SUMMARY OF PRODUCT CHARACTERISTICS

INTACYCLINE SKIN OINTMENT

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1. Name of the medicinal product

a) Proprietary name of a medicine

Intacycline Skin Ointment

b) Approved generic name(s)

Tetracycline Hydrochloride

2 Qualitative and quantitative composition

Tetracycline Hydrochloride 3.0% w/w

For Excipients 6.1

3 Pharmaceutical form Dosage form

Ointment

4 Clinical particulars

4.1 Therapeutic indication(s)

Tetracycline is applied topically for the treatment of superficial pyogenic infections of the and for the prevention of infections in wounds, abrasions and after surgery. It is indicated for caused by both gram-positive and gram-negative organisms including streptococci, staphylococci and the coli-aerogenes group

4.2 Posology and method of administration

Topical

Directions for use:

The dose medicines in this class will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of these medicines. If your dose is different, do not change it unless your doctor tells you to do so. The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

Adults, adolescents and the elderly

A small quantity of Intacycline Skin should be applied to the affected area one to three times daily or as directed by physician until improvement occurs. It may then be possible to maintain improvement by applying once a day, or even less often, or by using the appropriate ready diluted (1 in 4) preparation, Intacycline Skin Ointment.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Intacycline Skin can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions; thereafter improvement can usually be maintained by regular application without

occlusion.
Paediatric population
Tetracycline Hydrochloride is contraindicated in children under 12 years of age.
Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults; Courses should be limited to five days. Occlusion should not be used.
Care should be taken when using Tetracycline Hydrochloride to ensure the amount applied is the minimum that provides therapeutic benefit.
Elderly
Many medicines have not been tested in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information about the use of topical tetracyclines in the elderly..
Renal / Hepatic Impairment
In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

4.3 Contra-indications

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. Check with your doctor as soon as possible if any of the following side effects occur:.

***4.4* Special warnings and precautions for use**

For patients using either the cream form or the topical liquid form of this medicine for acne:

Some people may notice improvement in their acne within 4 to 6 weeks. However, if there is no improvement in your acne after you have used this medicine for 6 to 8 weeks or if it becomes worse, check with your health care professional. The treatment of acne may take up to 8 to 12 weeks before full improvement is seen.

If your doctor has ordered another medicine to be applied to the skin along with this medicine, it is best to wait at least 1 hour before you apply the second medicine. This may help keep your skin from becoming too irritated. Also, if the medicines are used too close together, they may not work properly.

The liquid form of this medicine may also cause the skin to become unusually dry, even with normal use. If this occurs, check with your doctor.

This medicine may cause faint yellowing of the skin, especially around hair roots. This may be more easily seen in people with light complexions. The color may be removed by washing. However, the medicine should be left on the skin as long as possible. Do not wash immediately after applying the medicine. To do so will keep the medicine from working properly. If the yellow color is bothersome during the daytime, the medicine may be applied after school or work and again at bedtime, unless

otherwise directed by your doctor.

Treated areas of the skin may glow bright yellow under "black" (ultraviolet or UV) light such as that used in some discos. To help reduce or avoid this, apply the medicine later in the evening or wash it off before exposure to "black" light.

You may continue to use cosmetics (make-up) while you are using this medicine for acne. However, it is best to use only "water-base" cosmetics. Also, it is best not to use cosmetics too heavily or too often. They may make your acne worse. If you have any questions about this, check with your doctor. For patients using the topical ointment form of this medicine: If your skin infection does not improve within 2 weeks, or if it becomes worse, check with your health care professional.

4.5 Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine

4.6 Pregnancy and lactation

Studies have not been done in humans. In studies in rats and rabbits, chlortetracycline and tetracycline topical preparations have not been shown to cause birth defects or other problems. However, studies in rabbits have shown meclocycline to cause a slight delay in bone formation

It is not known whether tetracycline topical preparations pass into breast milk. Although most medicines pass into breast milk in small amounts, many of them may be used safely while breast-feeding. Mothers who are using any of these medicines and who wish to breast-feed should discuss this with their doctor

Effects on the ability to drive and operate machinery

Not applicable

4.6 Undesirable effects:

Local skin burning/skin pain and pruritus.

