QHBio Co., Ltd

Wellstox Caine Cream

Lidocaine 2.5% and Prilocaine 2.5%

Topical Anesthetics

[Composition]

[Lidocaine 25mg

Prlocaine 25mg

Methyloaraben 1.6mg

Popybaraben 4mg

[Description]

White Cream

[Indications]

Wellstox Caine cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on: normal intact skin for local analgesia, genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia,

[Dosage and Administration]

Adult Patients-intact Skin. A thick laver of Wellstox Caine cream is applied to intact skin and covered with an occlusive dressing.

Minor Dermal Procedures: For minor procedures such as intravenous cannulation and venipuncture, apply 2.5 grams of Wellstox Caine cream over 20 to 25 cm/ of skin surface for at least 1 hour. In controlled clinical trials using Wellstox Caine cream, two sites were usually prepared in case there was technical problems with cannulation or venipuncture at the first site.

Major Dermal Procedures: For more painful dermatological procedures involving a larger skin area such as split thickness skin graft harvesting, apply 2 grams of Wellstox Caine cream per 10 cam2 of skin and allow to remain in contract with the skin for at least 2 hours.

Adult Male Genital Skin: As an adjunct prior to local anesthetic infiltration, apply a thick layer of Wellstox Caine cream (1 g/ 10 cm2) to skin surface for 15 minutes. Local anesthetic infiltration should be performed immediately after removal of Wellstox Caine cream.

Dermal analgesia can be expected to increase for up to 3 hours under occlusive dressing and persist for 1 to 2 hours after removal of the cream. The amount of Lidocaine and Prilocaine absorbed during the period of application.

Age and body Weight Requirements	Maximum Total Dose of Wellstox Caine cream	Maximum Application Area	Maximum Application Hour
0 upto 3 monthsor<5kg	1g	10cm2	1 Hour
3 up to 12 months and>5kg	2g	20cm²	4 Hour
1 to 6 years and>10kg	10g	100 cm²	4Hour
7 to 12 years and 20 kg	20g	200 cm²	4 Hour

Adult Female Patients-Genital Mucous Membranes.

For Minor procedures on the female external genitalia such as removal of condylomata acuminate, as well as for use as pretreatment for anesthetic infiltration, apply a thick layer (5 to 10 grams) of Wellstox Caine cream for 5 to 10 minutes.

Occlusion is not necessary for absorption but may be helpful to keep the cream in place, Patients should be laying down during the cream application, especially if no occlusion is used. The procedure or the local anesthetic infiltration should be performed immediately after the removal of the cream.

The following are the maximum recommended does, application areas and application times have not shown cross sensitivity to lidocaine and/or prilocaine, however, Wellstox Caine cream based on a child's age and weight.

Please note: If a patient greater than 3 months old does not meet the minimum weight requirement, the maximum total does of the cream should be restricted to that which corresponds to the patient's weight.

Practitioners should carefully instruct caregivers to avoid application of excessive amounts of the cream.

When applying Wellstox Caine cream to the skin of young children, care must be taken to maintain careful observation of the child to prevent accidental ingestion of the cream or the occlusive dressing.

A secondary protective covering to prevent inadvertent disruption of the application site may be useful.

Wellstox Caine cream should not be sued in neonates with a gestational age less than 37 week nor in infants under the age of 12 months who are receiving treatment with methemoglobin-inducing agents.

When Wellstox Caine cream (lidocaine 2.5% and prilocaine 2.5%) is used concomitantly with other products containing local anesthetic agents, the amount absorbed form all formulations must be considered. The amount absorbed in the case of Wellstox Caine cream is determined by the area over which it is applied and the duration of the application under.

Although the incidence of systemic adverse reactions with the cream is very low, caution should be exercised, particularly when applying it over larger areas and leaving it on for longer than 2 hours. The incidence of systemic adverse reactions can be expected to be directly proportional to the area and time of exposure.

