SUMMARY OF PRODUCT CHARACTERISTICS

SULPHUR OINTMENT

Table of Contents

1. Name of the medicinal product

a) Proprietary name of a medicine

Sulphur Ointment

b) Approved generic name(s)

Precipitated Sulphur BP

2 Qualitative and quantitative composition

Precipitated Sulphur BP 10.0% w/w.

3 Pharmaceutical form Dosage form

Ointment

4 Clinical particulars

4.1 Therapeutic indication(s)

Sulphur ointment is a keratolytic, antiseptic, anti-fungal and a parasiticide.It is specially formulated for the treatment of acne, fungal infections including ring worms, parasitic infections, scabies and seborrheic conditions.

4.2 Posology and method of administration

Apply a thin layer of ointment on the affected area/s as directed by a doctor, and rub in gently.

4.3 Contra-indications

Sulphur ointment is contra-indicated in patients with known hypersensitivity to Sulphur.

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

For external use only. Wash hands thoroughly after use. Avoid use on broken skin, the eyes, nose or lips. Discontinue use if irritation occurs. If symptoms persist medical advice should be sought.

4.5 Interactions

No interaction studies have been performed.

4.6 Pregnancy and lactation

Pregnancy

No clinical data on exposed pregnancies are available. Animal studies do not indicate harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3 Preclinical safety data). As a precautionary measure, it is preferable to avoid the use of Sulphur ointment

during pregnancy.

Breastfeeding

It is not known if sulphur is excreted in human milk. However, based on its rapid elimination from the body via the expired air, it is considered that the breastfeeding can be resumed two to three hours after administration of Sulphur ointment

Fertility

No clinical data are available. Animal studies do not indicate harmful effects on fertility.

4.7 Effects on the ability to drive and operate machinery

Sulphur ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Although side effects are uncommon, long term use of sulphur ointment may cause dermatitis.

4.9 Overdose

Since there have been no cases of overdose reported to date, neither signs nor symptoms of overdose have been identified. In a Phase I study doses up to 52 mL of Sulphur ointment were administered to normal volunteers without serious adverse events being reported. In the event of overdose occurring, the patient should be observed and treated symptomatically.

5 Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: **D10AB**

Precipitated Sulphur

Precipitated sulphur exhibits antiseptic, antifungal, and antiparasitic properties. Additionally anti-acne, anti-pruritic and antiseborrhoeic properties are reported for sulphur. Sulphur is a keratolytic agent. Precipitated sulphur belongs to the group of non-metallic elements.

The pharmacological activity of topically applied Precipitated sulphur is mediated through the formation of disulphides and polythionic acids formed by the interaction of sulphur with organic substances or micro-organisms present on the skin.

5.2 Pharmacokinetic properties

1% of topically applied sulphur has been shown to be absorbed.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity and toxicity to reproduction. Caecal lesions observed in some repeat-dose studies with rats, but not in monkeys, are not relevant for humans under normal conditions of administration.

6 Pharmaceutical particulars

6.1 List of excipients

- White Soft Paraffin

6.2 Incompatibilities - None known.

6.3Shelf-life -

- **In the original unopened container;** 36 months
- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

6.4 Special precautions for storage:

Mediven Cream should be stored below 25^{o}C, in a dry and dark place.

Keep out of the reach of children

6.5 **Nature and composition of containers**

Pack Size: 25gm, Sulphur Ointment Leaflets, Sulphur Ointment labels, Sulphur Ointment Aluminum Tubes.

6.6Instruction for use/handling

For **external** use only

Restriction on sale / distribution:

Prescription Only Medicine

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. **Registration number**. H2001/0279

ii. Date of first registration- 01/08/2001

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 JAMES ATEBE
Position in the company: COMPANY PHARMACIST

Signature: .....

Date: 10th June 2019

Official stamp:.....

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