROAT SPRAY contains

Each 30 ml contains:
Benzydamine hydrochloride 45,00 mg (0,15 % w/v)
Chlorhexidine gluconate 36,00 mg (0,12 % w/v)

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 THROAT SPRAY looks like and contents of the pack

Oral spray.

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

CHLORZYD ANTISEPTIC THROAT SPRAY is packed in a white HDPE bottles with a spray applicator and the secondary package material is carton box.

30 ml

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle & Pontac Streets

Woodstock, Cape Town

South Africa

8001

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This leaflet was last revised in

March 2024

Registration number

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Chlorhexidine gluconate 36,00 mg (0,12 % w/v)

53/16.4/0607