



**National Agency for Food & Drug Administration &
Control (NAFDAC)**

**Registration & Regulatory Affairs (R & R)
Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC) TEMPLATE**

1. NAME OF THE MEDICINAL PRODUCT

Galways Nerve & Bone Liniment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Turpentine Oil	12.50% w/v
Ammonium Bicarbonate	3.70% w/v
Ammonium Chloride	1.87% w/v
Strong Ammonia Solution	2.50% w/v
Oleic Acid	2.50% w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liniment for topical application to human beings.

White emulsion with a characteristic odour.

4. Clinical particulars

4.1 Therapeutic indications

Galways Nerve & Bone Liniment is a rubefacient, which is a substance that warms the skin. It is indicated for the relief of joint and muscular pains, pains and strains, sprains, bruises, stiffness of muscles resulting from exertion, backache and other rheumatic conditions.

4.2 Posology and method of administration

Posology

Adults, including the elderly, and children (12 years and older):

Rub the liniment thoroughly onto the affected area twice daily or as required.

Not recommended for use in children under 12 years of age unless instructed by a doctor.

If symptoms persist talk to your doctor or pharmacist.

If anyone accidentally swallows some see a doctor straight away. Take the product with you so that it can be identified.

Method of administration

Topical administration to the skin. For external use only

4.3 Contraindications

- Hypersensitivity to the active substances or any of the excipients in the excipients listed in section 6.1.
- Not to be used on children under 12 years old.
- Do not apply to skin abrasions.
- Do not apply to irritated skin

4.4 Special warnings and precautions for use

- Avoid contact with the eyes, inflamed or broken skin and other sensitive areas
- Wash hands thoroughly after use.
- Keep out of sight and reach of children.
- For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with other medicines.

4.6 Pregnancy and Lactation

Consult your doctor or pharmacist for advice before using this medicine.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Hypersensitivity or allergic reactions, skin irritation.

4.9 Overdose

Excessive use may cause some of the effects of poisoning (local burning, stomach upset, coughing/choking, rapid heartbeat).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: M02A Topical Products for Joint and Muscular Pain.

Mechanism of action

When the product is applied to intact skin it causes a sensation of warmth which is followed by a mild local anaesthesia.

Pharmacodynamic effects

Nerve and Bone liniment is used externally as a counter irritant and rubefacient, in the treatment of chronic inflammatory conditions and to relieve neuralgia, rheumatic pains, stiffness and lumbago.

5.2 Pharmacokinetic properties

The effect of the product is limited to its topical action.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Deionised Water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

It is available in flint bottles with aluminium screw cap.

Pack Size: 200ml

6.6 Special precautions for disposal

No special requirements.

7 . APPLICANT/MANUFACTURER

SKG-Pharma Limited
7/9 Sapara Street,
Ikeja, Lagos State, Nigeria.
Tel: +234(1)44544640
Email: skgpharma@yahoo.com