

COCAINE HYDROCHLORIDE SOLUTION 10% W/V

USER GUIDE

Instructions for assembly of Pump + Actuator to Bottle



Bottle



Pump



Actuator

1. Immediately before use, remove the screw cap and rubber stopper from the bottle.
2. Screw the pump onto the bottle.
3. Push the actuator onto the top of the pump.
4. Press down on the pump-actuator 3 times to prime the pump before use.
5. The pump spray is now ready for use. Refer to the Patient Information Leaflet or Summary of Product Characteristics for dosing instructions.

Priming the Pump

While holding the bottle upright, the pump should be activated three times before use to prime it.



Continued overleaf

Other Information

The pump dispenser will deliver a dose volume of 130µl in each spray. Thus, each spray is equivalent to 13mg of Cocaine Hydrochloride Ph Eur.

Always hold the bottle upright to ensure diptube is immersed in the solution at its tip.

This product is sterile until opened, and contains no preservative.

Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner. Do not use if packaging is damaged.

Keep out of the sight and reach of children.

This product also contains Water for Injections, with Dilute Hydrochloric Acid to adjust pH.

Do not store above 25°C. Protect from light.

MA Number: 12064/0016

For further information contact

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PACKAGE LEAFLET: INFORMATION FOR THE USER

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Cocaine Hydrochloride Solution 10%w/v

Cocaine Hydrochloride
(Referred to as Cocaine Solution this leaflet)

Read all of this leaflet carefully before you are given Cocaine Solution

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor or nurse
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse

In this leaflet:

1. What Cocaine Solution is and what it is used for
2. Before Cocaine Solution is given
3. How Cocaine Solution is given
4. Possible side effects
5. How to store Cocaine Solution
6. Further information

This leaflet contains a summary of the information available for this medicine. You should ask your doctor or nurse if you are unsure about any aspect of this medicine.

1. What Cocaine Solution is and what it is used for

Cocaine Hydrochloride is a local anaesthetic.

Cocaine Solution is used to numb an area of the ear, nose or throat ready for surgery. It may also be used to reduce bleeding in the area during surgery.

2. Before Cocaine Solution is given

You should not be given Cocaine Solution if:

- you are allergic (hypersensitive) to Cocaine Hydrochloride or other local anaesthetics, or to any of the other ingredients of the solution listed in section 6 of this leaflet
- you suffer from glaucoma (raised pressure in the eye)
- you suffer from a disease that causes muscle weakness, known as myasthenia gravis
- you or any of your close relatives suffer from a blood enzyme (pseudocholinesterase) deficiency
- you suffer from epilepsy (fits)
- you have porphyria (a blood disorder).

Cocaine Solution is not suitable for children and the elderly.

Take special care with Cocaine Solution

Tell your doctor if:

- you have open wounds in the area to be numbed
- you have high blood pressure or heart problems
- you have thyroid problems
- you have diabetes.

If any of the above applies to you, please tell your doctor or nurse.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of the following:

- ecothiopate eye drops (a medicine used to treat glaucoma)
- neostigmine (a medicine used to treat myasthenia gravis)
- medicines that affect the nervous system e.g. adrenaline, ephedrine or amphetamines
- monoamine oxidase inhibitors (MAOIs) a group of medicines used to treat severe depression
- medicines used to treat high blood pressure e.g. guanethidine sulphate and reserpine
- medicines used to treat depression (tricyclic anti-depressants) e.g. imipramine and amitriptyline
- CNS depressants (medicines that act on the brain and can cause drowsiness or sleepiness e.g. opiates and barbiturates).

You are advised not to drink alcohol whilst being treated with Cocaine Solution.

Pregnancy & breast-feeding

You should not be given this medicine if you are pregnant, trying for a baby or breast-feeding.

Driving and using machines

You should not drive or use machinery after being given Cocaine Solution until your doctor advises that you are safe to do so.

Continued overleaf

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How Cocaine Solution is given

This medicine is a solution which will be given to you by a doctor using a pump dispenser. The solution will be sprayed directly on to the inside of the area to be numbed.

Adults:

The usual dose is a maximum of 1.5mg per kilogram of body weight.

The elderly and children:

This medicine is not suitable for the elderly and children.

If you think you have been given too much Cocaine Solution

This medicine will be given to you by your doctor so it is unlikely that you will be given too much. If you are concerned about your treatment, please talk to your doctor.

4. Possible side effects

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

Possible side effects include:

- restlessness, excitement, a feeling of intense happiness
- excessive talking or rambling
- involuntary or jerky movements
- confusion, paranoia
- seeing or hearing things that are not real, mental disturbances
- changes in your sensation of touch
- a rise in body temperature
- fast breathing
- a migraine-like headache
- high blood pressure
- enlarged pupils
- sweating, shaking, fits
- rumbling stomach
- a lack of blood in the fingers, toes, spinal cord, kidneys, spleen, and intestines
- problems sleeping
- loss of appetite.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How to store Cocaine Solution

Keep out of the reach and sight of children.

You should not be given this medicine if it has passed the expiry date printed on the bottle. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

This product will be stored by your doctor below 25°C and protected from light in the original carton

6. Further Information

What Cocaine Solution contains:

The active substance is Cocaine Hydrochloride Ph Eur 10%w/v
The other ingredients are dilute hydrochloric acid and water for injections.

What Cocaine Solution looks like and contents of the pack:

Cocaine Solution is supplied in clear glass bottles. Each bottle contains 2.5ml of solution. A pump and actuator are included in the pack.

Marketing Authorisation Holder: Manufacturer:

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.



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