4.7 **Overdose**

Not applicable.

5.1 Pharmacodynamic properties

Tetracycline hydrochloride is a broad-spectrum bacteriostatic antibiotic.

Tetracyclines are taken up into sensitive bacterial cells by an active transport process. Once within the cell they bind reversibly to the 30S subunit of the ribosome, preventing the binding of aminoacyl transfer RNA and inhibiting protein synthesis and hence cell growth. Although tetracyclines also inhibit protein synthesis in mammalian cells they are not actively taken up, permitting selective effects on the infecting organism.

5.2 Pharmacokinetic properties

Most tetracyclines are incompletely absorbed from the gastrointestinal tract, about 60-80% of a dose of tetracycline usually being available. The degree of absorption is diminished by the presence of divalent and trivalent metal ions with which tetracyclines form stable insoluble complexes and to a variable degree by milk or food. Formulation with phosphate may enhance the absorption of tetracycline.

Plasma concentrations will depend upon the degree of absorption. Administration of tetracycline 500mg every 6 hours generally produces steady-state concentrations of 4-5µg/ml. Peak plasma concentrations occur about 1-3 hours after ingestion. Higher concentrations can be achieved after intravenous administration; concentrations may be higher in women than in men.

In the circulation 20-65% of tetracycline is bound to plasma proteins.

They are widely distributed throughout the body tissues and fluids. Concentrations in cerebrospinal fluid are relatively low, but may be raised if the meninges are inflamed. Small amounts appear in saliva, and the fluids of the eye and lung. Tetracyclines appear in the milk of nursing mothers where concentrations may be 60% or more of those in the plasma. They diffuse across the placenta and appear in the foetal circulation in concentrations of about 25 to 75% of those in the maternal blood. Tetracyclines are retained at sites of new bone formation and recent calcification and in developing teeth. The tetracyclines have been classified in terms of their duration of action in the body, although the divisions appear to overlap somewhat.

The tetracyclines are excreted in the urine and in the faeces. Renal clearance is by glomerular filtration. Up to 55% of a dose is eliminated unchanged in the urine; concentrations in the urine of up to 300µg/ml of tetracycline may be reached two hours after a usual dose is taken and be maintained for up to 12 hours. Urinary excretion is increased if urine is alkalinized. The tetracyclines are excreted in the bile where concentrations 5-25 times those in plasma can occur. Since there is some enterohepatic reabsorption complete elimination is slow. Considerable quantities occur in the faeces after administration.

5.4 Preclinical safety data

Not applicable.

6 Pharmaceutical particulars

6.1 List of excipients

White Soft Paraffin

Liquid Paraffin

6.2 Incompatibilities - None known.

6.3Shelf-life -

- **In the original unopened container;** 24 months
- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

Special precautions for storage:

Intacycline Skin Ointment should be stored below 25^{O}C, in a dry and dark place.

Keep out of the reach of children

6.4 **Nature and composition of containers**

Pack Size: 15g. Intacycline Skin Ointment aluminum Tubes, Intacycline Skin Ointment Leaflets, Intacycline Skin Ointment unit cartons,

Instruction for use/handling

For external use only

Wash hands before and after use.

Restriction on sale / distribution:

Prescription only medicine (POM)

7 Administrative data

i. **Name and address of holder of a registration.**

Regal Pharmaceuticals Limited

Phone: 8564211/2/3/4

Fax: 8560946/8564093

Email: info@regalpharmaceuticals.com

Plot No.: 7879/18, Off Baba Dogo Road, Ruaraka,

P.O. Box 44421-00100, Nairobi, Kenya

8.i Registration number. – H94/320

ii. Date of first registration- 15/12/1994

DECLARATION BY AN APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules*

Name: DR. MANDERE ATEBE JAMES
Position in the company: COMPANY PHARMACIST

Signature: .....

Date: 26th September 2019

Official stamp:.....

* Note: If fees have been paid, attach proof of payment