[Side Effect]

Localized Reactions: During or immediately after treatment with Lidocaine and Prilocaine cream on intact skin, the skin at the site of treatment may develop erythema or edema or may be the locus of abnormal sensation. Rare cases of discrete purpuric or petechial reactions at the application site have been reported. Rare case of hyperpigmentation following the use of lidocaine and Prilocaine cream nave been reported. The relationship to Lidocaine and Prilocaine cream or the underlying procedure has not been established. In clinical studies on intact skin involving over 1,300 Lidocaine and Prilocaine cream-treated subjects one or more such local reactions were noted in 56% of patients, and were generally mild and transient, resolving spontaneously within 1 or 2 hours. There were no serious reactions that were ascribed to lidocaine and Prilocaine cream.

Two recent reports describe blistering on the foreskin in neonates about to undergo circumcision.

Both neonates received 1.0g of Lidocaine and Prilocaine cream.

In patients treated with Lidocaine and Prilocaine cream on intact skin, local effects observed in the trials included" paleness (pallor or blanching) 37%, redness (erythema) 30%, alterations in temperature sensations 7%, edema 6%, itching 2% and rash less than 1%

In clinical studies on genital mucous membranes involving 378 Lidocaine and Prilocaine cream-treated patients, one or more application site reactions, usually mild and transient, were noted in 41% of patients. The most common application site reactions were redness (21%), burning sensation (17%) and edema (10%)

Allergic Reactions: Allergic and anaphylactoid reactions associated with lidocaine or prilocaine can occur.

They are characterized by urticaria, angloedema, bronchospasm, and shock. If they occur they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

PRECAUSION FOR USET

1. Contraindications

Lidocaine and Prilocaine cream (lidocaine 2.5% and prilocaine 2.5%) is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type or to nay other component of the product.

2. Special precaution for use

Labor and Delivery: Neither lidocaine nor prilocaine are contraindicated in labor and delivery. Should Lidocaine and Prilocaine cream be used concomitantly with other products containing lidocaine and/or prilocaine, cumulative doses from all formulations must be considered.

Nursing Mothers : Lidocaine, and probably prilocaine, are excreted in human milk. Therefore, caution should be exercised when Lidocaine and Prilocaine cream is administered to a nursing mother since the milk plasma ratio of lidocaine is 0.4 and is not determined for prilocaine.

Pediatric Use: Controlled studies of Lidocaine and Prilocaine cream in children under the age of seven vears have shown less overall benefit than in older children or adults. These results illustrate the importance of emotional and psychological support of younger children undergoing medical or surgical procedures. Lidocaine and Prilocaine cream should be used with care in patients with conditions or therapy associated with methemoglobinemia.

3. General precautions

Repeated doses of Lidocaine and Prilocaine cream may increase blood level of Lidocaine and Prilocaine.

Lidocaine and Prilocaine cream should be used with caution in patients who may be more sensitive to the systemic effects of Lidocaine and Prilocaine including acutely ill debilitated or elderly patients.

Lidocaine and Prilocaine cream should not be applied to open wounds.

Care should be taken not to allow Lidocaine and Prilocaine cream to come in contact with the eve because animal studies have demonstrated severe eye irritation. Also the loss of protective reflexes can permit corneal irritation and potential abrasion. Absorption of Lidocaine and Prilocaine cream in conjunctival tissues has not been determined. If eye contact occurs, immediately wash out the eve with water or saline and protect the eye unti sensation returns.

Patients allergic to paraminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine and/or prilocaine, however, Lidocaine and Prilocaine cream should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

Lidocaine and Prilocaine have been shown to inhibit viral and bacterial growth. The effect of Lidocaine and Prilocaine cream on intradermal injections of live vaccines has not been determined.

4. Caution in storage/handling

1) Do not apply near eyes or open wounds.

2) Keep out of the reach of children.

3) If your child becomes very dizzy, excessively sleepy, or develops duskiness of the face of lips after applying Lidocaine and Prilocaine cream, remove the cream and contact the child's physician at once.

[ISRATGE AMD EXPIRY DATE]

1) STORE AT ROOM TEMPERATURE (1 - 30 C)

2) Expiry date" 36 months from manufacturing date.

[PACKING]

30g Tube

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