Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
OXOFERIN Solution

2. Qualitative and quantitative composition
100 ml Oxoferin Solution contains:
TCDO forming "Reaction Product"
with biological activity: 138.0 x 10^6 Pmol
For full list of excipients, see Section 6.1.

3. Pharmaceutical form
Topical Wound Healing Agent (Sterile Solution)
Colorless Liquid (for External Use only)

4. Clinical particulars
4.1 Therapeutic indications
Oxoferin Solution (sterile) is indicated for all complicated and resistant wounds including:

- Complicated infected wounds.
- Decubitus ulcers (bed sores).
- Chronic leg ulcers combined with venous insufficiency.
- Delayed wound healing and ulcer cases involving impaired arterial circulation, such as in old age and diabetes.
- Suppurative cavities or fistular tracts.
- Post-traumatic wounds.
- Complicated post-operative wounds.

4.2 Posology and method of administration
Apply directly or cover the wound with a gauze piece soaked with Oxoferin Solution (sterile) on the affected area. The quantity of Oxoferin Solution (sterile) to be applied depends on the size of the wound. Generally 5ml per dressing of 4" x 4" twice a day is sufficient. If the area of the wound is big (e.g. in burns), Oxoferin Solution (sterile) can be applied mixed with normal saline. Oxoferin Solution (sterile) should be used within 30 days, once the bottle is opened.

4.3 Contraindications
None.

4.4 Special warnings and precautions for use
Mild itching or burning sensation is an indication that healing process has started. Spontaneous bleeding after application of Oxoferin Solution (sterile) is a positive sign indicating that capillaries have started to multiply.

4.5 Interaction with other medicinal products and other forms of interaction
Oxoferin Solution (sterile) is a complete wound healing agent thus no other

topical therapeutic agent is used. Oxoferin Solution (sterile) can be used as monotherapy.

4.6 Pregnancy and Lactation
None

4.7 Effects on ability to drive and use machines
None

4.8 Undesirable effects
No reaction was observed when Oxoferin was tested for toxicology. A systemic dose as high as 50ml/kg body weight did not result in any incompatibility. Ld50 in case of local application does not exist. Oral Ld50 in mouse/rat is 50ml/kg body weight (occasional). Mild itching or burning sensation is an indication that healing process has started. In severe cases, the wound can be remoistened with physiological saline.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the relevant national regulatory authority pharmacovigilance.

4.9 Overdose
Sometimes excessive application of Oxoferin Solution (sterile) may cause greenish smear on the wound surface which disappears once the dose is reduced.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Oxoferin Solution (sterile) acts by stimulating the immune system of the body and that is why it is also known as IMMUNOMODULATOR.

5.2 Pharmacokinetic properties
When applied topically Oxoferin Solution (sterile) is absorbed rapidly both by wound surface and border area. Oxoferin Solution (sterile) combines with the haem part of hemoglobin, myoglobin and peroxidase, forming a TCDO–haem complex, this in turn activates the macrophages and accelerates the process of Phagocytosis.
This process of phagocytosis engulfs all the pathogens present on the surface of the wound including the cell debris, thus cleans the wound surface, a prerequisite for Regenerative Phase. Oxoferin Solution (sterile) also helps in the Regenerative Phase by giving rise to two impulses, namely Mitogenic and Chemotactic.
The mitogenic impulse gives rise to two factors, MDGF (Macrophage derived growth factor) and WAF (Wound angiogenesis factor). The MDGF causes the proliferation of fibroblasts resulting in an increased synthesis of collagen, the basic material for new granulation tissue to fill gaps of wounds. The WAF causes endothelial cells to proliferate and to form new capillaries resulting in the vascularization of the new granulation tissue. The chemotactic impulse acts on the myocyte (muscle cell) and causes it to contract, thereby reducing

the wounds surface. All these three factors are influencing the regenerative phase simultaneously and thus accelerate the wound healing with minimal scarring.

5.3 Preclinical safety data
Not applicable

6. Pharmaceutical Particulars
6.1 List of Excipients
- Glycerin 85% pure
- Water for injection

6.2 Incompatibilities
Not applicable

6.3 Shelf-Life
4 years

6.4 Special Precautions for storage
Store at temperature below 30^0C away from light.

6.5 Nature and Content of container
Packed in 50ml white opaque round plastic bottle made up of H.D.P.E sealed with plastic plug having blue colored plastic cap and sticker label further packed in carton with insert.

6.6 Special precautions for disposal and other handling
Once opened, the solution should be used within 30 days.
Oxoferin Solution should only be used when the solution is clear and colorless.
Contact of the opening of the bottle with the skin or the wound should be avoided. (Occasional) mild itching or burning sensation is an indication that healing process has started. In severe cases, the wound can be remoistened with physiological saline.

7. Marketing Authorization Holder
Brookes Pharma Private Limited

58 & 59, Sector 15, Korangi Industrial Area, Karachi-Pakistan

8. Marketing Authorization Number
H2022/CTD8868/18641

9. Date of first authorization/renewal of the authorization
12/09/2022

10. Date of revision of the text

12/09/2022