SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: Aksoken

Product name: Lidocaine hydrochloride Gel

Strength: 2.5%

Pharmaceutical: Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by its' salt or hydrate form if relevant

Lidocaine hydrochloride

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Lidocaine hydrochloride 25mg

3. PHARMACEUTICAL FORM

A clear colorless gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lidocaine hydrochloride Gel is used for temporary relief of pain associated with minor burns, sunburn, minor cuts or scrapes and minor skin irritations.

4.2 Posology/Dosage and method of administration

FOR EXTERNAL USE ONLY.

Adults and children over 2 years of age:- Clean the affected area and gently dry;

Apply to the affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a physician.

4.3 Contraindication

For external use only.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

When using this product, avoid contact with eyes.

Stop use and ask a doctor if condition gets worse, or if smptoms persist for more than 7 days or clear up and then occur again with a few days, discoutinue use of this product and consult a physician.

4.4 Special warnings and precautions for use

For external use only.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

When using this product, avoid contact with eyes.

Stop use and ask a doctor if condition gets worse, or if smptoms persist for more than 7 days or clear up and then occur again with a few days, discoutinue use of this product and consult a physician.

4.5 Interaction with other drug products and other forms of interaction

If absorbed, this product can interact with the following drugs: (1) When combined with cimetidine and β receptor blockers, such as propranolol, metoprolol, Nadolol, lidocaine metabolism is inhibited by liver, lidocaine blood concentration increases, cardiac and nervous system adverse reactions can occur, lidocaine dose should be adjusted, and the blood concentration of lidocaine should be monitored and monitored by electrocardiography; (2) Barbiturates can promote the metabolism of lidocaine, and the combination of the two drugs can cause bradycardia and sinus arrest; (3) Combined with procainamine, can produce transient delirium and hallucination, but does not affect the blood concentration of this product; (4) Isopropyl epinephrine can increase the total clearance rate of this product due to increased liver blood flow; The total clearance rate of norepinephrine decreased due to the decrease of hepatic blood flow. (5) Incompatibility with the following drugs: phenobarbital, sodium thiopental, sodium nitroprusside, mannitol, amphotericin B, ampicillin, sulfadiazine.

4.6 Fertility, pregnancy and lactation

This product transits the placenta and binds fetal proteins higher than adults, which can cause fetal bradycardia or tachycardia after maternal administration, and can also cause neonatal methemoglobinemia.

4.7 Effects on ability to drive and use machines

Lidocaine hydrochloride Gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Side effects following the administration of Lidocaine Hydrochloride USP are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported;

Central Nervous System:

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness,nervousness,apprehension,euphoria,confusion,dizziness,drowsiness,tinnitus,blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in

which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular system:

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic:

Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions.

Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

4.9 Overdose

Excess can cause convulsions and cardiac arrest.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

After blood absorption, lidocaine amides have obvious biphasic effects of excitatory and inhibitory on the central nervous system, and there is no precursor excitement. When the blood concentration is low, analgesia, sleepiness and pain threshold are increased. With the increase of dose, the effect or toxicity increased, and the subtoxic blood concentration had anticonvulsant effect; Convulsions may occur when the blood concentration exceeds 5μg • ml-1. At low dose, this product can promote k+ outflow in cardiomyocytes, reduce the slope of phase 4, slow down the automatic depolarization during diastole, reduce the automaticity of myocardium, and has the effect of anti-ventricular arrhythmia. At the treatment dose, the electrical activity of cardiomyocytes, atrioventricular conduction and myocardial contraction had no significant effect. The further increase of blood concentration can cause the heart conduction speed to slow down, atrioventricular block, inhibit myocardial contractility and reduce cardiac output.

5.2 Pharmacokinetic properties

After lidocaine absorption, the tissue distribution is fast and wide, and it can pass through the blood-brain barrier and placenta. This product has high anesthetic intensity, rapid effect, wide dispersion, strong penetration, and no obvious vasodilation effect. It takes about 2 hours for the drug to be locally eliminated, and most of the drug is first decomposed by liver microenzyme into the deethylated intermediate metabolite monoethyl glycine xylene which still has local anesthetic effect, resulting in increased toxicity. It is then hydrolyzed by amidase

and excreted in urine, about 10% of the dosage is excreted in its original form, and a small amount appears in bile.

5.3 Preclinical safety data

Lidocaine hydrochloride Gel indications for local anesthetic, transurethral examination and treatment of local anesthesia.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Benzalkonium Chloride
Sodium Hydroxide
Menthol
Carbomer Homopolymer
Polysorbate 80
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep this medicine where children cannot reach it.
Store Lidocaine hydrochloride Gel in a cool, dry place where it stays below 30°C.
Protect it from sunlight.

6.5 Nature and contents of container

Collapsible aluminum tubes having a screw threaded neck finish sealed with an aluminum membrane. Each tube is supplied with a white polyethylene screw cap which has a piercing tip to puncture open the aluminum membrane on the neck.
Pack size: 20g

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

Tel: 09118269061

8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui, China

Tel: 86-0563-2625199

Fax: 86-0563-2625199

E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)